Corporate concerned with the work of liquidating the assets of closed insured institutions, or the liquidation of loans or the handling of contributions to insured institutions and the purchase of assets therefrom, and all temporary field positions of the Federal Savings and Loan Insurance Corporation the work of which is concerned with paying the depositors of closed insured institutions.

§ 6.357 Federal Home Loan Bank Board. (a) One Assistant to the Board.
(b) One Director, Federal Home Loan Bank Operations.
(c) One General Counsel.
(d) One Director, Division of Supervision.
(e) One Secretary to the Chairman of the Board.
(f) Two Secretaries to Board Members.
(g) One General Manager, Federal Savings and Loan Insurance Corporation.
(h) One Deputy General Manager, Federal Savings and Loan Insurance Corporation.

United States Civil Service Commission,
[Seal] Wm. C. Hull, Executive Assistant.
[F. R. Doc. 55-10151; Filed, Dec. 19, 1955; 8:46 a.m.]

PART VI—EXCEPTIONS FROM THE COMPETITIVE SERVICE

FEDERAL HOME LOAN BANK BOARD

Effective upon publication in the Federal Register, paragraph (b) of § 6.142 and paragraph (d) of § 6.342 are revoked, and §§ 6.187 and 6.357 are added as set out below.

§ 6.157 Federal Home Loan Bank Board. (a) One Secretary, Federal Home Loan Bank Board.
(b) One Director, Division of Examinations.
(c) All temporary field positions in the Federal Savings and Loan Insurance

PART VI—EXCEPTIONS FROM THE COMPETITIVE SERVICE

TREASURY DEPARTMENT

Effective upon publication in the Federal Register, paragraph (c) is added to § 6.203 as set out below.

§ 6.203 Treasury Department. * * *
(c) Not to exceed two positions of Accountant (Tax Specialist) at grades

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GS-13 and above to serve as specialists on the accounting analyses and treatment of corporation taxes. Employments under this paragraph shall not exceed a period of 18 months in any individual case.


UNITED STATES CIVIL SERVICE COMMISSION, [seal.] WM. C. HULL, Executive Assistant.

[F. R. Doc. 55-10150; Filed, Dec. 19, 1955; 8:46 a.m.]

PART 6—EXCEPTIONS FROM THE COMPETITIVE SERVICE DEPARTMENT OF STATE; GOVERNMENT PRINTING OFFICE Effective upon publication in the Federal Register, paragraph (a) of § 6.139 is revoked and paragraph (e) of § 6.102 is amended as set out below.

§ 6.330 Department of State. * * * *(e) Office of the Assistant Secretary for Economic Affairs. * * *

(4) One Special Assistant to the Assistant Secretary.


UNITED STATES CIVIL SERVICE COMMISSION, [seal.] WM. C. HULL, Executive Assistant.

[F. R. Doc. 55-10152; Filed, Dec. 19, 1955; 8:47 a.m.]

PART 37—GROUP LIFE INSURANCE CESSATION AND CONVERSION OF INSURANCE COVERAGE Section 37.5 (f) is amended as set out below.

§ 37.5 Cessation and conversion of insurance coverage. * * *

(f) The insurance of an insured employee who enters on active duty in or with the Army, Navy, Air Force, Marine Corps, or Coast Guard of the United States shall cease, subject to a 31-day extension of life insurance coverage, on the day preceding his entrance on such active duty. For this purpose, the employee is considered as performing active duty only if he enters or is called to active military service for a specified term or an indefinite period which is expected to exceed 15 days and is subject to control by military authority for full-time active military service.

(Se. 11, 68 Stat. 742; 5 U. S. C. 2100)

UNITED STATES CIVIL SERVICE COMMISSION, [seal.] WM. C. HULL, Executive Assistant.

[F. R. Doc. 55-10163; Filed, Dec. 19, 1955; 8:57 a.m.]

TITLE 7—AGRICULTURE

Chapter IX—Agricultural Marketing Service (Marketing Agreements and Orders), Department of Agriculture

PART 914—NAVAL ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA EXPENSES AND FIXING OF RATE OF ASSESSMENT FOR 1955-56 FISCAL YEAR

On November 23, 1955, notice of proposed rule making was published in the Federal Register (20 F. R. 8640) regarding the expenses and rate of assessment for the 1955-56 fiscal year under Marketing Agreement No. 117, as amended, and Order No. 14, as amended (19 F. R. 2941) regulating the handling of Navel oranges grown in Arizona and designated part of California, effective September 22, 1955, under the applicable provisions of The Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.). After consideration of all relevant matters and pertinent data submitted in the proposals set forth in the aforesaid notice which were submitted by the Navel Orange Administrative Committee (established pursuant to the marketing agreement and order), it is hereby found and determined that:

§ 914.203 Expenses and rate of assessment for the 1955-56 fiscal year (a) The expenses necessary to be incurred by the Navel Orange Administrative Committee, established pursuant to the provisions of the aforesaid marketing agreement and order, for its maintenance and functioning during the period November 1, 1955, through October 31, 1956, will amount to $156,832.83; and the rate of assessment to be paid by each handler who first handles oranges shall be seven one-half mills ($0.0075) per carton of oranges handled by such handler as the first handler thereof during the 1955-56 fiscal year. Such rate of assessment is hereby fixed as each such handler’s pro rata share of the aforesaid expenses.

It is hereby further found that it is impracticable and contrary to the public interest to postpone the effective time hereof until 30 days after publication in the Federal Register (60 Stat. 237; 7 U. S. C. 1901 et seq.) in that (1) in accordance with the provisions of said marketing agreement and order, the rate of assessment is applicable to all fresh oranges handled during the aforesaid fiscal year; (2) Navel oranges are now being handled; (3) the provisions hereof do not impose any obligations on a handler until such handler handles Navel oranges; and (4) it is essential that the specification of the assessment rate be issued immediately so that the aforesaid assessments may be collected and thereby enable the Navel Orange Administrative Committee to perform its duties and functions in accordance with said marketing agreement and order.

As used in this section, "handle," "handler," "oranges," and "fiscal year" shall have the same meaning as is given to each such term in said amended marketing agreement and order; and "carton" shall mean the standard one-half orange, grapefruit, or lemon box set forth as standard container number 55 as specified in California and designated part of the Agricultural Code of California.


[SEAL] ROY W. LEXINGTON, Deputy Administrator.

[F. R. Doc. 55-10165; Filed, Dec. 19, 1955; 8:53 a.m.]

TITLE 16—COMMERCIAL PRACTICES

Chapter I—Federal Trade Commission

PART 13—DIGEST OF CASE AND DESIST ORDERS

ADVERTISING

Subpart—Advertising falsely or misleadingly: §§ 13.20 Comparative data or merits; § 13.23 Size or weight; Subpart—Misrepresenting on label and goods—Good fro: §§ 13.1575 Comparative data or merits; § 13.175 Size or weight.


This proceeding was heard by Earl J. Kolb, hearing examiner, upon the complaint of the Commission—which charged a corporate manufacturer of television sets with representing falsely by radio and television broadcasts, advertisements in magazines, newspaper, etc., and advertising material furnished to its distributors, that the screen area of its television sets which were equipped with its Giant 21" picture tube was 20 percent larger than that of its competitors' television sets likewise equipped—and an agreement between the parties providing for the entry of a consent order.

Upon this basis, the hearing examiner made his initial decision and order to cease and desist, which by the Commission's order of December 2, 1955, became, on December 3, 1955, the 'Decision of the Commission'

The order to cease and desist is as follows:

It is ordered, That respondent, Admiral Corporation, a corporation, and its officers, agents, representatives, and employees, directly or through any corporate or other device, in connection with the offering for sale, sale, or distribution of television sets in commerce, do forthwith cease and desist from: Misrepresenting, directly or by implication, that the screen area of its television sets which were equipped with its Giant 21" picture tube was 20 percent larger than that of its competitors' television sets.

By said 'Decision of the Commission' report of compliance was required as follows:

2 New.
It is ordered, That the respondent herein shall within sixty (60) days after service upon it of this order, file with the Commission a report in writing setting forth in detail the manner and form in which it has complied with the order to cease and desist.

Issued: December 2, 1955.

By the Commission.

[Seal] Robert M. Parhish, Secretary.

[F. R. Doc. 55–10466; Filed, Dec. 19, 1955; 8:45 a.m.]

TITLE 20—EMPLOYEES' BENEFITS

Chapter III—Bureau of Old-Age and Survivors Insurance, Social Security Administration, Department of Health, Education, and Welfare

[Reg. 1, Further Amended]

PART 401—DISCLOSURE OF OFFICIAL RECORDS AND INFORMATION

ENFORCEMENT OF IMMIGRATION AND NATIONALITY ACT

On October 5, 1955, there was published in the Federal Register (30 F R. 72398) a notice of proposed rule making incorporating the requirements of section 290 (c) of the Immigration and Nationality Act into a proposed amendment to Social Security Administration Regulation No. 1, as amended (20 CFR 401 et seq.), Interests persons were thereby given an opportunity to present their data, views and arguments relative to such proposed amendment within 30 days from the date of such publication.

Expressions of views and objections to the proposed amendment have been received pursuant to this notice, and due consideration has been given them. The proposed amendment, however, is based upon the provision of section 290 (c) of the Immigration and Nationality Act which requires the Secretary of Health, Education, and Welfare to disclose certain information, and merely serves the purpose of incorporating the statutory requirement into the regulation so that the regulation will fully set forth all purposes.

Section 401.3 of Regulation No. 1, as amended (20 CFR 401.3) is accordingly further amended by adding thereto a new paragraph (p) reading:

§ 401.3 Information which may be disclosed and to whom. Disclosure of any such file, record, report or other paper, or any other matter, thereby authorized in the following cases and for the following purposes:

• • • • •

(p) Pursuant to the provisions of section 320 (a) of the Immigration and Nationality Act, to any officer or employee of the Department of Justice of the United States lawfully charged with the administration of title II of such act available information required to be furnished by such section, for the purpose of such administration only, upon written request of the Attorney General of the United States or of an officer of the Department of Justice duly authorized by him to make such request.

(See Secs. 206, 1102, 49 Stat. 624, 647 as amended; 42 U.S.C. 405, 1393.) Interprets or applies sec. 1102, 63 Stat. 1388, as amended; 42 U.S.C. 1393.)


Approved: December 14, 1955.

M. B. Folston, Secretary of Health, Education, and Welfare.

[F. R. Doc. 55–10155; Filed, Dec. 19, 1955; 8:47 a.m.]

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

REPUBLICATION OF REGULATIONS

Chapter II—Bureau of Narcotics, Department of the Treasury

REDESIGNATION OF PARTS

EDITORIAL NOTE: For republication of the regulations of the Food and Drug Administration, see Part II of this issue.

Chapter III—Bureau of Old-Age and Survivors Insurance, Social Security Administration, Department of Health, Education, and Welfare

TITLE 38—PENSIONS, BONUSES, AND VETERANS' RELIEF

Chapter I—Veterans Administration

PART 14—LEGAL SERVICES, GENERAL COUNSEL

MISCELLANEOUS AMENDMENTS

1. Section 14.627 is revised to read as follows:

§ 14.627 Accredited representatives. Recognized organizations shall file with the Veterans Administration on the prescribed form furnished by the Veterans Administration (Form 2–21, Recommendation for Accreditation of Representative of an Organization) the name of any person whom they desire recognized as accredited representative thereof. In recommending a person for recognition as a representative, the organization, through its appropriate officer, shall certify to the following: (1) That the person is a national officer of the United States, of good character and reputation, that he is qualified by ability and experience to present claims, that he is a member of such organization in good standing, or a full-time, paid employee thereof; and that the major portion of his time will be devoted to the preparation or presentation of claims for that organization or other organizations to which he may be accredited or that he is a national officer of the organization requesting accreditation; (2) whether accredited to any other recognized organizations, and, if so, the name or names thereof; (3) that he is not now employed in any civil, or military department or agency of the United States and was or was not so employed within 2 years next preceding the date of recommendation for accreditation; (4) if a veteran, the nature of his discharge or separation from the active service. Recommendations for accreditation of representatives of national service organizations will be accepted only if approved by the national certifying officer of such organization; those of State organizations only if approved by the director or higher officer of the organization.

(a) The recommendation for accreditation (VA Form 2–21) executed by a national organization or by a recognized State organization shall be filed with the Office of the General Counsel. A recommendation received in Central Office may be sent to the appropriate regional office, if necessary, to secure sufficient facts to justify a determination whether the designee is qualified. The report of the Chief Attorney, including the recommendation, if any, of the Manager, together with VA Form 2–21 will be transmitted to the General Counsel, who will approve or disapprove the recommendation. If the designee is approved, FL 2–3, Notice to Designee of Recognition, will be issued by the General Counsel.

(b) Letters of recognition (FL 2–3) or card issued by the General Counsel (VA Form 2–3129, Service Organization Representative Identification Card) will constitute authorization for the recognition of accredited representatives designated therein, in all offices (including hospitals and domiciliaries) of the Veterans Administration. Record will be maintained in the office of the General Counsel of all recognitions issued.

(c) Recognition of an accredited representative will be canceled at the request of the organization, and such cancellation may suspend recognition in any case for cause, sending a report to Central Office, attention of the General Counsel, for final determination.

(d) An Information bulletin will be issued monthly by the office of the General Counsel listing all new recognitions and cancellations. This will constitute notice to all concerned on this subject.

2. In § 14.629 paragraphs (a), (b), and (d) are amended to read as follows:

§ 14.629 Recognition of attorneys and agents. (a) Claim agents will be granted recognition and certified by the office of the General Counsel upon satisfaction of the following requirements: (1) He shall present evidence of qualification, including good reputation and knowledge of applicable law and procedure. Upon presentation to the General Counsel of a properly executed application on the form prescribed by the Administrator, VA Form 2–3187, Application for Recognition as Agent, any competent person of good moral character and of good repute...
who is a citizen of the United States, or who has declared his intention to become such a citizen, and who is not engaged in the practice of law may be recognized as an agent to represent claimants before the Veterans Administration. The recognition of an attorney is not precluded by any statutory or regulatory provision and he has never been convicted, whether on trial or plea, of a serious penal offense, or of any violation of any penal provisions respecting fees. Applicants for recognition as agents may be required to prove their fitness to render substantial service, if his recognition is not precluded by any statutory or regulatory provision, and he has never been convicted, whether on trial or plea, of a serious penal offense, or of any violation of any penal provisions respecting fees, his application will be approved and he will be notified by letter. Any duly recognized attorney will be accorded recognition in any case by Central Office or by any other office of the Veterans Administration, including hospitals and domiciliaries, to which he presents a duly executed or an authenticated copy of his notification of recognition as attorney or VA Form 2-3192a, Identification Card, together with the original or an exemplified copy of power of attorney. (See § 14.630 as to recognition in individual cases.) VA Form 2-3192a, Identification Card, will be issued only by the General Counsel. The approval of application for recognition as an attorney, will notify the attorney (by letter and informal VA Form 2-3192a, Identification Card, will be issued by the General Counsel. The approval application will be retained in the files of the approving office. A 3 x 5 inch card will be prepared showing the attorney's name, address, and date of recognition. A copy of this card will be forwarded to the office of the General Counsel for record and issuance of VA Form 2-3192a, Identification Card, and to any other office in which the General Counsel requests that his recognition be recorded. When an attorney has been recognized by the General Counsel, no copy of the 3 x 5 inch card will be sent to any office unless the attorney specifically requests that his recognition be recorded in a certain office. (Secs. 5, 33 Stat. 629, as amended, secs. 2, 5, 63 Stat. 2016, secs. 7, 52 Stat. 6; 56 U. S. C. 111, 428, 707, Interpret or apply ccss. 292-293, 49 Stat. 2031, as amended, 2925; 36 U. S. C. 101-104.)

This regulation is effective December 20, 1955.


[5 F. R. Dec. 55-10111; Filed, Dec. 19, 1955; 8:49 a.m.]

PART 17—MEDICAL MISCELLANEOUS AMENDMENTS

1. Section 17.30 is revised to read as follows:

§ 17.30 Refusal of treatment by unnecessarily breaking appointments. A patient under outpatient medical treatment who breaks an appointment without a reasonable excuse for such action, will be informed that a repetition of the offense will be deemed to be a refusal of Government treatment. If such patient breaks a second appointment, without at least 24 hours' notice, or a reasonable excuse, it will be deemed that he has refused Government treatment. Thereafter no further treatment will be furnished until he has made a specific formal application therefor and has satisfactorily evinced a willingness to accept Government treatment and to comply with the Government agency providing the treatment, by keeping his appointments, or by giving at least 24 hours' notice where an appointment must necessarily be broken. Where an appoint- ment is broken without notice and satisfactory reasons are shown for the breaking of the appointment, and it is also satisfactorily shown that circumstances attending the breaking of the appointment were such that notice could not be given, the patient will not be deemed to have refused treatment.

Nothing in this section is intended to prevent a patient from receiving the benefit of treatment for an emergency condition that may arise during the time when he has been determined to be "Not entitled to treatment" as a result of refusal.

2. In § 17.60, that portion of paragraph (a) preceding subparagraph (1) is amended to read as follows:

§ 17.60 Outpatient treatment. (a) Outpatient treatment, medical or dental, of nonservice-connected noncompensable disabilities, and other services, may be rendered to the following applicants under the conditions stated, except that applicants for dental treatment as defined for recognition in subparagraphs (g) and (h), as defined in paragraph (a) of this section, must also meet the applicable provisions of § 17.123:

3. In § 17.120, paragraph (a) is amended to read as follows:

§ 17.120 Authorization of dental examinations. * * *

(a) There being a dental disability adjudicated as incurred or aggravated in military or naval service in war or peace time, or the necessity for determining whether the dental disability is service-connected. The word "peace-time" as used in this paragraph does not include service on or after June 27, 1950, and prior to February 1, 1955.

4. Sections 17.123, 17.124, and 17.129 are revised to read as follows:

§ 17.123 Authorization of outpatient dental treatment. Outpatient dental treatment may be authorized by the chief, dental service, or his professional designate, for beneficiaries defined in § 17.60 (a) (1) to (6), inclusive, (g) (9) and (b), to the extent prescribed and in accordance with the applicable classification and provisions set forth in this section:

(a) Class I. Those having a service-connected compensable dental disability or condition, may be authorized any dental treatment indicated as reasonably necessary to maintain oral health and masticatory function. There is no time limitation for making application for treatment and no restriction as to the number of repeat episodes of treatment.

(b) Class II. Those having a service-connected noncompensable dental condition or disability shown to have been in existence at time of discharge or release from active service may be authorized any treatment indicated as reasonably necessary for the one-time correction of the service-connected noncompensable dental disability or condition, but only if application for treatment is made within 1 year after discharge or release, or by December 31, 1954, whenever the services rendered on a one-time basis, as provided in this class, are found unacceptable within the limitations of good professional standards, such additional services may be authorized as required to complete professionally acceptable treatment. The foregoing limitations in this class II as to existence of disability is time limitation are not applicable to Classes II (a), and (b).
§ 17.129 Dental services for hospital patients and domiciled members. Persons hospitalized or domiciled pursuant to the provisions of §§ 17.46 and 17.47, will be furnished such dental services as are professionally determined necessary for the correction of such service-connected condition or disability.

§ 17.135 Replacement of dental prosthesis is revoked. This regulation is effective December 20, 1959.

J. C. PALMER, Assistant Deputy Administrator.

[For Dec. 25, 1959; Filed, Dec. 19, 1955; 8:40 a.m.]

TITLE 43—PUBLIC LANDS: INTERIOR

Chapter I—Bureau of Land Management, Department of the Interior

Appendix—Public Land Orders

[Public Land Order 1281]

{Dec. 14, 1955]

UTAH

WITHDRAWING PUBLIC LANDS FOR USE OF GEOLOGICAL SURVEY AS SEDIMENT TESTING LABORATORY SITE

By virtue of the authority vested in the President and pursuant to Executive Order No. 10355 of May 26, 1952, it is ordered as follows:

Subject to valid existing rights, the following described public lands in Utah are hereby withdrawn from all forms of appropriation under the public land laws, including the mining and mineral leasing laws, and reserved under the jurisdiction of the Department of the Interior for use of the Geological Survey as a site for a sediment testing laboratory.

SALT LAKE COUNTRY

T. S4 S., R. 13 E., Sec. 26, St. M.N.E.1/4, N.W.1/4, Sec. 33, lot 1.

The areas described aggregate 44.00 acres.

The use of the lands by the Geological Survey shall be subject to existing withdrawals for power purposes, and to the condition that should the lands be required for power purposes, any structures placed thereon which interfere therewith will be removed by the Geological Survey.

This order shall take precedence over but not otherwise affect the Departmental order of May 7, 1933, establishing Utah Grazing District No. 5.


[For Dec. 25, 1959; Filed, Dec. 10, 1955; 8:40 a.m.]

TITLE 39—POSTAL SERVICE

Chapter I—Post Office Department

Part 41—Service in Post Offices

POST OFFICE BOXES

In § 41.3 Post office boxes make the following changes:

1. Amend paragraph (a) to read as follows:

(a) Rental rates—(1) Post office. Box rent rates are based on the gross receipts of the office for the calendar year.

2. Amend paragraph (f) to read as follows:

(f) Keys—(1) Regular. A patron renting a key-lock box must be supplied with one or two keys, according to his needs. Renters of lock boxes are not permitted to use any keys except those issued through the post office.

(2) Additional. Keys in excess of two may be issued by a patron upon completion of Form 1004 (application for additional keys to post office box) and payment of a 50 cents fee for each key.

(3) Duplicate. Duplicates of lost keys may be secured by payment of a 50 cents fee for each key.
(4) Fees not refundable. Fees for duplicate and additional keys are not refundable.

(5) Worn and broken. Worn or broken keys shall be replaced without charge if the damaged key is surrendered.

(6) Return. All keys must be returned when the box is surrendered. If the patron has lost a regular key, he must pay a fee of 50 cents for each missing key.


[seal] AB McGREGOR Goff, The Solicitor

[F. R. Doc. 55-10142; Filed, Dec. 19, 1955; 8:43 a.m.]

TITLE 49—PUBLIC WELFARE

Chapter V—Foreign Claims Settlement Commission of the United States

Subchapter C—Receipt, Administration and Payment of Claims Under the International Claims Settlement Act of 1949, as Amended

PART 531—FILING OF CLAIMS AND PROCEEDURES THEREFOR

PRESETTLEMENT CONFERENCE

Section 531.7 is added to read as follows:

§ 531.7 Presettlement conference. The Commission on its own initiative or upon the application of a claimant for good cause shown, may direct that a presettlement conference be held with respect to any issue involved in a claim.

This addition shall become effective as of the date of filing with the Federal Register.

PROPOSED RULE MAKING

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service [7 CFR Part 908]

[Docket No. AO-243-A1]

MILK IN CENTRAL ARKANSAS MARKETING AREA

NOTICE OF RECOMMENDED DECISION AND OPPORTUNITY TO FILE WRITTEN EXCEPTIONS THERETO WITH RESPECT TO PROPOSED MARKETING AGREEMENT AND PROPOSED AMENDMENTS TO ORDER

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.) and the applicable rules of practice and procedure, as amended, governing proceedings to formulate marketing agreements and marketing orders (7 CFR Part 900) notice is hereby given of the filing of the Hearing Clerk of the recommended decision of the Deputy Administrator, Agricultural Marketing Service, United States Department of Agriculture, with respect to proposed amendments to the tentative marketing agreement and to the order, regulating the handling of milk in the Central Arkansas marketing area.

Interested parties may file written exceptions to the decision with the Hearing Clerk, United States Department of Agriculture, Washington 25, D. C., not later than the close of business on the 5th day after publication of this decision in the Federal Register. Exceptions should be filed in quadruplicate.

Preliminary statement. The hearing on the record of which the proposed amendment to the tentative marketing agreement and to the order was formulated was conducted at Little Rock, Arkansas, on November 22, 1955. Pursuant to notice thereof which was issued on November 15, 1955 (20 F. R. 6547).

The material issues of the hearing relate to:

(1) The pricing of Class I milk; and

(2) The need for emergency action with respect to Issue No. 1.

Findings and conclusions. The order should be amended to correlate Class I price changes in the Central Arkansas marketing area with those resulting under Order No. 52 regulating the handling of milk in the Memphis, Tennessee, marketing area.

The pricing provisions of the Central Arkansas Order No. 5 became effective December 1, 1955. Class I prices under the Central Arkansas and Memphis orders are established by adding identical differential to handlers for manufacturing milk. The monthly price resulting from the price formula under the Memphis order, however, is subject to an adjustment based on the relationship of Class I sales to receipts of producer milk under that order. During the months of July through November, 1955, an average of 19 cents was added to the Class I price by the operation of this supply-demand adjustment. No adjustment resulted in prices for the months of May and June or for December of this year. Thus, the Class I prices under the two orders are the same for the month of December.

Starting in April of 1955 and continuing until the pricing provisions of the Central Arkansas order become effective (December 1, 1955) the Central Arkansas Milk Producers Association had an arrangement with the principal handlers of the Central Arkansas marketing area to furnish their total milk requirements at the class prices prevailing under the Memphis order. Thus, in effect the order continues the pricing arrangement negotiated by producers and handlers prior to the effective date of the order.

Under the association’s full supply agreement with the handlers, it was necessary for the association to furnish milk from outside sources starting in July. During the months of shortest supply namely September and October, 1.6 and 2.1 million pounds of milk, respectively, were furnished from outside sources.

The Central Arkansas Milk Producers’ proposal would provide for an automatic adjustment of the Class I price of the Central Arkansas order based upon the supply-demand adjustment provided in the Class I pricing provisions of the Memphis order.

On the basis of the present deficit condition of the market and increased costs of production, producers contended at the hearing that the Class I price under the Central Arkansas order should be increased 20 to 30 cents per hundredweight. They further argued that this should be accomplished either through an increase in the Class I price differentials or through a supply-demand adjustment provided in the Memphis order but by the application of the receipt of utilization of milk in the Central Arkansas marketing area.

Neither this record nor the promulgation hearing record contains data which fully reflect the receipts and sales of fluid milk in the Central Arkansas area. It is not possible to develop a “normal” or “standard” relationship between receipts or sales. The evidence does not indicate that the adoption of the Memphis supply-demand relationship in the Central Arkansas order is justified. Furthermore, it is not possible to appraise the production responses which can be ex-
PROPOSED RULE MAKING

It was previously concluded in the Secretary's decision of October 7, 1955, (20 F. R. 7658) with respect to the proposed order for the Central Arkansas marketing area, that because the previous price and supply history of the market could not be fully relied upon, it was not possible to arrive at an appropriate price and supply history of the market area, and the minimum prices specified in the proposed marketing agreement and the order, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, ensure a sufficient quantity of pure and wholesome milk and be in the public interest; and

(c) The proposed order, as hereby proposed to be amended, will regulate the handling of milk in the same manner as and will be applicable only to persons in the respective classes of industrial and commercial activity specified in the order, as hereby proposed to be amended, upon which a hearing has been held.

Rule 2 [CGFR 55-120, dated July 31, 1950 (15 F. R. 6521) and Treasury Department Order 167-14, dated November 29, 1954 (19 F. R. 8026)] and in compliance with the authority cited with each item of equipment, the following approvals of equipment are terminated because (1) the manufacturer is no longer in business; or (2) the manufacturer does not desire to retain the approval; or (3) the item is no longer being manufactured; or (4) the item of equipment no longer complies with present Coast Guard requirements; or (5) the approval has expired. Except for those approvals which have expired, all other terminations of approvals made by this document shall be made effective upon the thirty-first day after the date of publication of this document in the Federal Register. Notwithstanding this termination of approval of any item of equipment as listed in this document, such equipment in service may be continued in use so long as such equipment is in good and serviceable condition.

DEPARTMENT OF THE TREASURY
United States Coast Guard

CGFR 55-51

TERMINATION OF APPROVAL OF EQUIPMENT

By virtue of the authority vested in me as Commandant, United States Coast Guard, by the Secretary of Transportation, by the Treasury Department Order No. 120, dated July 31, 1950 (15 F. R. 6521) and Treasury Department Order 167-14, dated November 29, 1954 (19 F. R. 8026) and in compliance with the authority cited with each item of equipment, the following approvals of equipment are terminated because (1) the manufacturer is no longer in business; or (2) the manufacturer does not desire to retain the approval; or (3) the item is no longer being manufactured; or (4) the item of equipment no longer complies with present Coast Guard requirements; or (5) the approval has expired. Except for those approvals which have expired, all other terminations of approvals made by this document shall be made effective upon the thirty-first day after the date of publication of this document in the Federal Register. Notwithstanding this termination of approval of any item of equipment as listed in this document, such equipment in service may be continued in use so long as such equipment is in good and serviceable condition.

NOTICES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

Notice of Filing for Establishment of Tolerance for Residues of Sodium-o-phenylphenate

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sect. 408 (d) (1) (I) 68 Stat. 612; 21 U. S. C. 3449a (d) (1)), the following notice is issued:

A petition has been filed by The Dow Chemical Company, Midland, Michigan, proposing the establishment of a tolerance of 10 parts per million for residues of sodium-o-phenylphenate, determined as orthophenylphenol, in or on citrus fruits.

The analytical method proposed in the petition for determining residues of orthophenylphenol is as follows: An acidified sample of orange peel or pulp is steam distilled. Orthophenylphenol is extracted from the distillate with petroleum ether. The petroleum ether solution obtained is washed with sodium hydroxide, and the orthophenylphenol in the alkaline extract is determined colorimetrically by the 4-aminoantipyrine method.

References:


Geo. P. Larrick,
Commissioner of Food and Drugs.

[8:53 a.m., Dec. 13, 1955; Filed at Washington, D. C., this 15th day of December 1955.]

[Seal] ROY W. LENNARTSON,
Deputy Administrator.

[8:53 a.m., Dec. 13, 1955.]

F. R. Doc. 55-10189; Filed, Dec. 19, 1955.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

TOLERANCES FOR ORTHOPHENYLPHENOL

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sect. 408 (d) (1) (I) 68 Stat. 612; 21 U. S. C. 3449a (d) (1)), the following notice is issued:

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The analytical method proposed in the petition for determining residues of orthophenylphenol is as follows: An acidified sample of orange peel or pulp is steam distilled. Orthophenylphenol is extracted from the distillate with petroleum ether. The petroleum ether solution obtained is washed with sodium hydroxide, and the orthophenylphenol in the alkaline extract is determined colorimetrically by the 4-aminoantipyrine method.

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Deputy Administrator.

[8:53 a.m., Dec. 13, 1955.]

F. R. Doc. 55-10189; Filed, Dec. 19, 1955.]

NOTICES

DEPARTMENT OF THE TREASURY

United States Coast Guard

CGFR 55-51

TERMINATION OF APPROVAL OF EQUIPMENT

By virtue of the authority vested in me as Commandant, United States Coast Guard, by the Secretary of Transportation, by the Treasury Department Order No. 120, dated July 31, 1950 (15 F. R. 6521) and Treasury Department Order 167-14, dated November 29, 1954 (19 F. R. 8026) and in compliance with the authority cited with each item of equipment, the following approvals of equipment are terminated because (1) the manufacturer is no longer in business; or (2) the manufacturer does not desire to retain the approval; or (3) the item is no longer being manufactured; or (4) the item of equipment no longer complies with present Coast Guard requirements; or (5) the approval has expired. Except for those approvals which have expired, all other terminations of approvals made by this document shall be made effective upon the thirty-first day after the date of publication of this document in the Federal Register. Notwithstanding this termination of approval of any item of equipment as listed in this document, such equipment in service may be continued in use so long as such equipment is in good and serviceable condition.

NOTICES
FOILIER, HEATING


**TABLE:**

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(Approved Federal Register November 11, 1950. Termination of approval effective November 11, 1955.)

**VALVES, RELIEF, HOT WATER HEATING SYSTEMS**

Termination of Approval No. 162.013/6/0, Type No. 420 relief valve for hot water heating boilers, maximum set pressure 50 p. s. i., relieving capacity 1,000,000 B. t. u. per hour, dwg. No. RA-13 dated July 13, 1950, size 2", manufactured by Ball & Gossett Company, 8200 North Austin Avenue, Morton Grove, III. (Approved Federal Register February 17, 1951.)

**APPLIANCES, LIQUID PROpane GAs CONSUMING**

Termination of Approval No. 162.020/32/0, Magic Chef gas deep fryer, Model No. 316-72, approved by the American Gas Association, Inc., under Certificate No. 13-9-1.011 for liquefied petroleum gas service, manufactured by American Stove Co., 4931 Daggett Avenue, St. Louis 10, Mo. (Approved Federal Register November 11, 1950. Termination of approval effective November 11, 1953.)

Termination of Approval No. 162.020/33/0, Magic Chef gas deep fryer, Model No. 310-72, approved by the American Gas Association, Inc., under Certificate No. 13-9-1.011 for liquefied petroleum gas service, manufactured by American Stove Co., 4931 Daggett Avenue, St. Louis 10, Mo. (Approved Federal Register November 11, 1950. Termination of approval effective November 11, 1953.)

Termination of Approval No. 162.020/34/0, Magic Chef gas deep fryer, Model No. 312-72, approved by the American Gas Association, Inc., under Certificate No. 13-9-1.011 and 13-9-1.011 for liquefied petroleum gas service, manufactured by American Stove Company, 4931 Daggett Avenue, St. Louis 10, Mo. (Approved Federal Register November 11, 1950. Termination of approval effective November 11, 1953.)
Notices

Approval of Equipment and Change in Manufacturer's Address

By virtue of the authority vested in me as Comptroller General of the Treasury and of the United States, by Treasury Department Order No. 120, dated July 31, 1950 (15 F. R. 6521) and by Treasury Department Order 167-14, dated November 26, 1954 (15 F. R. 9920) and in compliance with the authority cited with each item of equipment: It is ordered, That:

(a) All the approvals listed in this document which extend approvals previously published in the Federal Register are prescribed and shall be in effect for a period of five years from their respective dates as indicated at the end of each approval, unless sooner canceled or suspended by proper authority; and,

(b) All the other approvals listed in this document (which are not covered by paragraph (a) above) are prescribed and shall be in effect for a period of five years from the date of publication of this document in the Federal Register, unless sooner canceled or suspended by proper authority.

(c) The change in the name of the manufacturer of approved equipment shall be made as indicated below.


Cleaning Processes for Life Preservers

Where buoyancy fillers are not removed from envelope covers during cleaning process.

Approval No. 160.008/24/0, Rex cleaning process for kapok life preservers without vinyl covered pad inserts, as outlined in letter of October 1, 1955, from Rex Cleaner and Accessories, Inc., 180-18 West 12th Street, Oakland, Calif.

Approval No. 160.009/16/5, MSA Model "S" all-service gas mask, with all-vision facepiece assembly or with all-vision clear face speaking diaphragm facepiece assembly which may be used in conjunction with the MSA Masktone, Bureau of Mines Approval No. EM-1434, MSA assembly dwg. No. A-1129-1 dated November 20, 1939, Rev. 10 dated August 29, 1950, manufactured by Mine Safety Appliances Co., 201 North Braddock Avenue, Pittsburgh 8, Pa. (Extension of the approval published in Federal Register November 11, 1950, effective November 11, 1955.)

Approval No. 160.011/15/1, MSA Model "S" all-service gas mask, with all-vision facepiece assembly or with all-vision clear face speaking diaphragm facepiece assembly which may be used in conjunction with the MSA Masktone, Bureau of Mines Approval No. EM-1434, MSA assembly dwg. No. A-1129-1 dated November 20, 1939, Rev. 10 dated August 29, 1950, manufactured by Mine Safety Appliances Co., 201 North Braddock Avenue, Pittsburgh 8, Pa. (Extension of the approval published in Federal Register November 11, 1950, effective November 11, 1955.)

Approval No. 160.011/18/3, MSA standard all-service gas mask, with all-vision facepiece assembly or with all-vision clear face speaking diaphragm facepiece assembly which may be used in conjunction with the MSA Masktone, Bureau of Mines Approval No. EM-1434, MSA assembly dwg. No. A-1129-1 dated November 20, 1939, Rev. 10 dated August 29, 1950, manufactured by Mine Safety Appliances Co., 201 North Braddock Avenue, Pittsburgh 8, Pa. (Extension of the approval published in Federal Register November 11, 1950, effective November 11, 1955.)

Approval No. 160.012/9/1, MSA standard all-service gas mask, with all-vision facepiece assembly or with all-vision clear face speaking diaphragm facepiece assembly which may be used in conjunction with the MSA Masktone, Bureau of Mines Approval No. EM-1434, MSA assembly dwg. No. A-1129-1 dated November 20, 1939, Rev. 10 dated August 29, 1950, manufactured by Mine Safety Appliances Co., 201 North Braddock Avenue, Pittsburgh 8, Pa. (Extension of the approval published in Federal Register November 11, 1950, effective November 11, 1955.)
BUOYANT VESTS, KAPOK

Note: Approved for use on motorboats of Classe A, 1, or 2 not carrying passengers for hire.


Noble Products Company, Box 327, Caldwell, Ohio.

Approval No. 160.048/34/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i) manufactured by The American Pad & Textile Co., Greenfield, Ohio, for The Firestone Tire & Rubber Co., Akron 17, Ohio.

Approval No. 160.048/35/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i) manufactured by International Cushion Co., 1110 North-East Eighth Avenue, Fort Lauderdale, Fla.

Approval No. 160.048/36/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i) manufactured by The Safeguard Corp., Box 66, Station B, Cincinnati 22, Ohio, for Sears, Roebuck and Co., 925 South Homan Avenue, Chicago 7, Ill.

Approval No. 160.048/37/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i) manufactured by The American Pad & Textile Co., Greenfield, Ohio, for Montgomery Ward & Co., 619 West Chicago Avenue, Chicago 7, Ill.


Approval No. 160.048/39/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i) manufactured by Atlantic-Pacific Manufacturing Corp., 124 Atlantic Avenue, Brooklyn 1, N. Y., for Montgomery Ward & Co., Inc., 619 West Chicago Avenue, Chicago 7, Ill.

Approval No. 160.048/40/0, group approval for rectangular or trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i) manufactured by Fortier Upholstering Co., Manuette, Mich.

Approval No. 160.048/41/0, special approval for 13'' x 18'' x 2'' rectangular ribbed-type kapok buoyant cushion, 21 oz. kapok, dwg. No. 1, dated September 28, 1955, manufactured by Noble Products Co., Box 327, Caldwell, Ohio.

Approval No. 160.048/45/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i) manufactured by A. L. Robertson, Inc., 113 South Gay Street, Baltimore 2, Md.

Approval No. 160.048/47/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i) manufactured by The American Pad & Textile Co., Greenfield, Ohio, for The Firestone Tire & Rubber Co., Akron 17, Ohio.


Approval No. 160.048/49/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i) manufactured by The Safeguard Corp., Box 66, Station A, Greenville, S. C., for Montgomery Ward & Co., Inc., 619 West Chicago Avenue, Chicago 7, Ill.


BUOYANT CUSHIONS, UNICELLULAR PLASTIC FOAM

Note: Approved for use on motorboats of Classes A, B, or C not carrying passengers for hire.

Approval No. 160.049/4/0, group approval for rectangular and trapezoidal unicellular plastic foam buoyant cushions, U. S. C. G. Specification Subpart 160.049, sizes to be as per Table 160.049-4 (c) (1) (i) manufactured by Iowa Fibre Products, Inc., 316 Court Avenue, Des Moines 9, Iowa.

Approval No. 160.049/8/0, group approval for rectangular and trapezoidal unicellular plastic foam buoyant cushions, U. S. C. G. Specification Subpart 160.049, sizes to be as per Table 160.049-4 (c) (1) (i) manufactured by The Safeguard Corp., Box 66, Station B, Cincinnati 22, Ohio, for Sears, Roebuck and Co., 925 South Homan Avenue, Chicago 7, Ill.

Approval No. 160.049/9/0, group approval for rectangular and trapezoidal unicellular plastic foam buoyant cushions, U. S. C. G. Specification Subpart 160.049, sizes to be as per Table 160.049-4 (c) (1) (i) manufactured by Iowa Fibre Products Inc., 316 Court Avenue, Des Moines 9, Iowa.


Table 160.048-4

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<td>A. L. Robertson, Inc.,</td>
<td>113 South Gay Street, Baltimore 2, Md.</td>
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<td>for The Firestone Tire &amp; Rubber Co., Akron 17, Ohio.</td>
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<tr>
<td>160.048-4 (c) (1) (i)</td>
<td>Manufactured by</td>
<td>International Cushion Co.,</td>
<td>1110 North-East Eighth Avenue, Fort Lauderdale, Fla.</td>
</tr>
<tr>
<td>160.048-4 (c) (1) (i)</td>
<td>Manufactured by</td>
<td>The Safeguard Corp., Box 66, Station B, Cincinnati 22, Ohio,</td>
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<td>160.048-4 (c) (1) (i)</td>
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</table>

NOTICES

Balloons, Heating

FIRE EXTINGUISHERS, PORTABLE, HAND, VAPORIZING LIQUID TYPE

Approval No. 162.004/82/1, Kidde Model 2VG (Symbol GEN), 1 qt. carbon tetrachloride vaporizing liquid pump type hand portable fire extinguisher, as approved for the following size and relieving capacities:

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<tr>
<th>Inlet size (inches)</th>
<th>Inlet (B. t. u. per hr. at)</th>
</tr>
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<tr>
<td>1</td>
<td>470,000</td>
</tr>
<tr>
<td>1 1/4</td>
<td>750,000</td>
</tr>
<tr>
<td>2</td>
<td>1,050,000</td>
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Model B.


Approval No. 162.013/29/0, Type No. 150-15 relief valve for hot water heating boilers, relieving capacity 200,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-41-12, dated September 2, 1955, approved for 5/8" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/28/0, Type No. 150-15 relief valve for hot water heating boilers, relieving capacity 200,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-41-12, dated September 2, 1955, approved for 5/8" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/27/0, Type No. 750-15 relief valve for hot water heating boilers, relieving capacity 500,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-42-23, dated September 26, 1955, approved for 3/4" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/26/0, Type No. 750-15 relief valve for hot water heating boilers, relieving capacity 500,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-42-23, dated September 26, 1955, approved for 3/4" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/25/0, Type No. 450-15 relief valve for hot water heating boilers, relieving capacity 300,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-42-23, dated September 26, 1955, approved for 3/4" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/24/0, Type No. 450-15 relief valve for hot water heating boilers, relieving capacity 300,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-42-19, dated September 2, 1955, approved for 3/4" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/23/0, Type No. 450-15 relief valve for hot water heating boilers, relieving capacity 300,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-42-19, dated September 2, 1955, approved for 3/4" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/22/0, Type No. 350-15 relief valve for hot water heating boilers, relieving capacity 250,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-41-12, dated September 2, 1955, approved for 3/4" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/21/0, Type No. 250-15 relief valve for hot water heating boilers, relieving capacity 200,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-41-12, dated September 2, 1955, approved for 3/4" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/18/0, Type No. 150-15 relief valve for hot water heating boilers, relieving capacity 100,000 B. t. u. per hour at a maximum set pressure of 15 p. s. l., dwg. No. RA-41-12, dated September 2, 1955, approved for 3/4" inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.004/82/1, Kidde Model 2VG (Symbol GEN), 1 qt. carbon tetrachloride vaporizing liquid pump type hand portable fire extinguisher, as approved for the following size and relieving capacities:

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</tr>
</tbody>
</table>

Manufactured by Watts Regulator Company, Lawrence, Mass.

The address of The American Pad & Textile Co., Greenfield, Ohio, has been changed to The American Pad & Textile Co., Greenfield, Ohio, New Orleans, La., and Fairfield, Calif., for Approval Nos. 160.048/3/0, 160.043/4/0, 160.043/5/0, and 160.043/6/0 previously published in the Federal Register. Dated: December 13, 1955.

CE. RICHMOND, Vice Admiral, U. S. Coast Guard, Commandant.

CIVIL AERONAUTICS BOARD

NOTICE OF HEARING ON APPLICATION FOR RENEWAL OF FOREIGN AIR CARRIER PERMIT

In the matter of the application of Air Ambulance Service, Department of Public Health, Government of Saskatchewan, for renewal of the foreign air carrier permit issued pursuant to section 402 of the Civil Aeronautics Act, to perform operations of a casual, occasional or infrequent nature, in common carriage, into the United States.

Notice is hereby given that a hearing in the above-entitled proceeding is assigned to be held on December 27, 1955, at 11:00 a.m., e. t., in Forum E-200, Temporary Building No. 5, Sixteenth Street and Constitution Avenue N.W., Washington, D. C., before Examiner Joseph L. Filarmurce.


Ffed., Dec. 10, 1955; 8:43 a.m.

A. C. RICHMOND, Chief Examiner.

AIR AMBULANCE SERVICE; SASKATCHEWAN

[FR Doc. No. 7631]

NOTICE OF HEARING ON APPLICATION FOR RENEWAL OF FOREIGN AIR CARRIER PERMIT

In the matter of the application of Air Ambulance Service, Department of Public Health, Government of Saskatchewan, for renewal of the foreign air carrier permit issued pursuant to section 402 of the Civil Aeronautics Act, to perform operations of a casual, occasional or infrequent nature, in common carriage, into the United States.

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FRANCIS W. BROWN, Chief Examiner.

Ffed., Dec. 10, 1955; 8:43 a.m.
NOTICE OF HEARING ON [Docket No. 7517]

QUEEN CHARLOTTTE AIRLINES LTD.

NOTICE OF HEARING ON APPLICATION FOR EXTENSION OF FOREIGN AIR CARRIER PERMIT

In the matter of the application of Queen Charlotte Airlines Ltd. for an extension of its air carrier permit dated November 20, 1952 issued pursuant to section 402 of the Civil Aeronautics Act to perform operations of a regular air ferry route between Juneau, Alaska and the terminal Prince Rupert, British Columbia.

Notice is hereby given that a hearing in the above-entitled proceeding is assigned to be held on December 27, 1955, at 10:00 a.m., before Examiner Joseph L. Pimentel, at Washington, D.C., on application of Charles E. Hall, Secretary, at which hearing the Respondents shall be in default.


FRANCIS W. BROWN
Chief Examiner.

[F. R. Doc. 55-10168; Filed, Dec. 19, 1955; 8:49 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[Docket No. 11029; FCC 55M-1031]

VOICE OF LAKE TAHOE

ORDER SCHEDULING HEARING

In re application of Charles E. Hall, called Voice of Lake Tahoe, Zephyr Cove, Nevada, Docket No. 11029, for construction permit.

The Hearing Examiner having under consideration a Motion to Fix Date for Hearing filed November 29, 1955, on behalf of the Chief, Broadcast Bureau, Federal Communications Commission; and

It appearing that the hearing in this proceeding was continued by Hearing Examiner's order of September 21, 1954, until such time as may be established by a subsequent order pending Commission action on (1) another application that might be designated for hearing in consolidation with the above application, and (2) a Petition to the Full Commission for Reconsideration and Grant of the instant application; and

It further appearing that the Commission's records indicate that the application referred to in (1) above was dismissed at the applicant's request on August 9, 1955, and that the petition for reconsideration and grant was denied by Commission's order released November 17, 1955; and

It further appearing that no objection to the instant motion has been filed and that a grant thereof will conducive to the orderly dispatch of the Commission's business, now therefore

It is ordered, that at 9:00 a.m. on the 16th day of December 1955, that the Motion to Fix Date for Hearing be and is hereby granted, and that the hearing in this proceeding shall be commenced at 10:00 a.m. on Thursday, January 26, 1956, at the offices of the Commission in Washington, D.C., and

[F. R. Doc. 55-10169; Filed, Dec. 19, 1955; 8:49 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[SEAL]

MARY JANE MORRIS,

Secretary.

[F. R. Doc. 11571; FCC 55M-1034]

JOHNSONVILLE BROADCASTING CO.

ORDER SCHEDULING HEARING

In re application of Dr. Alexander Leech and William E. Leech, d/b/a Johnsonville Broadcasting Company, New Johnsonville, Tennessee, Docket No. 11571, for construction permit.

It is ordered, This 13th day of December 1955, that Annie Neal Huntting will preside at the hearing in the above-entitled proceeding which is hereby scheduled to commence on February 20, 1956, in Washington, D. C.

Released: December 14, 1955.

FEDERAL COMMUNICATIONS COMMISSION

[SEAL]

MARY JANE MORRIS,

Secretary.

[F. R. Doc. 55-10169; Filed, Dec. 19, 1955; 8:49 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[Docket Nos. 11493, 11494; FCC 55M-1030]

RADIO BROADCASTING SERVICE AND DANA W. ADAMS

FIRST STATEMENT CONCERNING PRE-HEARING CONFERENCES AND ORDER CONTINUING HEARING

In re applications of Louis Alford, Phillip D. Brady and Albert Mack Smith, d/b/a Radio Broadcasting Service, Tyler, Texas, Docket No. 11493, for construction permit,

It appearing that no objection to the instant motion has been filed and that a grant thereof will conducive to the orderly dispatch of the Commission's business, now therefore

It is ordered, that the Secretory send a copy of this order by Registered Mail—Return Receipt Requested to the applicant named at P. O. Box 19, Zephyr Cove, Nevada.

FEDERAL COMMUNICATIONS COMMISSION

[SEAL]

MARY JANE MORRIS,

Secretary.

[F. R. Doc. 55-10169; Filed, Dec. 19, 1955; 8:49 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[SEAL]

MARY JANE MORRIS,

Secretary.

[F. R. Doc. 55-10169; Filed, Dec. 19, 1955; 8:49 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

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FEDERAL COMMUNICATIONS COMMISSION

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MARY JANE MORRIS,

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[F. R. Doc. 55-10169; Filed, Dec. 19, 1955; 8:49 a.m.]

FEDERAL COMMUNICATIONS COMMISSION

[SEAL]

MARY JANE MORRIS,

Secretary.
FEDERAL REGISTER

Tuesday, December 20, 1955

9315

desires to be produced for cross-examination (a) in Washington, or (b) through deposition procedures.
8. All parties shall attempt to reach a stipulation with reference to engineering facts.
9. On January 25, 1956, at 10:00 a.m., a further pre-hearing conference shall be held for the purposes stated in section 1.841 (c).
10. Hearing is continued from January 12, 1956, to 10:00 a.m., January 31, 1956.

It is further ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.


FEDERAL COMMUNICATIONS COMMISSION,

[SEAL] MARY JANE MORRIS,

Secretary.

[F. R. Doc. 55-11015; Filed, Dec. 19, 1955; 8:49 a.m.]

[Docket No. 11574]

WARNER AND TAMABLE RADIO SERVICE, INC.,

ORDER TO SHOW CAUSE WHY LICENSE FOR RADIO TELEPHONE STATION SHOULDN'T BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WA-7204, licensed to Warner and Tamable Radio Service, Inc., P. O. Box 165, Memphis 1, Tennessee, and located aboard the vessel "Louisiana",

It appears that notices of the violations of the Commission's rules in the operation of said station were given the licensee as follows:

(a) Notice dated June 6, 1955, specifying, among other things, that the licensee on April 24, 1955, failed to answer either of the above-mentioned official violation notices; It is ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.


FEDERAL COMMUNICATIONS COMMISSION,

[SEAL] MARY JANE MORRIS,

Secretary.

[F. R. Doc. 55-10167; Filed, Dec. 19, 1955; 8:49 a.m.]

[Docket No. 11575]

MISSISSIPPI VALLEY BARGE LINE CO.

ORDER TO SHOW CAUSE WHY RADIO TELEPHONE STATION LICENSE SHOULD NOT BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WA-7204, licensed to Warner and Tamable Radio Service, Inc., P. O. Box 165, Memphis 1, Tennessee, and located aboard the vessel "Louisiana",

It appears that notices of the violations of the Commission's rules in the operation of said station were given the licensee as follows:

(a) Notice dated May 18, 1955, specifying, among other things, that the licensee on April 24, 1955, failed to answer either of the above-mentioned official violation notices; It is ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.


FEDERAL COMMUNICATIONS COMMISSION,

[SEAL] MARY JANE MORRIS,

Secretary.

[F. R. Doc. 55-11017; Filed, Dec. 19, 1955; 8:49 a.m.]

It is ordered, This 14th day of December 1955 pursuant to section 312 (a) of the Communications Act of 1934, as amended, that the said Warner and Tamable Radio Service, Inc., P. O. Box 165, Memphis 1, Tennessee, show cause why the aforementioned license should not be revoked and appear and give evidence in respect thereto at a hearing to be held before this Commission at Washington, D. C., on the 15th day of February 1956.

It is further ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.
to the said Mississippi Valley Barge Line Company, 1017 Olive Street, St. Louis, Missouri.


FEDERAL COMMUNICATIONS COMMISSION,
[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10168; Filed, Dec. 19, 1955; 8:49 a.m.]

[Docket No. 11576]

DUNCAN CAMERON

ORDER TO SHOW CAUSE WHY LICENSE FOR RADIOtelefone STATION SHOULD NOT BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WE-5783 licensed to Duncan Cameron and located aboard the vessel "Kimberly":

It appearing that notices of the violations of the Commission's rules in the operation of said station were given to the licensee as follows:

(a) Notice dated June 8, 1955, specifying, among other things, that on April 21 and 22, 1955, said licensee violated section 3.364 of the Commission's rules by failing to announce the assigned call letters at the beginning and at the end of the communication;

(b) Notice dated July 22, 1955, sent by Registered Mail, Return Receipt Requested, received by the licensee on July 29, 1955, calling attention to the above-noted violations and also the further violation of section 8.601 (a) of the Commission's rules for failure to reply therefor. This notice also requested a response within 10 days of receipt;

It further appearing that as of this date the licensee has not answered either of the above-mentioned official violation notices; it is ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.


FEDERAL COMMUNICATIONS COMMISSION,
[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10169; Filed, Dec. 19, 1955; 8:49 a.m.]

It is further ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.

ORDER TO SHOW CAUSE WHY LICENSE FOR RADIOtelefone STATION SHOULD NOT BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WE-5783 licensed to Duncan Cameron and located aboard the vessel "Kimberly":

It appearing that notices of the violations of the Commission's rules in the operation of said station were given to the licensee as follows:

(a) Notice dated June 8, 1955, specifying, among other things, that on April 21 and 22, 1955, said licensee violated section 3.364 of the Commission's rules by failing to announce the assigned call letters at the beginning and at the end of the communication;

(b) Notice dated July 22, 1955, sent by Registered Mail, Return Receipt Requested, received by the licensee on July 29, 1955, calling attention to the above-noted violations and also the further violation of section 8.601 (a) of the Commission's rules for failure to reply therefor. This notice also requested a response within 10 days of receipt;

It further appearing that as of this date the licensee has not answered either of the above-mentioned official violation notices; it is ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.


FEDERAL COMMUNICATIONS COMMISSION,
[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10171; Filed, Dec. 19, 1955; 8:49 a.m.]

[Cuba Change List 6]

CUBAN RADIO STATIONS

NOTIFICATION OF NEW STATIONS, CHANGES, MODIFICATION AND DELETIONS OF EXISTING STATIONS

November 18, 1955.


<table>
<thead>
<tr>
<th>Call letters</th>
<th>Location</th>
<th>Power (kw)</th>
<th>Antenna</th>
<th>Schedule</th>
<th>Class</th>
<th>Probable date of change or commencement of operation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMQ</td>
<td>Habana, Habana</td>
<td>600 kilocycles</td>
<td>U</td>
<td>I-D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMAB</td>
<td>Pinar del Rio</td>
<td>700 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>II</td>
<td></td>
</tr>
<tr>
<td>CMOH</td>
<td>Habana, Habana</td>
<td>500 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>III-E</td>
<td></td>
</tr>
<tr>
<td>New</td>
<td>Matanzas</td>
<td>500 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>IV</td>
<td></td>
</tr>
<tr>
<td>CMIZ</td>
<td>Santa Clara, Las Villas</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>CMOM</td>
<td>Habana, Habana (video 1600 kc) (delete)</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>CMDD</td>
<td>Bayamo, Oriente</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>II</td>
<td></td>
</tr>
<tr>
<td>CMDE</td>
<td>Bayamo, Oriente</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>IV</td>
<td></td>
</tr>
<tr>
<td>CMDO</td>
<td>Holguin, Oriente (video 1500 kc)</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>CMBG</td>
<td>Habana, Habana (change in call letters)</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>IV</td>
<td></td>
</tr>
<tr>
<td>CMDU</td>
<td>Holguin, Oriente (video 1200 kc)</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>CMZ</td>
<td>Habana (video 1600 kc) (delete)</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>III</td>
<td></td>
</tr>
<tr>
<td>CMOX</td>
<td>Habana (change in call letters)</td>
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<td>ND</td>
<td>U</td>
<td>IV</td>
<td></td>
</tr>
<tr>
<td>CMZ</td>
<td>Habana (video 1500 kc) (video)</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>III</td>
<td></td>
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<tr>
<td>CMCS</td>
<td>Ciego de Avila, Camagayo (correction in error in call letters)</td>
<td>1,000 kilocycles</td>
<td>ND</td>
<td>U</td>
<td>II</td>
<td></td>
</tr>
</tbody>
</table>

[Cuba Change List 6]

[SEAL]

[SEAL]

[SEAL]

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10171; Filed, Dec. 19, 1955; 8:49 a.m.]

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<td>500 kilocycles</td>
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[Cuba Change List 6]

[SEAL]

[SEAL]

[SEAL]

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10171; Filed, Dec. 19, 1955; 8:49 a.m.]

Schooner Corp.

ORDER TO SHOW CAUSE WHY LICENSE FOR RADIOtelefone STATION SHOULD NOT BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WC-4703, licensed to Schooner Corporation, 20 Fish Pier, Boston 10, Massachusetts, and located aboard the vessel "Ocean Clipper":

It appearing that notices of the violations of the Commission's rules in connection with the operation of station WC-4703, licensed to Schooner Corporation, 20 Fish Pier, Boston 10, Massachusetts, and located aboard the vessel "Ocean Clipper":

It further appearing that as of this date the licensee has not answered either of the above-mentioned official violation notices; it is ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.


FEDERAL COMMUNICATIONS COMMISSION,
[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10171; Filed, Dec. 19, 1955; 8:49 a.m.]

[SEAL]

[SEAL]

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10171; Filed, Dec. 19, 1955; 8:49 a.m.]

[SEAL]

[SEAL]

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10171; Filed, Dec. 19, 1955; 8:49 a.m.]

[SEAL]

[SEAL]

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10171; Filed, Dec. 19, 1955; 8:49 a.m.]

[SEAL]

[SEAL]
(2) Section 8.131 by operating with a frequency deviation greater than the tolerance allowed.
(b) Notice dated September 28, 1955, sent by Registered Mail, Return Receipt Requested, which was received by the licensee on September 29, 1955, calling attention to the above noted violations and the further violation of section 8.601 (a) for failure to reply thereto.

The license was also requested to respond within ten days of receipt;

It further appearing that as of this date the licensee has not answered either of the above-mentioned official violation notices;

It is ordered, This 14th day of December 1955, pursuant to the provisions of section 312 (o) of the Communications Act of 1934, as amended, that the said Schooner Corporation, 20 Fish Pier, Boston 10, Massachusetts, show cause why the aforementioned license should not be revoked and appear and give evidence in respect thereto at a hearing 1 to be held before this Commission at Washington, D. C., on the 17th day of February, 1956;

It is further ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.


FEDERAL COMMUNICATIONS
COMMISSION,

[SEAL]
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10172; Filed, Dec. 19, 1955; 8:50 a.m.]

[Cuba Change List 7]

CUBAN RADIO STATIONS
NOTIFICATION OF NEW STATIONS, CHANGES, MODIFICATION AND DELETION OF EXISTING STATIONS

November 25, 1955.


Call letters Location Tower (ft) Antenna Schedule Class Probable date of change or commencement of operation

CMEN, Cleanagos, Las Villas.................. 639 Meters No U II

CMFA, Santa Clara, Las Villas.................. 1,439 Meters No U III Correction to power.

[SEAL]

FEDERAL COMMUNICATIONS
COMMISSION,
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10172; Filed, Dec. 19, 1955; 8:50 a.m.]

FEDERAL POWER COMMISSION

[Docket Nos. G-8854—8854 etc.]

C. R. RIDGWAY ET AL.
NOTICE OF SEVERANCE

December 14, 1955.

In the matters of C. R. Ridgway and W. B. Ridgway, Docket Nos. G-8854—

Section 1.902 of the Commission's rules provides that in order to have the opportunity to appear at the hearing at the time and place specified in an order to show cause, a licensee shall within thirty (30) days from the date of the receipt of a show cause order submit a written statement informing the Commission whether said licensee will appear at the designated hearing and present evidence upon the matters specified, or whether the rights to such a hearing are waived. Waiver of the hearing may be accompanied by a statement setting forth the reasons why the licensee believes that an order of revocation should not be issued. A waiver unaccompanied by such a statement will be deemed to be an admission of the allegations specified in the order to show cause and failure to respond by a show cause order within the above-mentioned thirty (30) day period, or, having informed the Commission in writing within the above-mentioned thirty (30) day period that the licensee will appear at the hearing and present evidence upon the matter specified and then failing to appear at the hearing, will be deemed to be a waiver of the right to a hearing and an admission of the allegations specified in the order to show cause.


By notice issued November 29, 1955, the above-captioned proceedings were consolidated and set down for hearing in Washington, D. C., on December 29, 1955.

Each of the above applications for certificate of public convenience and necessity involves the sale of natural gas in interstate commerce to United Gas Pipe Line Company for resale. In addition, however, the proceeding in Docket No. G-9052 involves an application for a certificate authorizing the acquisition of natural-gas properties.

It appears appropriate, therefore, to sever Docket No. G-9052 from the above-captioned proceedings, and to that end: The proceeding in Docket No. G-9052 be and is hereby severed from the proceedings consolidated with Docket No. G-8864.

Also take notice that the public hearing concerning the matters involved in and the issues presented by the application for a certificate of public convenience and necessity in Docket No. G-9052 will be held at a date and time to be fixed by further notice.

[SEAl] LEON M. FUGUAY,
Secretary.

[F. R. Doc. 55-10183; Filed, Dec. 19, 1955; 8:52 a.m.]

SOUTHERN NATURAL GAS CO.

NOTICE OF ORDER REQUIRING CERTIFICATE OF PUBLIC CONVENIENCE AND NECESSITY

December 14, 1955.

Notice is hereby given that on November 29, 1955, the Federal Power Commission issued its order adopted November 23, 1955, in the above-entitled matter, modifying order issued November 21, 1955, to require a certificate of public convenience and necessity authorizing the construction and operation of facilities for the sale and delivery of natural gas to Mississippi Valley Gas Company, in lieu of the North Central Gas District and the Carthage Gas District.

[SEAl] LEON M. FUGUAY,
Secretary.

[F. R. Doc. 55-10183; Filed, Dec. 19, 1955; 8:52 a.m.]

SOUTHERN PRODUCTION CO., INC.

NOTICE OF APPLICATION AND DATE OF HEARING

December 14, 1955.

Take notice that Southern Production Company, Inc. (Applicant), a Delaware corporation whose address is Fort Worth, Texas, filed on November 26, 1954, an application for a certificate of public convenience and necessity to continue making sales in interstate commerce of natural gas for resale, pursuant to section 7 of the Natural Gas Act, authorizing Applicant to render service as hereinafter described, subject to the jurisdiction of the Commission, all as more fully represented in the application which is on file with the Commission and open for public inspection.

Applicant produces natural gas from the Panhandle and Sprayberry Trend

[DOCKET NO. G-6093]
NOTICES

Gas Fields located in Gray, Upton, Rea-
gan, Midland and Glasscock Counties,
Texas, which it sells in interstate com-
merce to the following buyers for resale:
Phillips Petroleum Company who resells
10 Northern Natural Gas Company, Con-
solidated Gas Utilities Company and
Permian Basin Pipe Line Company also
sells are made to Texas Gas Production
Corporation for resale to El Paso Natural
Gas Company. The natural gas so pur-
chased by Northern Natural Gas Com-
pany, Consolidated Gas Utilities Com-
pn., Permian Basin Pipe Line Company
and El Paso Natural Gas Company is
transported in interstate commerce and
resold for ultimate public consumption
by each of them.

This matter is one that should be dis-
posed of as promptly as possible under
the applicable rules and regulations, and
to that end:

Take further notice that, pursuant to
the authority contained in and subject
to the jurisdiction conferred upon the
Federal Power Commission by sections 7
and 15 of the Natural Gas Act, and the
Commission’s rules of practice and pro-
cedure, a hearing will be held on Janu-
ary 13, 1956, at 9:30 a.m., e. s. t., in
a hearing room of the Federal Power
Commission, 441 G Street NW., Wash-
ington, D. C., concerning the matters in-
volved in and the issues presented by
such application: Provided, however
That the Commission may, after a non-
contested hearing, dispose of the pro-
ceedings pursuant to the provisions of
section 1.30 (a) (1) or (c) (2) of the
Commission’s rules of practice and pro-
cedure. Under the procedure herein
provided for, unless otherwise advised,
it will be unnecessary for Applicant to
appear or be represented at the hearing.
Protests or petitions to intervene may
be filed with the Federal Power Com-
mission, Washington 25, D. C., in ac-
cordance with the rules of practice and
procedure (18 CFR 1.8 or 1.10) on or
before January 6, 1956. Failure of any
party to appear at and participate in
the hearing shall be construed as a waiver
of and concurrence in omission herein of
the intermediate decision procedure in
cases where a request therefor is
made.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10175; Filed, Dec. 19, 1955;
8:50 a.m.]

P. E. HARRIS AND CO., ORGANIZED
VILLAGE OF KAKIE, ALASKA
NOTICE OF ORDER APPROVING TRANSFER
OF LICENSE (MINOR)

DECEMBER 14, 1955.

Notice is hereby given that on No-
ember 30, 1955, the Federal Power
Commission issued its order adopted
November 23, 1955, approving transfer
of license (Minor) in the above-entitled
matter.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10184; Filed, Dec. 19, 1955;
8:53 a.m.]

DOUGLAS WHITAKER ET AL.
NOTICE OF APPLICATIONS AND DATE OF
HEARING

DECEMBER 14, 1955.

In the matters of Douglas Whitaker,
Docket No. G-6749; E. E. Hammond,
Gasoline Co., Docket No. G-6751, Ojai
O & G Corporation, Docket No. G-6732;
Sun Oil Company, Docket Nos. G-6833
to G-6835 and G-6839; Houston
Oil Company of Texas, Docket No. G-
6849; Beaver Lodge Oil Corporation,
Docket No. G-6886; J. R. Howe and G. D.
Beauchamp, Docket No. G-6838; Pecos

There were filed on November 30, 1954,
with the Federal Power Commission ap-
plications as hereinafter specified.

Docket No., Address; Location of Field; Buyer
G-6749; Shreveport, Louisiana; Sibley
Field, Webster Parish, Louisiana; Arkansas
Louisiana Gas Company.
G-6751; Fort Worth, Texas; Keystone Field,
Winkler County, Texas; El Paso Natural Gas
Company.
G-6752; Fort Worth, Texas; Keystone Field,
Winkler County, Texas; El Paso Natural Gas
Company.
G-6833; Philadelphia, Pennsylvania (Ad-
dress of Applicant Sun Oil Company, who has
filed applications in G-6833 to G-6839 incl.
and G-6889; North Staris Field, Beauregard and Calcasieu Parishes, Louisi-
ana; Transcontinental Gas Pipe Line Corpo-
ration.
G-6834; East Gibson Field, Terrebonne
Parish, Louisiana; United Gas Pipe Line
Company.
G-6835; Gist Field, Jasper and Newton
Counties, Texas; Standard Oil Company of
Texas.
G-6836 and G-6838; Egan Field, Acadia
Parish, Louisiana; Transcontinental Gas
Pipe Line Corporation.
G-6837; Midland, Grand Chenier, and Hog
Bayou Fields, Acadia Parish, Louisiana;
Ten-
nessee Gas Transmission Company.
G-6839; Hinkamer, Gilbert Ranch, North
Winnie and Stowell Fields, Chambers, Jeffer-
sun, and Liberty Counties, Texas; Texas
Eastern Transmission Corporation.
G-6889; Eugene Island Field, Louisiana;
United Gas Pipe Line Company.
G-6940; Houston, Beaumont and Hunts
Field, Victoria County, Texas; United Gas
Pipe Line Company.
G-6942; El Paso, Texas; San Juan Basin
Area, San Juan and Rio Arriba Counties,
New Mexico; El Paso Natural Gas Company.
G-6943; San Antonio, Texas; Kelsey Field,
 Starr County, Texas; Sun Oil Company.
G-6945; Lubbock, Texas; Benedict, Tex
Harvey, and Santa Rosa Fields, Upton, Mid-
land and Pecos County, Texas; El Paso Nat-
ural Gas Company.

Each has filed an application for a cer-
tificate of public convenience and neces-
sary pursuant to section 7 of the Natural
Gas Act, authorizing Applicants to ren-
der services as hereinbefore described,
subject to the jurisdiction of the Com-
mision, all as more fully represented in
their respective applications which are
on file with the Commission and open for
public inspection.

Applicants produce and sell natural
gas for transportation in interstate com-
merce for resale, as indicated above.

These related matters should be heard
on a consolidated record and disposed of
as promptly as possible under the ap-
plicable rules and regulations, and to
that end:

Take further notice that, pursuant to
the authority contained in and subject to
the jurisdiction conferred upon the Fed-
eral Power Commission by sections 7 and
15 of the Natural Gas Act, and the
Commission’s rules of practice and pro-
cedure, a hearing will be held on January 20,
1956, at 9:30 a.m., e. s. t., in a hearing
room of the Federal Power Commission,
441 G Street NW., Washington, D. C.,
concerning the matters involved in and
the issues presented by such applications:
Provided, however, That the Com-
mmission may, after a non-contested hear-
ing dispose of the proceedings pursuant
to the provisions of section 1.30 (a) (1)
or (c) (2) of the Commission’s rules of
practice and procedure. Under the pro-
cedure herein provided for, unless other-
wise advised, it will be unnecessary for
Applicants to appear or be represented
at the hearing.
Protests or petitions to intervene may
be filed with the Federal Power Com-
mision, Washington 25, D. C., in accordance
with the rules of practice and procedure
(18 CFR 1.8 or 1.10) on or before Janu-
ary 5, 1956. Failure of any party to
appear at and participate in the hearing
shall be construed as a waiver of and concurrence in omission herein of the
intermediate decision procedure in cases
where a request therefor is made.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10178; Filed, Dec. 19, 1955;
8:51 a.m.]

MONTANA-DAKOTA UTILITIES CO.
NOTICE OF ORDER AUTHORIZING ISSUANCE OF
PREFERRED STOCK

DECEMBER 14, 1955.

Notice is hereby given that on No-
ember 30, 1955, the Federal Power Com-
mision issued its order adopted November
29, 1955, authorizing issuance of preferred
stock in the above-entitled matter.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10179; Filed, Dec. 19, 1955;
8:51 a.m.]

HOPE NATURAL GAS CO.
NOTICE OF FINDINGS AND ORDER

DECEMBER 14, 1955.

Notice is hereby given that on No-
ember 29, 1955, the Federal Power Com-
mision issued its findings and order adopted
November 29, 1955, in the above-entitled
matters, issuing certificate of public con-
venience and necessity and authorizing
abandonment of service to Carnegie
Natural Gas Company.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10178; Filed, Dec. 19, 1955;
8:51 a.m.]
Tuesday, December 20, 1955

[DOCUMENT] United Gas Pipe Line Co. et al.
NOTICE OF FINDINGS AND ORDERS
December 14, 1955.


Notice is hereby given that on November 29, 1955, the Federal Power Commission issued its findings and orders adopted November 23, 1955, issuing certificates of public convenience and necessity in the above-entitled matters.

[SEAL] Leon M. Fugnay, Secretary.

[F. R. Doc. 55-10179; Filed, Dec. 19, 1955; 8:51 a.m.]

[DOCUMENT] Thomas A. Kendall et al.
NOTICE OF APPLICATION AND DATE OF HEARING
December 14, 1955.


Take notice that Thomas A. Kendall, an individual whose address is 314 Travis Building, San Antonio, Texas, as operator of the hereinafter described lease and agent for the remaining parties as captioned above, filed on March 15, 1955, for and on behalf of himself and aforesaid parties (Applicants) an application for certificates of public convenience and necessity under section 7 of the Natural Gas Act, authorizing Applicants to render service as hereinafter described, subject to the jurisdiction of the Commission, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Applicants propose to sell natural gas in interstate commerce from production of 179 acres of a lease, Blanco Field, East Central Bee County, Texas, to United Pipe Line Company for resale.

This matter is one that should be disposed of as promptly as possible under the applicable rules and regulations and to that end:

Take further notice, that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 16 of the Natural Gas Act, and the Commission's rules of practice and procedure, a hearing will be held on Monday, January 23, 1956, at 8:30 a.m., in the Hearing Room of the Federal Power Commission, 441 G Street, NW., Washington, D. C., concerning the matters involved in and the issues presented by such application: Provided, however, that the Commission may, after a non-contested hearing, dispose of the proceedings pursuant to the provisions of section 130 (c) (1) or (c) (2) of the Commission's rules of practice and procedure. Under the procedure herein provided for, unless otherwise indicated, it will be unnecessary for Applicants to appear or be represented at the hearing.

Protests or petitions to intervene may be filed with the Commission, Washington, D. C., in accordance with the rules of practice and procedure (18 CFR 1.9 or 1.110) on or before January 2, 1955. Failure of any party to appear at and participate in the hearing shall be construed as waiver of and consent in omission herein of the intermediate decision procedure in cases where a request thereof is made.

[SEAL] Leon M. Fugnay, Secretary.

[F. R. Doc. 55-10180; Filed, Dec. 19, 1955; 8:51 a.m.]

SECURITIES AND EXCHANGE COMMISSION
FILE NO. 210-1230

ORDER TEMPORARILY SUSPENDING EXHIBITION, STATEMENT OF REASONS THEREFOR, AND NOTICE OF OPPORTUNITY FOR HEARING
December 13, 1955.

I. Trans-Continental Uranium Corporation, a Nevada corporation, 358 South Third East Street, Salt Lake City, Utah, having filed with the Commission on October 1, 1934, a notification on Form 1-A, and subsequently filed amendments thereto, relating to a proposed public offering of 3,000,000 shares of common stock, par value 10 cents, at 10 cents per share for the purpose of obtaining an exemption from the registration requirements of the Securities Act of 1933, as amended, pursuant to the provisions of section 12 (a) (2) of the Securities Act of 1933, as promulgated thereunder; and

II. A. The Commission having reasonable cause to believe that the terms and conditions of Regulation A have not been met, has been, or will be, in that the company has failed to file on Form 2-A reports of sales as required by Rule 224 of Regulation A.

B. The Commission having been advised that Justin Steppler, Inc., a principal underwriter of the securities offered, and Beverly L. Steppler, a director of the issuer, have been permanently enjoined by the New York State Supreme Court, County of New York, from engaging in the business of acting as a broker or dealer in securities in the State of New York.

IX. It is ordered, Pursuant to Rule 223 (a) of the General Rules and Regulations under the Securities Act of 1933 that the exemption under Regulation A be, and it hereby is, temporarily suspended.

Notice is hereby given that any person having any interest in the matter may file with the Secretary of the Commission a written protest to the effect that, within 20 days after receipt of such request, the Commission will, or at any time upon its own motion may, set the matter down for hearing at a place to be designated by the Commission for the purpose of determining whether this order of suspension should be vacated or made permanent, without prejudice, however, to the consideration and presentation of additional matters at the hearing; and that notice of the time and place of said hearing will be promptly given by the Commission.

It is further ordered, That this order and notice shall be served upon Trans-Continental Uranium Corporation, 358 South Third East Street, Salt Lake City, Utah, Justin Steppler, Inc., 15 Exchange Place, Jersey City 2, New Jersey and Registrant and Transfer Co., 15 Exchange Place, Jersey City 2, New Jersey, personally or by registered mail or certified telegraphic notice, and shall be published in the Federal Register.

By the Commission.

[SEAL] Otto L. Dreiban, Secretary.

[F. R. Doc. 55-10181; Filed, Dec. 19, 1955; 8:45 a.m.]

[COPYRIGHT]

[DOCUMENT] Zenith Uranium & Mining Corp.
ORDER TEMPORARILY SUSPENDING EXHIBITION, STATEMENT OF REASONS THEREFOR, AND NOTICE OF OPPORTUNITY FOR HEARING
December 13, 1955.

I. Zenith Uranium & Mining Corp., 351 South State Street, Salt Lake City, Utah, having filed with the Commission on July 12, 1934, a Notification on Form 1-A and an offering circular, and having subsequently filed amendments thereto on July 20 and August 2, 1934, relating to a proposed public offering of 300,000 shares of 1 cent par value common stock at 1 cent per share, for the purpose of obtaining an exemption from the registration requirements of the Securities Act of 1933, as amended, pursuant to the provisions of section 3 (b) thereof and Regulation A promulgated thereunder; and

II. A. The Commission having reasonable cause to believe that the terms and conditions of Regulation A have not been met, has been, or will be, in that the company has failed to file reports of sales on Form 2-A as required by Rule 224; and

B. The Commission having been advised that a consent order was entered on October 25, 1934, by the New Jersey Superior Court for the District of Massachusetts, permanently enjoining Daniel M. Sheehan, Jr., doing business as Sheehan & Company, a director and promoter of the company, who is also one of the principal underwriters of the securities proposed to be offered hereunder, from further violations of sections 10 (b), 15 (a) (1) and 17 (a) of the Securities Exchange Act of 1934 and the Rules and Regulations promulgated thereunder, in connection with the purchase and sale of any security.

III. It is ordered, Pursuant to Rule 223 (a) of the general rules and regulations under the Securities Act of 1933, as amended, that the exemption under

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Regulation A be, and it hereby is, temporarily suspended.

Notice is hereby given that any person having any interest in the matter may file with the Secretary of the Commission a written request for a hearing that, within 20 days after receipt of such request, the Commission will, or at any time upon its own motion may, set the matter down for hearing at a place to be designated by the Commission for the purpose of determining whether this order of suspension should be vacated or made permanent, without prejudice, however, to the consideration and presentation of additional matters at the hearing; and that notice of the time and place for said hearing will be promptly given by the Commission.

It is further ordered, That this order and notice shall be served upon Vigorelli of Canada Ltd., Crisons Brothers, B. Fennekohl & Co. and Toronto General Trust Corporation personally or by registered mail or by confirmed telegraphic notice, and shall be published in the Federal Register.

By the Commission.

[SEAL]

ORVAL L. DUBoIS, Secretary.

[FR. R. Doc. 55-10145; Filed, Dec. 19, 1945; 8:45 a.m.]

American Research and Development Corp. and Paul Valve Corp.

NOTICE OF FILING REQUEST ORDER EXEMPTING PROPOSED TRANSACTION BETWEEN AFFILIATES

December 14, 1955.

Notice is hereby given that American Research and Development Corporation ("Research") a registered closed-end nondiversified investment company, has filed an application pursuant to section 17(b) of the Investment Company Act of 1940 ("act") seeking an order exempting the proposed transaction, described below, from the prohibition contained in section 17(a) (2) of the act.

Paul Valve Corporation ("Paul"), a New Jersey corporation organized in 1947, is engaged in the sale of valves for use in pulp mills, chemical process plants, product pipelines and other industrial applications.

Pursuant to a plan of reorganization consummated in April 1955, Paul exchanged new 10 cent par value common stock for all of its previously outstanding securities. Research received 22,621 shares of new common stock of Paul (22.6 percent of the new stock outstanding) in exchange for $62,000 principal amount of debentures and 26,940 shares of old common stock of Paul which is then held. This transaction was exempted by order of the Commission dated April 14, 1955 (Investment Company Act Release No. 5612).

It is stated that notwithstanding the reorganization Paul's business and credit have not improved; operations for the first four months of the fiscal year beginning May 1, 1955, resulted in a loss of $15,395, and have not unproved; operations for the first six months period following the consummation of the proposed transaction, described above, will not involve overreaching on the part of any person concerned, that the proposed transaction is consistent with the policy of each registered investment company concerned, as re- cited in its registration statement and reports filed under the act, and is consistent with the general purposes of the act.

By virtue of his position as an officer, director, and as a holder of more than 5 percent of the stock of Paul, Harvey is an affiliated person of a registered investment company. Therefore, since Harvey is an affiliated person of an affiliated person of a registered investment company (Research), the proposed transaction is prohibited by section 17(a) (2) of the act unless exempted by the Commission pursuant to section 17(b) of the act.

Research asserts that the proposed transaction was negotiated at arm's length and that except as stated above, Research is not affiliated directly or indirectly with Harvey.

Notice is further given that any interested person may, not later than December 7, 1955, at 5:30 p.m., submit to the Commission in writing any facts bearing upon the desirability of a hearing on the matter and may request that a hearing be held, such request stating the issues to be discussed, the reasons for such request and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission should order a hearing thereon. A request or request should be addressed: Secretary, Securities and Exchange Commission.
sion, Washington D.C. At any time after said date, the application may be granted as provided in Rule N-5 of the rules and regulations promulgated under the act.

By the Commission.

[Seal] ORVAL L. DEBOIS, Secretary.

[F. R. Doc. 55-10417; Filed, Dec. 19, 1955; 8:40 a.m.]

[File No. 70-8428]

GENERAL PUBLIC UTILITIES CORP. AND ASSOCIATED ELECTRIC CO.

NOTICE OF FILING OF APPLICATION-DECLARATION REGARDING RESOLUTION OF INTERMEDIATE HOLDING COMPANY, ACQUISITION OF ITS ASSETS BY TOP HOLDING COMPANY, AND CAPITAL CONTRIBUTION TO SUBSIDIARY OPERATING COMPANY

DECEMBER 14, 1955.

Notice is hereby given that General Public Utilities Corporation (“GPU”) and Associated Electric Company (“Aelec”), both registered holding companies, have filed with the Commission an application-declaration pursuant to the Public Utility Holding Company Act of 1935 (“act”) and have designated sections 9(a), 10, 11, 12(b) and (c) of the act, and Rules U-42 and U-44(c) promulgated thereunder, as applicable to the proposed transactions, which are summarized as follows:

GPU, a New York Corporation, owns all of the outstanding securities (consisting of 400,000 shares of common stock) of Aelec, a Delaware Corporation. It is proposed, if the Commission shall find that the proposed agreement does not comply with the exemption provisions of Rule U-45(b) (b) in that it provides that (i) the declaration be permitted to become effective forthwith, subject to the terms and conditions set forth in Rule U-24; and (ii) the declaration not be taken into consideration in determining the merits of the application-declaration, to order the transfer from Aelec to GPU of all of the outstanding common stock of Meralco and Escudero, and the subsequent transfer by GPU to Meralco as a capital contribution of all of the outstanding common stock of Escudero, require the approval of the Public Service Commission of the Philippines.

Applicants-declarants stipulate and agree that the granting and permitting to become effective of the application-declaration and the carrying out of the transactions thereunder regarding a certain proposed transaction, which is summarized as follows:

Declarants propose to enter into an agreement regarding the allocation among said companies of the consolidated Federal income tax liability of such group of companies. It is stated that the proposed agreement does not comply with the exemption provisions of Rule U-45(b) (b) in that it provides that (i) the declaration be permitted to become effective forthwith, subject to the terms and conditions set forth in Rule U-24; and (ii) the declaration not be taken into consideration in determining the merits of the application-declaration.

Notice is hereby given that General Public Utilities Corporation (“GPU”) and Associated Electric Company (“Aelec”) both registered holding companies, have filed with the Commission an application-declaration pursuant to the Public Utility Holding Company Act of 1935 (“act”) and have designated sections 9(a), 10, 11, 12(b) and (c) of the act, and Rules U-42 and U-44(c) promulgated thereunder, as applicable to the proposed transactions, which are summarized as follows:

GPU, a New York Corporation, owns all of the outstanding securities (consisting of 400,000 shares of common stock) of Aelec, a Delaware Corporation. It is proposed, if the Commission shall find that the proposed agreement does not comply with the exemption provisions of Rule U-45(b) (b) in that it provides that (i) the declaration be permitted to become effective forthwith, subject to the terms and conditions set forth in Rule U-24; and (ii) the declaration not be taken into consideration in determining the merits of the application-declaration.

By the Commission.

[Seal] ORVAL L. DEBOIS, Secretary.

[F. R. Doc. 55-10417; Filed, Dec. 19, 1955; 8:40 a.m.]

[File No. 70-8410]

GENERAL PUBLIC UTILITIES CORP. ET AL.

ORDER REGARDING AGREEMENT PROVIDING FOR ALLOCATION OF CONSOLIDATED FEDERAL INCOME TAX LIABILITIES

DECEMBER 14, 1955.


Declarants propose to enter into an agreement regarding the allocation among said companies of the consolidated Federal income tax liability of such group of companies. It is stated that the proposed agreement does not comply with the exemption provisions of Rule U-45(b) (b) in that it provides that (i) the declaration be permitted to become effective forthwith, subject to the terms and conditions set forth in Rule U-24; and (ii) the declaration not be taken into consideration in determining the merits of the application-declaration.

Notice is hereby given that General Public Utilities Corporation (“GPU”) and Associated Electric Company (“Aelec”) both registered holding companies, have filed with the Commission an application-declaration pursuant to the Public Utility Holding Company Act of 1935 (“act”) and have designated sections 9(a), 10, 11, 12(b) and (c) of the act, and Rules U-42 and U-44(c) promulgated thereunder, as applicable to the proposed transactions, which are summarized as follows:

GPU, a New York Corporation, owns all of the outstanding securities (consisting of 400,000 shares of common stock) of Aelec, a Delaware Corporation. It is proposed, if the Commission shall find that the proposed agreement does not comply with the exemption provisions of Rule U-45(b) (b) in that it provides that (i) the declaration be permitted to become effective forthwith, subject to the terms and conditions set forth in Rule U-24; and (ii) the declaration not be taken into consideration in determining the merits of the application-declaration.

By the Commission.

[Seal] ORVAL L. DEBOIS, Secretary.

[F. R. Doc. 55-10417; Filed, Dec. 19, 1955; 8:40 a.m.]

DEPARTMENT OF JUSTICE

Office of Alien Property

HYALOS S.A.

NOTICE OF INTENTION TO RETURN VESTED PROPERTY

Pursuant to section 22 (2) of the Trading With the Enemy Act, as amended, notice is hereby given of intention to return, on or after 30 days from the date of publication hereof, the following property, subject to any increases or decreases resulting from the administration thereof prior to return, and after adequate provision for taxes and conservancy expenses:

Claimant, Claim No., Property, and Location

Hyalos S.A. a/k/a Hyalos, A.G., Bahnhofstrasse 23, Zug, Switzerland; Claim No. 62057,
NOTICES

Vesting Order No. 17970; $9,908.00 in the Treasury of the United States. Published in the Federal Register on April 30, 1955. For the Attorney General.

[SEAL]
PAUL V. MYRON,
Deputy Director
Office of Alien Property.

[F. R. Doc. 55-10173; Filed, Dec. 19, 1955; 8:50 a.m.]

ANGELA VERCELLI ET AL.
NOTICE OF INTENTION TO RETURN VESTED PROPERTY

Pursuant to section 32 (f) of the Trading With the Enemy Act, as amended, notice is hereby given of intention to return, on or after 30 days from the date of publication hereof, the following property, subject to any increase or decrease resulting from the administration thereof prior to return, and after adequate provision for taxes and conservancy expenses:

Claimant, Claim No., Property, and Location

Grounds for relief: Maintenance of port rate relations with north Atlantic seaboard ports in the United States, and circuitous routes.

Supplement, 78 to Agent Hinch's I. C. C. 4350 and seven other tariffs.

Supplement 24 to Agent Kratzmeier's I. C. C. 4112.

Supplement 24 to Agent Kratzmeier's I. C. C. 4112.

Supplement 24 to Agent Kratzmeier's I. C. C. 4112.

Supplement 24 to Agent Kratzmeier's I. C. C. 4112.

Supplement 24 to Agent Kratzmeier's I. C. C. 4112.

INTERSTATE COMMERCE COMMISSION
FOURTH SECTION APPLICATIONS FOR RELIEF

DECEMBER 15, 1955.

Protests to the granting of an application must be prepared in accordance with Rule 40 of the General Rules of Practice (49 CFR 1.40) and filed within 15 days from the date of publication of this notice in the Federal Register.

LONG-AND-SHORT HAUL

FSA No. 31423: Paint and materials to Missouri River crossings. Filed by W. J. Frueher, Agent, for interested rail carriers. Rates on paint, paint material and related articles, carloads from Chicago, Kansas, and Rockford, Ill., Milwaukee, Racine, and Waukesha, Wis., Minneapolis, Minnesota Transfer and St. Paul, Minn., and St. Louis, Mo., to specified points in Iowa, Kansas, Nebraska, and Dakota on or near the Missouri River.

Grounds for relief: Circuitous routes.

Supplement 49 to Agent Frueher's I. C. C. 4023.

FSA No. 31424: Iron and steel articles to Eastern Canadian Ports. Filed by H. R. Hinze, Agent, for interested rail carriers. Rates on iron and steel articles, carloads, also billets and articles taking same rates, carloads from specified points in central territory and in trunk-line arbitrary east of Pittsburgh, Pa., to specified eastern Canadian ports in the Provinces of New Brunswick, Nova Scotia, and Quebec.

Grounds for relief: Maintenance of port rate relations with north Atlantic seaboard ports in the United States, and circuitous routes.

Supplement, 78 to Agent Hinch's I. C. C. 4350 and seven other tariffs.

Supplement 24 to Agent Kratzmeier's I. C. C. 4112.

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Supplement 24 to Agent Kratzmeier's I. C. C. 4112.

Supplement 24 to Agent Kratzmeier's I. C. C. 4112.
ported on railroad flat cars between St. Louis, Mo., on the one hand, and Muskogee, Okla., on the other.

Grounds for relief: Motor carrier competition.

Tariff: Supplement 32 to Middlewest Motor Freight Bureau tariff MF-1 C. C. 223.

FSA No. 31435: Automobile bodies from Michigan to the East. Filed by H. R. Hinsch, Agent, for interested rail carriers. Rates on automobile bodies, freight or passenger, carloads from Ionia and Pontiac, Mich., to Metuchen, N. J., Framingham, Mass., and Wilmington, Del.

Grounds for relief: Carrier competition and circuitry.

By the Commission.

[SEAL]

Harold D. McCoy,
Secretary.

[FR Doc. 55-10458; Filed, Dec. 19, 1955; 8:43 a.m.]
TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

REPUBLICATION OF REGULATIONS

Chapter I of Title 21 is republished, reading as set forth below. In this republication minor editorial changes have been made and Parts 138, 145, 155, 170, 175, 185, and 186 have been redesignated as Parts 9, 10, 20, 21, 28, 281, 282, 285, and 4, respectively.


[SEAL]

Geo. P. Lareck, Commissioner of Food and Drugs.

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3 Statements of general policy or interpretation.
4 Official records and information.

Subchapter B—Food and Food Products

Part 10 General regulations relating to definitions and standards of identity.
16 Canned products; definitions and standards of identity.
17 Bakery products; definitions and standards of identity.
18 Milk and cream; definitions and standards of identity.
20 Cheeses; processed cheeses; cheese foods; cheese spreads; and related foods; definitions and standards of identity.
25 Dressings for foods.
27 Canned fruits; definitions and standards of identity; quality; and fill of container.
29 Fruit butters, fruit jellies, fruit preserves, and related products; definitions and standards of identity.
36 Shellfish; definitions and standards of identity; fill of container.
42 Eggs and egg products; definitions and standards of identity.
45 Oleomargarine, margarine; definitions and standards of identity.
51 Canned vegetables; definitions and standards of identity; quality; and fill of container.

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RULES AND REGULATIONS

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1.13 Food; labeling; forms of making required statements.

1.14 Conformity to definitions and standards of identity.

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1.15 Drugs; name.

1.16 Drugs and devices; labeling, misbranding.

1.17 Drugs and devices, labeling requirements.

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1.20 Drugs; statement of ingredients and proportion.

1.21 Drugs and devices; directions for use.

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1.23 Exemption from prescription requirements.

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1.715 Public notice of regulations.

A—General

§ 1.1 General regulation. (a) The provisions of regulations promulgated under the act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretation of terms contained in section 201 of the act shall be applicable also to such terms when used in regulations promulgated under the act.

(See Sec. 1.2 and 1.3 issued under Sec. 701 (a), 52 Stat. 1055; 21 U.S.C. 371 (a))

DEFINITIONS

AUTHORITY: §§ 1.2 and 1.3 issued under Sec. 701 (a), 52 Stat. 1055; 21 U.S.C. 371 (a). Statutory provisions interpreted or applied are cited to text in parentheses.

§ 1.1 Labeling; definition. Labeling includes all written, printed, or graphic matter accompanying an article at any time when such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

(See Sec. 201 (m), 52 Stat. 1041; 21 U.S.C. 321 (m))

§ 1.3 Difference of opinion among experts. The existence of a difference of opinion among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

(See Sec. 201 (a), 52 Stat. 1041; 21 U.S.C. 321 (a))

PROHIBITED ACTS AND PENALTIES

AUTHORITY: §§ 1.4 to 1.6 issued under Sec. 701 (a), 52 Stat. 1055; 21 U.S.C. 371 (a). Statutory provisions interpreted or applied are cited to text in parentheses.

§ 1.4 Guaranty. In the case of the giving of a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

(See Sec. 301 (b), 52 Stat. 1042; 21 U.S.C. 331 (b))

§ 1.5 Guaranty; definition, and suggested forms. (a) A guaranty or under-
§ 1.6 Presentation of views under section 305 of the act. (a) Presentation of views under section 305 of the act shall be private and informal. The views presented shall be confined to matters relevant to the contemplated proceeding. Such views may be presented by letter or in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request, seasonably made, by the person to whom a notice appointing a time and place for the presentation of views under section 305 of the act has been given, or by his representative, such request shall be addressed to the office of the Food and Drug Administration which issued the notice.

Food

Authority: §§1.7 to 1.14 issued under sec. 701 (a), 52 Stat. 1053; 21 U. S. C. 371 (a). Statutory provisions interpreted or applied are cited to text in parentheses.

§ 1.7 Food; labeling; misbranding.

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or its drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(2) For foreign manufacturers.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by such statement of weight, measure, or number of such smaller units, as the fact makes necessary.

(4) Statements shall contain only such fractions as are generally used in expressing the quantity of the food. A common fraction shall be expressed in the lowest terms; a decimal fraction shall not be carried out to more than two places.

(5) The statement that the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(6) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label shall state the principal place of business where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(7) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any person of the responsibility that its label shall not be misleading in any particular.

(8) The statement of the quantity of the contents shall reveal the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, viscous, or a mixture of solid and liquid; except that such statement may be expressed as "1 quart;" and not "1 quart and 1 pint" or "1 quart and 1 and three-quarters pints." However, in the case of canned foods, such statement may be expressed as "1 quart;" and not "1 quart and 1 pint;" instead of "24 ounces." The statement shall be "1 quart;" and not "1 quart and 1 pint;" instead of "24 ounces.

(9) In the case of a food with respect to which there exists an established custom or usage in the United States, any representation of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(10) The statement shall express the minimum quantity, or the average quantity, of the contents of the package if the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement may be made in accordance with the usual practice of the trade.

(11) If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be understood to express the average quantity.

(12) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except as provided below.

§ 1.8 Food; labeling; required statements; when excepted.

(1) The statement that the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as "Manufactured for and Packed by—" or "Distributed by —" or other similar phrase which expresses the facts.

(2) The statement of shipment or other delivery of a coal-tar color is required.

(3) The statement of the name of manufacturer and agent (Name of manufacturer and agent) hereby severally guarantee that

(4) The statement of the name of manufacturer and agent (Signature and post-office address of manufacturer)

(5) The statement of the name of manufacturer and agent (Signature and post-office address of agent)
(b) Where the statement does not express the minimum quantity

(1) Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) Variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting inedible substances which occur in good packing practice.

But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though averages in other packages in the same shipment or delivery compensate for such shortage.

(1) The extent of variations from the stated quantity of the contents permissible under (1) and at the time of manufacture or purchase of such food as provided for in this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A food shall be exempt from compliance with the requirements of clause (2) of section 403 (e) of the act if:

(1) The quantity of the contents, as expressed in the label applicable to such food under the provisions of paragraphs (e), (2) of this section, is less than one-half ounce avoirdupois, or less than one-half fluid ounce, or (in case the units of the food can be easily counted without opening the package) less than six units; or

(2) The statement of the quantity of the contents of the package, together with all other words, statements, and information required by or under authority of the act to appear on the label, cannot, because of insufficient label space, be so placed as to conform to all the requirements of section 403 (f) of the act and regulations promulgated thereunder.

(n) A food shall be exempt while held for sale from the requirements of clause (2) of section 403 (e) of the act (requiring a statement on the label of the quantity of contents) if said food, having been received in bulk containers at a retail establishment, is accurately weighed, measured, or counted within the view of the purchaser or in compliance with the purchaser’s order.

(See. 403 (e), 52 Stat. 1047; 21 U. S. C. 343 (t) (f).

§ 1.9 Food; labeling; prominence of required statements. (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 403 (f) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displaying

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device;

(6) Smallness or style of type in which such word, statement, or information, appears or any apparent background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No ingredient shall be designated on a label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term “coloring” shall not include any bleaching substance.

(c) An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring, as the case may be, unless such ingredient is designated by its specific name.

(d) A label may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients appear thereon, or the relative prominence otherwise given such names;

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

(e) A food shall be exempt from the requirements of clause (2) of section 403 (f) of the act if all words, statements, and other information required by or under authority of the act to appear on the label of such food, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 403 (f) of the act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the food is marked with the statement of the quantity of the contents signifies sufficient space to state legibly thereon all the information required by such clause (2), the statement of the quantity of the contents shall be omitted as authorized by § 1.8 (m) (2) and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(f) In the case of an assortment of different items of food, when variations in the items which make up different packages packed from such assortment normally occur in good packing practice, and when such variations result in variations in the ingredients in different packages, such food shall be exempt from compliance with the requirements of clause (2) of section 403 (f) of the act with respect to any ingredient which is not common to all packages. But such exemption shall be on the condition that:

(1) The label shall bear the name of the food; the names of such ingredients as are common to all packages, a statement in
terms which are as informative as practicable and which are not misleading, indicating that other ingredients may be present.

(2) A food shall be exempt while held for sale from the requirements of clause (2) of section 403 (1) of the act (requiring a declaration on the label of the common or usual name of each ingredient when prepared from one or more ingredients) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to clause (2) of section 403 (1).

§ 1.11 Special dietary uses. (a) The term "special dietary uses" as applied to food for man, means particular (as distinguished from general) uses of food, as follows:
(1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the consequences of disease, convalescence, pregnancy, lactation, allergic or other material in which such dye or artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.
(b) A food shall be exempt while held for sale from the requirements of section 403 (1) of the act if it is not in package form and the bulk container, if small enough that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.
(c) A food shall be exempt while held for sale from the requirements of section 403 (1) of the act (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403 (1).

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§ 1.11 Food; exemptions from labeling requirements. (a) (1) An open container is a container of rigid or semirigid construction, which is not closed by lid, wrapper, or otherwise.
(b) (2) An open container of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than one dry quart, shall be exempt from the labeling requirements of paragraphs (e), (g) (2) (with respect to the name of the food specified in the definition and standard) and (l) (1) of section 403 of the act; provided such container is so small that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of containers, and the identity of each, and the quantity of contents of each.

(b) Except as provided by paragraphs (e) (g), (h), (l), and (d) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (e), (g), (h), (l), (1) and (d). of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or
(2) The case such person is not such operator, such shipment or delivery is

made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will insure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the act upon completion of such processing labeling, or repacking. Such person and such operator, shall each keep a copy of such agreement under the act, which shall have been received from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(c) An exemption of a shipment or other delivery of a food under paragraph (b) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.
(d) An exemption of a shipment or other delivery of a food under paragraph (b) (2) of this section shall become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(e) An exemption of a shipment or other delivery of a food under paragraph (b) (2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or
(2) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

(f) The word "processed" shall include the holding of cheese in a suitable warehouse at a temperature of not less than 35° F. for the purpose of aging or curing to bring the cheese into compliance with requirements of an applicable definition and standard of identity. The exemptions provided for in paragraph (b) of this section shall apply to cheese which is, in accordance with the practice of the trade, shipped to a warehouse for aging or curing, on condition that the cheese is identified in the manner set forth in one of the applicable following subparagraphs, and in such case paragraphs (e), (g), (h), (l), and (d) of this section shall also apply:

(1) In the case of varieties of cheeses for which definitions and standards of identity have been promulgated, whether or not they are made from pasteurized milk, each such cheese shall bear on the cheese a legible mark showing the date at which the preliminary
manufacturing process has been completed and at which date curd commences, and to each cheese, on its wrapper or immediate container, shall be affixed a removable tag bearing the statement "Uncured cheese for manufacturing purposes only."

The requirement that the label shall not be misleading in any respect, there may be substituted for the phrase which renders such drug or device misleading in any respect.

There is no substitute for the phrase which renders such drug or device misleading in any respect.

The labeling of a drug which contains two or more ingredients in such a way that it can be misleading by reason of (among other reasons) the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients.

The rule that the quantity of a drug shall be stated in terms of weight, measure, number, or in terms of other units applicable to such drug under general usage in expressing accurate information as to such quantity.

A statement that the quantity of a drug which is not in tablet, capsule, ampule, or other unit form shall be in terms of weight if the drug is solid, semi-solid, or viscous, and the number of such smaller units, or of the quantity of each active ingredient in each such unit.

The statement of the quantity of a device shall be expressed in terms of numerical count.

A statement that the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(b) Unless made in accordance with the provisions of subparagraph (2) of this paragraph, a statement of the quantity of a drug, in the terms of weight, measure, number, or in terms of other units applicable to such drug under general usage in expressing accurate information as to such quantity.

The stated number of any unit which is smaller than the largest unit (specified in such paragraph) contained in the package (for example, the stated number on the label of a package which contains one pint of a drug shall be "1 pint") and not "16 fluid ounces") where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (for example, 1/4 pounds may be expressed as "1/4" pounds, the statement on the label of the drug shall be "1/4 pound" and not "16 fluid ounces").
The statement of the quantity of a drug or device shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement, except in the case of ampules, shall be considered to express the average quantity. The quantity of a drug in ampules shall be considered to express the minimum quantity.

Where the statement expresses the minimum quantity, no variation below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated quantity shall not be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. In the case of a liquid drug in ampules the variation above the stated measure shall comply with the excess volume prescribed by The National Formulary for filling of ampules.

Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) Variations from the stated weight, measure, or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting the contents of individual packages which occur in good packing practice.

But under subparagraph (2) of this paragraph variations shall not be permitted when the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no shortage or shortage package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts and circumstances of each case.

(a) A drug or device shall be exempt from compliance with the requirements of clause (2) of section 502 (b) of the act if:

(1) The statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of paragraph (e) of this section, together with all other words, statements, and information required by or under authority of the act to appear on the label of such drug or device, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 502 (c) of the act and regulations promulgated thereunder or

(2) The quantities of the contents of the package, as expressed in terms of numerical count in compliance with paragraphs (e) (2) or (3) of this section, is less than such units that such units cannot be easily counted without opening the package, or

(3) It is an ointment, is labeled "Sample" or "Physician's Sample," or with a device, a statement, and the contents of the package do not weigh more than 8 grams.

§ 1.103 Drugs and devices; forms of making required statements. (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 502 (c) of the act by reason of other reasons of the size of the body of characters or of the size of the area of the container or package, as expressed in terms of weight, measure, or numerical count of the drug. Such statement, or a substantially similar statement, and the contents of the container or package do not weigh more than 8 grams.

(b) The statement of the quantity of a drug or device shall appear on the label of such drug or device to comply with the requirements of section 502 (b), (c), (d), or (e) of the act and regulations promulgated thereunder, or

(1) The failure of such word, statement, or information to appear on the label in a manner prescribed by the regulations shall not be considered to fail if such constituent is a derivative, unless it is designated solely by a name recognized in an official compendium or derived therefrom, or

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so destined as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, design, or information, or to any device or design; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, absence of lines or vertical or horizontal lines, or crowded with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502 (b) or (c) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502 (c) of the act; or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the act to appear on the label of a drug or device shall appear the same on the label of the drug or device as on the labeling shall appear therein in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

§ 1.104 Habit-forming drugs; label requirements. (a) (1) The name of a substance or derivative required to be labeled on the label of the act to appear on the label or labeling; or under authority of the act shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium or derived therefrom, or

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in section 502 (d) of the act, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) If the drug is in tablet, capsule, ampule, or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(c) If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involving no possibility of habit formation;

(1) A drug shall not be considered to be so labeled unless it appear on the label the statement "Warning— May be habit forming;" shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is distributed and sold in such external use or label, or

(2) The only substance or derivative subject to section 502 (d) of the act contained in such drug shall be chlorobutanol, which constitutes the maximum, unless it is used in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

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(3) If the only substance or derivative subject to section 502 (d) of the act contained in such drug is chlorobutanol which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 5.0 percent, and such drug contains one or more other active ingredients and is for parenteral use only, § 1.105 Drugs; statement of ingredients and proportion. (a) (1) The name of an ingredient, substance, derivative, or preparation required by section 502 (e) (2) of the act to be borne on the label of a drug shall be the name thereof which is listed in such section 502 (e) (2) or which, if not so listed, shall be a specific name and not a collective name. But if an ingredient is an article the name of which is recognized in an official compendium and such article complies with the specifications set forth therefor in such compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth.

(2) Where an ingredient contains a substance the quantity or proportion of which is required and for which a unit of the act to appear on the label, and such ingredient is not a derivative or preparation of such substance as defined in paragraph (d) of section 502 (c) of the act, the label shall bear, in conjunction with the name of the ingredient, a statement of the quantity or proportion of such substance in such drug.

(3) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name “acetophenetidin” shall be considered to be the same as the name “acetophenetidin,” “aminopyrine” the same as “amidopyrine.” The name “alcohol” without qualification, means ethyl alcohol.

(b) (1) A derivative or preparation of a substance named in section 502 (e) (2) of the act is an article which is derived or prepared from such substance by any method, including actual or theoretical combination, and such article shall be a specific name and not a collective name. But if an ingredient is an article the name of which is recognized in an official compendium and such article complies with the specifications set forth therefor in such compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth.

(2) A statement on the label of a drug of the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance as defined in section 502 (e) (2) of the act, shall state how the substance from which such ingredient is derived or prepared and that such ingredient is a derivative or preparation thereof.

(c) (1) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of a substance, derivative, or preparation contained in such unit shall express the weight or measure of such substance, derivative, or preparation in such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance, derivative, or preparation in a specified unit of weight or measure of the drug, or the percentage of such substance, derivative, or preparation thereof. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) A statement of the percentage of alcohol shall be expressed as the weight or measure of absolute alcohol at 60° Fahrenheit (15.56° Centigrade) A statement of the percentage of a substance, derivative, or preparation other than alcohol shall express the percentage by weight; except that, if both the substance, derivative, or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68° Fahrenheit (20° Centigrade) but in such case the statement shall be so qualified that it is evident that the percentage is expressed by volume.

(d) In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative to consumers or users of the activity or consequences of use thereof as a statement of the quantity or proportion of the substance from which such derivative or preparation is derived or prepared, the quantity or proportion of such substance shall also be stated on the label of such drug.

(e) A label of a drug may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients, substances, derivatives, or preparations appear thereon, or the relative prominence otherwise given such names; or

(2) Failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative, or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative, or preparation is a constituent of such drug.

(f) (1) A drug shall be exempt from the requirements of clause (3) of section 502 (e) (2) of the act if all words, statements, and other information required by or under authority of the act to appear on the label of such drug, cannot, because of insufficient label space, be placed on the label as to comply with the requirements of section 502 (e) (2) of the act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity or proportion of the contents of the drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscynamus, scopola, stramonium, or otherwise, shall be made as prominent as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) A drug shall be exempt from the requirements of clause (2) of section 502 (e) (2) (1) with respect to the alkaloids atropine, hyoscynamus contained in such drug, if such alkaloid contained therein as a constituent of belladonna, hyoscynamus, scopola, stramonium, or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of such alkaloid in such ingredient.

But such exemption shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient.

§ 1.106 Drugs and devices; directions for use—(a) Adequate directions for use. “Adequate directions for use” means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed to prescribe, recommend, or suggest such use.

(2) Quantity of dose (including usual quantities for each of the uses for which it is labeled and usual quantities for persons of different ages and different physical conditions)

(3) Frequency of administration or application.

(b) Exemption for prescription drugs. A drug subject to the requirements of section 503 (b) (1) of the act shall be exempt from the requirements of section 502 (e) (1) (1) if all of the following conditions are met:

(i) The drug is:

(A) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or

(B) In the possession of a retail hospital, clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; and

(C) To be dispensed in accordance with section 503 (b) (2) of the act.

(ii) The label of the drug bears:

(A) The statement “Caution: Federal law prohibits dispensing without prescription”;

(B) The recommended or usual dosage; and

(C) The route of administration, if it is not for oral use; and

(D) If it is fabricated from two or more ingredients and is not designated浓度ously by a name recognized in an official compendium, the quantity or proportion of each active ingredient, and if it is not for oral use the names of all other ingredients.
Provided, however, That the information referred to in subdivisions (ii) (iii) and (iv) of this subparagraph may be contained in the labeling on or within the package from which the drug is dispensed, except under the supervision of a licensed veterinarian, and, in the case of ampuls too small or otherwise unable to accommodate a label, but which are packaged in a container from which they are withdrawn for dispensing or use, the information referred to in subdivision (i) of this subparagraph may be placed on the outside container only.

The labeling of the drug (which may include brochures readily available to licensed practitioners) bears information as to the use of the drug by practitioners licensed by law to administer it: Provided, however, That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to administer the drug.

(c) Exemption for veterinary drugs. A drug intended solely for veterinary use, which, because of toxicity or other potentiality for harmful effect, or the method of its use, or the dosage in use, or the disease for which it is used, or the route of administration, is not safe for animal use except under the supervision of a licensed veterinarian, is not safe for animal use except to licensed practitioners licensed by law to administer it: Provided, however, That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to administer the drug.

(i) Statement of caution. A drug intended solely for use in the professional practice of such a licensed practitioner and the directions for use and cautionary statements, which it is to be dispensed.

(ii) The recommended or usual dosage for use or order the use of such device.

(iii) The route of administration, if it is to be dispensed.

(iv) The quantity or proportion of such drug or device subject to paragraph (f) if the drug bore a labeling, shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The drug is in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such drug or device

(2) The label of a drug bears:

(i) The statement "Caution: Federal law restricts this device to sale by or on the order of a _________," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(ii) The method of its application or use.

(3) The labeling of the device (which may include brochures readily available to licensed practitioners) bears information as to the use of the device by practitioners licensed by law to use it or direct its use: Provided, however, That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to use or order the use of such device.

(a) The drug or device shipped directly to licensed practitioners, hospitals, clinics, or public-health agencies for professional use. Except as provided in paragraph (g) of this section, a drug or device shipped directly to or in the possession of a practitioner licensed by law to administer the drug or to use or direct the use of the device, or shipped directly to or in the possession of a hospital, clinic, or public-health agency, for use in the course of the professional practice of such a licensed practitioner, shall be exempt from section 502 (f) (1) of the act if it meets the conditions for which it so sold.

(b) The labeling of a drug bears:

(i) The statement "Caution: Federal law restricts this drug to sale by or on the order of a _________," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(ii) The method of its application or use.

(3) The labeling of the device (which may include brochures readily available to licensed practitioners) bears information as to the use of the device by practitioners licensed by law to use it or direct its use: Provided, however, That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to use or order the use of such device.

(e) Exemption for prescription chemicals and other prescription components. A drug prepared, packaged, and primarily sold as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions or for dispensing in dosage unit form upon prescriptions shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The drug is an official liquid acid or official liquid alkali, or is not a liquid solution, emulsion, suspension, tablet, capsule, or other dosage unit form;

(2) The label of the drug bears:

(i) The statement "For prescription compounding"; and

(ii) If in substantially all dosage forms in which it may be dispensed it is subject to section 503 (b) (1) of the act, the statement "Caution: Federal law prohibits dispensing without a prescription.

(f) Exemption for processing, repacking, or manufacturing. A drug in a bulk package (except as to tablets, capsules, or other dosage unit forms) or a device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt from section 502 (f) (1) of the act if its label bears the statement "Caution: For manufacturing..."
ing, processing, or repacking" and, if in substantially all dosage forms in which it may be dispensed is subject to section 503 (b) (1) the statement "Caution: Federal law prohibits dispensing without, processing, or repacking", and, if in the intent of the persons legally responsible thereof, of a drug or device which is not involving clinical use, or engaged in commerce and is to be processed, labeled, or repacked, as the case may be, of such new drug limited to investigational use, and the delivery of a new drug limited to investigational use, the label statement "Caution: For manufacturing, processing, or repacking" is immediately preceded by the words, "in the preparation of a new drug limited by Federal law to investigational use," and the delivery is made for use only in the manufacture of such new drug limited to investigational use, in accordance with § 11.114.

(m) Exemption for drugs and devices for use in teaching, research, and analysis. A drug or device subject to paragraphs (b) and (c) of this section shall be exempt from section 502 (b) (1) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, research, analysis, or testing.

(n) Expiration of exemptions. (1) If a shipment or delivery, or any part thereof, of a drug or device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such article, in accordance with the practice of the trade, to be processed, labeled, or repacked, in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from the requirements of the labeling and packaging requirements of sections 501 (b) and 502 (b), (d) (e) (f) and (g) of the act if:

1. The person who made such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or
2. In case such purchase or sale is made to such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will ensure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking.

Such person or operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copy available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.

(o) Intended uses. The words "intended uses" or words of similar import in paragraphs (a) (g) (1) (j), (d) and (l) of this section refer to the objective intent of the persons legally responsible for the labeling of drugs and devices. The intent is determined by the words, statements, and other information required by section 502 (b) and (e) of the act during the time such drug is to be processed, labeled, or repacked, as the case may be, of such drug or device in such establishment as will ensure, if such information is followed, that such drug or device will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking.

In the event the person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug is to be processed, labeled, or repacked, an exemption of such shipment or delivery under paragraph (a) (2) of this section shall become void ab initio at the beginning of the act of removing such shipment or delivery or any part thereof, from such establishment, become void ab initio if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.
As soon as practicable after completion of the hearing, the final regulations, granting or refusing the exemption shall be issued, effective on a date specified therein. If the Commissioner for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in a regulation) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, he may issue the final regulation forthwith.

§ 1.108 Exemption from prescription requirements.—(a) Exemption for certain habit-forming drugs. The prescription-dispensing requirements of section 503 (b) (1) (A) of the act are not necessary for the protection of the public health with respect to the following drugs subject to section 503 (d) (1):

- Exempt narcotic preparations described in 26 CFR 151.2 and sold as required by 26 CFR 151.160 through 151.165.

- Drugs containing chlorbutanol, intended for external use only.

- Ephedrine solution, 1 percent, preserved with chlorobutanol and intended for a spray.

- Drugs containing one or more of the derivatives of barbituric acid in addition to a sufficient quantity or proportion of another drug or drugs to prevent the measurement of a sufficient amount of barbiturate derivative to cause a hypnotic or soporific effect.

- Duration of prescription requirement. When the provisions of a new drug application under section 503 (b) (1) (C) of the act remains so limited until it is exempted as provided in paragraph (c) of this section.

(b) Prescription exemption procedure for drugs limited by a new-drug application. The exemption of a drug from the prescription-dispensing requirements of section 503 of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, stating reasonable grounds therefor, and requesting in substance that the Secretary grant, or issue a regulation granting, a new-drug application. Upon receipt of such a petition, or on its own initiative at any time, the Commissioner will publish a notice of proposed rule making and invite written comments. After consideration of all available data, including any comments submitted, the Commissioner may issue a regulation granting or refusing the exemption, effective on a date specified therein. Whenever the Commissioner concludes, either at the time of publication of the notice of proposed rule making or after considering the written comments submitted, that granting or refusing the exemption requires a more thorough development of the facts than is possible in a written presentation, he may call for the hearing thereon. The notice of such hearing shall specify the questions to be considered. As soon as practicable after completion of the hearing, the final regulation granting or refusing the exemption shall be issued, effective on a date specified therein. If the Commissioner for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in a regulation) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, he may issue the final regulation forthwith.

(d) New-drug status of drugs exempted from the prescription requirement. A drug exempted from the prescription requirement under the provisions of paragraph (c) of this section continues to be a "new drug" within the meaning of section 201 (p) of the act until it has been on the market for a material time and has become generally recognized as safe when used in accordance with the directions for use contained in its labeling.

- Prescription legend not allowed on exempted drugs. The use of the prescription caution statement quoted in section 503 (b) (4) of the act, in the labeling of a drug exempted under the provisions of this section, constitutes misbranding. Any other statement or suggestion in the labeling of a drug exempted under this section, that such drug is limited to prescription use, may cause misbranding.

(See. 503, 52 Stat. 1051, as amended; 21 U. S. C. 353 (a))

§ 1.109 New drugs; applications. (a) Each application submitted for filing with the Secretary shall be in duplicate. If any part of the application is in a foreign language, an accurate and complete translation shall be appended to such part.

(b) An application shall not be accepted for filing if only one copy is submitted or if it is incomplete on its face if:

- It does not contain all the matter required by clauses (1) (2) (3) (4), and (6) of section 505 (b) of the act;

- It purports to state the conditions under which the drug was manufactured or distributed; or

- The specimen of labeling proposed for use or within the retail package do not expressly or by reference to a brochure or other printed matter prescribe, recommend, or suggest the use of such drug under such conditions.

The Food and Drug Administration shall notify the applicant of such nonacceptance and the reason therefor and, in case of incompleteness as to matter required, by any clause of section 505 (b) (6), shall specify such clause. Otherwise, the date on which an application is received by the Department shall be considered to be the date on which such application is filed, and the Food and Drug Administration shall notify the applicant of such date. If the applicant withdraws his application, such application shall be considered as not having been filed.

(c) The applicant may file an amendment to an application which has been filed and is pending before the Secretary but in such case the unamended application shall be considered as having been withdrawn and the amended application shall be considered as having been filed on the date on which the amendment is received by the Department. The Food and Drug Administration shall notify the applicant of such date.

(d) After an application has become effective with respect to a drug the applicant may file a supplemental application with respect thereto setting forth any proposed change in the conditions under which such drug is marketed, in the labeling thereof, in any circumstance relating to its production, or in any other information contained in the effective application. Such supplemental application may omit statements made in the effective application concerning which no change is proposed.

§ 1.110 Notification of applicant. If the Secretary determines, before the date prescribed by section 505 (c) of the act for an application to become effective, that he has no cause to issue an order under section 503 (d) of the act refusing to permit such application to become effective, the Food and Drug Administration shall notify the applicant in writing and such application shall become effective on the date of the notification.

(See. 505 (c), 52 Stat. 1023; 21 U. S. C. 355 (c))

§ 1.112 Insufficient information in application. The information contained in an application may be insufficient.
cient for the Secretary to determine whether a drug is safe for use if it fails to include (among other things) a statement showing whether the drug is to be exempt under any provision of §1106, as amended, promulgated pursuant to section 505 (a) of the act, from the requirement that its labeling bear adequate directions for use. If the drug is to be so exempt, the information may also be insufficient if: (a) The label of the drug fails to incorporate a specifically identified brochure or other printed matter containing information adequate for the use of such drug by physicians, dentists, or veterinarians, as the case may be; (b) Such label fails to state that the drug is to be used as shown in such brochure or printed matter and that such brochure or printed matter will be sent to physicians, dentists, or veterinarians, as the case may be, on request; (c) The application fails to contain copies of such brochure or printed matter; or (d) The application fails to show that such brochure or printed matter is readily available to physicians, dentists, or veterinarians, as the case may be, or if not that it is to be made so when the application becomes effective.

§1.113 Untrue statements in application. Among the reasons why an application may contain an untrue statement of a fact are changes in:
(a) Conditions of use prescribed, recommended, or suggested by the applicant for the drug from the conditions of such use stated in the application;
(b) Articles used as components of the drug from those listed in the application;
(c) Composition of the drug from that stated in the application;
(d) Methods used in, or the facilities or controls used for, the manufacture, processing, or packing of the drug from such methods, facilities, and controls described in the application;
(e) Labeling from the specimens contained in the application.

§1.114 New drugs; exemptions from section 505 (a) (1) Except as provided by paragraph (b) of this section a shipment or delivery of a new drug shall be exempt from the operation of section 505 (a) of the act if all the following conditions are complied with:
(1) The label of such drug bears the statement "Caution: New drug—Limited by United States law to investigational use."
(2) The importer of such drug bears the statement "Caution: New drug—Limited by United States law to investigational use." (3) The operator uses such drug solely for such investigation in such establishment, or such operator or agent otherwise disposes of such drug only to, and solely for investigation by or under the direction of, such an expert other than one in such establishment.
(4) Such importer, prior to disposing of any such drug to such an expert, obtains a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation, unless and until an application becomes effective with respect to such drug under section 505 of the act. This subparagraph shall not apply when such shipment or delivery is to the Government of the United States (including the National Research Council) or of any State or municipality, whose official functions involve investigations of new drugs by such experts.
(5) Such person keeps the statement referred to in subparagraph (3) of this paragraph, and complete records showing the date, quantity, and batch or code marks (if any) of each such shipment and delivery.
(6) Such person makes all records and statements referred to in subparagraphs (3) and (4) of this paragraph available for inspection upon the request of any officer or employee of the Department at any reasonable hour until 3 years after the introduction of such shipment or delivery into interstate commerce.

§1.200 Cosmetics; coal-tar hair dye defined. The term "coal-tar hair dye" includes all articles containing any coal-tar color or intermediate which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

§1.201 Cosmetics; labeling; misbranding. (a) Among representations in labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device.
(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.
metric is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such cosmetic such as "Manufactured for..." and "Distributed by..." or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packages, or distributes a cosmetic at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any cosmetic from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with the cosmetic.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and measure, which are generally used by consumers to express quantity of such cosmetic and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such cosmetic exists, the statement shall be in terms of liquid measure if the cosmetic is liquid, or in terms of weight if the cosmetic is solid, semisolid, or viscous, or in such terms of numerical count, or numerical count and weight or measure, as will give accurate information as to the quantity of the cosmetic in the package.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 331 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall express the volume at 68° Fahrenheit (20° Centigrade). However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subparagraph (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(g) Unless an unqualified statement of numerical count gives accurate information as to the quantity of cosmetic in the package, it shall be supplemented by such statement in terms of the metric system of weight or measure.

(h) Statements shall contain only such fractions as are generally used in expressing the quantity of the cosmetic. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(i) (1) If the quantity of cosmetic in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this section, and if such a cosmetic under the provisions of paragraph (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, "16 fluid ounces", "1 quart 1 pint", etc.), or if none of such units is applicable to such cosmetic, the label of a package which contains one pint of cosmetic shall be "1 pint" and not "16 fluid ounces") unless the statement is made in accordance with the provisions of subparagraph (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for examples, 1 1/4 quarters may be expressed as "1 quart 1 1/2 pints" or "1 quart 1 pint 6 fluid ounces"; 1 1/4 pounds may be expressed as a combination of 1 pound 4 ounces") the stated number of any unit which is smaller than the largest unit (specified in such paragraph (f) contained in the package shall not be expressed in terms of a smaller unit, but if such smaller units in the next larger unit so specified (for examples, instead of "1 quart 6 fluid ounces" the statement shall be "1 1/4 quarts" or "1 pint" instead of "24 ounces" the statement shall be "1 1/4 pounds" or "1 pound 8 ounces").

(2) In the case of a cosmetic with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(j) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is in terms of a uniform quantity, the statement shall be considered to express the average quantity.

(k) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonable large.

(l) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure.

(2) Variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting in good distribution practice. But under this subparagraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the cosmetic is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in the packages comprising the same shipment or other delivery compensate for such shortage.

(i) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A cosmetic shall be exempt from compliance with the requirements of clause (2) of section 602 (b) of the act if the quantity of the contents of the package, as expressed in terms applicable to such cosmetic, is less than one-quarter ounce avoirdupois, or less than one-eighth fluid ounce, or in case the units of the cosmetic can be exactly counted without opening the package) less than six units.

Sec. 602 (b) 62 Stat. 1554 21 U.S.C. 362 (b)

1.203 Cosmetic; labeling requirements, form of stating. (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 602 (c) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear in two or more parts or panels of the label, each of which has sufficient space therefor, and which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to a design or device;

(6) Smallness or style of type in which such word, statement, or information appears, insubstantial background
contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) (1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(c) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

(Sec. 602 (c), 52 Stat. 1054; 21 U. S. C. 362 (c))

§ 1.204 Cosmetic; labeling requirements; exemptions. (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a cosmetic, which the operator of the establishment in which said cosmetic is to be processed, labeled, or repacked, in the course of the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that of origin, and in accordance with the labeling requirements of sections 601 (a) and 602 (b) of this act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such cosmetic is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, and packaging of such cosmetic as may be, of such cosmetic in such establishment as will insure, if such specifications are followed, that such cosmetic will not be adulterated or misbranded; and

(3) Such person or such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishments, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(c) Any shipment or other delivery of a cosmetic under paragraph (a) (2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(2) Upon refusal by the operator of the establishment where such cosmetic is to be processed, labeled, or repacked, to make available an inspection copy of the agreement, as required by such clause.

(Sec. 603, 53 Stat. 1054; 21 U. S. C. 363)

IMPORTS AND EXPORTS


§ 1.315 Definitions. For the purposes of the regulations prescribed under section 801 (a) (b) and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The term "owner" or "consignee" means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U. S. C. 1483, 1484, 1485).

(b) The term "chief of district" means the chief of the district of the Food and Drug Administration having jurisdiction over the port of entry through which an article is imported or offered for import, or such officer of the district as he may designate to act in his behalf in administering and enforcing the provisions of section 801 (a) (b) and (c).

§ 1.318 Notice of sampling. When a sample of an article offered for import has been released by the chief of district, the collector of customs having jurisdiction over the article shall give to the owner or consignee prompt notice of the event. The owner or consignee shall deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the chief of district or the collector of customs of the results of examination of the sample.

§ 1.317 Payment for samples. The Food and Drug Administration will pay for all import samples which are found to be in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act.Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration district headquarters in whose territory the shipment was offered for import. Payment for samples will not be made if the article is found to be in violation of the act, even though subsequently brought into compliance under the terms of the authorization to bring the article into compliance that was rendered not a food, drug, device, or cosmetic as set forth in § 1.319.

§ 1.319 Hearing. (a) If it appears that the article may be subject to denial of admission, the chief of district shall give the owner or consignee a written notice to that effect, stating the reasons therefor. Upon timely request, giving reasonable grounds therefor, such time and place may be changed. Upon timely request, the hearing shall be confined to matters relevant to the admissibility of the article, and may be introduced orally or in writing.

(b) If the owner or consignee submits or indicates his intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing, the chief of district shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

§ 1.320 Granting of authorization. (a) When authorization contemplated by § 1.319 is granted, the chief of district shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration having jurisdiction over the port of entry from which the article is imported, or to render it other than a food, drug, device, or cosmetic;

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

§ 1.321 Other conditions as are necessary to maintain adequate supervision and control over the article.

(a) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the chief of district may grant such additional time as he deems necessary.

(b) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the chief of district.

(c) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained
a new authorization. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

§ 1321 Bonds. (a) The bonds required under section 801 (b) of the act may be executed by the owner or consignee of the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise or any part thereof upon demand of the collector of customs and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic, in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with the collector of customs.

(b) The collector of customs may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if he receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under this regulation in any case unless the chief of district is in full agreement with the action.

§ 1322 Costs chargeable in connection with relabeling and reconditioning inadmissible imports. The cost of supervising the relabeling or other action in connection with the above is chargeable against the owner of the food, drug, device, or cosmetic, which fails to comply with the Federal Food, Drug, and Cosmetic Act, and shall be paid by the owner or consignee who files an application requesting such action and executes a bond, pursuant to section 801 (b) of the act, as amended. The cost of such supervision shall include, but not be restricted to, the following:

(a) Travel expenses of the supervising officer.

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law, or at the supervising officer's station, to be calculated at a flat rate of $4.00 per hour (which shall include administrative expense) except that such services performed by a customs officer shall subject to the provisions of section 5 of the act of February 13, 1911, as amended (19 U. S. C. 287) shall be calculated as provided in that act.

(c) Salaries of analyst, to be calculated at a flat rate of $5.00 per hour (which shall include the use of the chemical laboratories and equipment of the Food and Drug Administration).

(d) The minimum charge for services of supervising officers and of analysts shall not be less than the charge for 1 hour, and time after the first hour shall be computed at the same rate, except that fractional parts less than ½ hour shall be disregarded.

ADMINISTRATIVE

§ 1700 Examinations and investigations; samples. (a) (1) When any officer or employee of the Department collects a sample of a food, drug, or cosmetic for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any employee of the Department indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was imported, or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term “analysis” includes examinations and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated;

(2) The cost of twice the quantity so estimated exceeds $10;

(3) The sample is not perishable;

(4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States.

(c) The sample shall be collected from a person named on the label of the article, or his agent, and such person is also the owner of the article;

(d) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon;

(e) The analysis consists principally of rapid analytical procedures, organoleptic examination, or other field inspection examinations or tests, made at the place where the sample is collected or in a mobile or temporary laboratory. In addition to the quantity of sample prescribed above the officer or employee shall, if practicable, collect as part of the sample such further amount of the article as he estimates to be sufficient for use as exhibits in the trial of any case that may arise under the act based on the sample.

(e) The Food and Drug Administration has completed such analyses of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded, within the meaning of the act, or otherwise subject to the prohibitions of the act. If it has reserved an amount of the sample it estimates to be adequate for use as exhibits in the trial of any case that may arise under the act based on the sample, a part of such sample, if sufficient remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when:

(1) After collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or

(2) The request is not made within a reasonable time before the trial of any case under the act, based on the sample, to which such person or owner is a party. The person, owner, attorney, or agent who requests the part of sample shall specify the amount desired. A request from such person or owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefor.

(d) When an official sample of a food, drug, or cosmetic is the basis of a notice given under section 305 of the act, or of a case under the act, and the person to whom the notice is given, or any person who is a party to the case, has no right under paragraph (c) of this section to a part of the sample, such person or his attorney may obtain a part of the sample upon request accompanied by a written waiver of right under such paragraph (c) from each person named on the label of the article and owner thereof, who has not exercised his right under such paragraph (c). The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph (c) of this section.

(e) The Food and Drug Administration is authorized to destroy:

(1) Any official sample when it determines that no analysis of such sample will be made;

(2) Any official sample or part thereof when it determines that no notice under section 305 of the act, and no case under the act, is or will be based on such sample;

(3) Any official sample or part thereof when the sample was the basis of a notice under section 305 of the act, and no case under the act, is or will be based on such sample; and

(4) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(f) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(g) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(h) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(i) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(j) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(k) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(l) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(m) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(n) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(o) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.

(p) Any official sample or part thereof when a sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample.
RULES OF PRACTICE FOR HEARINGS


DEFINITIONS

§ 1.701 Definitions. As used in §§ 1.701–1.715:
(b) The term “Department” means the Department of Health, Education, and Welfare of the United States.
(c) The term “Secretary” means the Secretary of Health, Education, and Welfare.
(e) The term “person” includes an individual, partnership, corporation, and association.
(f) The term “hearing clerk” means the hearing clerk of the Department.

HEARINGS AND NOTICE THEREOF

§ 1.702 Hearings under section 701 of the act, except hearings with reference to regulations under section 404 of the act. The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of the act: 401, 403 (1) 406 (a) and (b) 501 (b) 502 (d) (b) 504, and 604.

§ 1.703 Notice of hearing. The Secretary shall give notice of the hearing by filing the same with the Archivist of the United States for publication in the Federal Register. The notice shall set forth the proposal in general terms and shall state, whether such rules are inapplicable or incomplete, in accordance with the directions of the presiding officer. Such rule shall be conducted in an informal but orderly manner in accordance with the rules in §§ 1.701–1.715 and, when such rules are inapplicable or incomplete, in accordance with the directions of the presiding officer. The presiding officer shall have power to administer oaths, examine witnesses, and receive evidence, and to rule upon the admissibility of evidence and other matters that arise in the course of the hearing, but, except where the presiding officer is the Secretary, shall have no power to decide any matter which involves final determination of the merits of the proceeding.

§ 1.704 Designation and powers of presiding officer. (a) Each such hearing shall be conducted by a presiding officer, who shall be the Secretary or such officer of the Secretary as the Department may designate for the purpose. Any such designation may be made or revoked by the Secretary or such officer of the Secretary as the Department may designate at any time. Such hearing shall be conducted in an informal but orderly manner in accordance with the rules in §§ 1.701–1.715 and, when such rules are inapplicable or incomplete, in accordance with the directions of the presiding officer. The presiding officer shall have power to administer oaths, examine witnesses, and receive evidence, and to rule upon the admissibility of evidence and other matters that arise in the course of the hearing, but, except where the presiding officer is the Secretary, shall have no power to decide any matter which involves final determination of the merits of the proceeding.

(b) The hearing shall be held at the time and place set forth in the notice of the hearing, but may at any time and place be continued from day to day and adjourned to a later day or to a different place, within the city designated in the notice, without notice other than the announcement thereof by the presiding officer at the hearing.

PROCEDURE AT HEARING

§ 1.705 Appearances. At the hearing, any interested person shall be given an opportunity to appear, either in person or through his authorized representative, and shall have the right to submit evidence relevant and material to the proposal. Any interested person who desires to be heard in person at any hearing under the rules in §§ 1.701–1.715 shall file with the presiding officer a written appearance setting forth his name, address and occupation. If such person desires to be heard through a representative, such person or such representative shall file with the presiding officer a written appearance setting forth the authority for such representative and the name, addresses, and occupations of such person or such representative. Any such person or such representative shall give such other information respecting his appearance as the presiding officer may request. All present at the hearing shall conform to all reasonable standards of orderly and ethical conduct.

§ 1.706 Order of procedure. (a) The presiding officer shall have noted on the record his designation as presiding officer and the notice of the hearing as filed with the Archivist of the United States. This shall be done by filing as an exhibit for the record a copy of the Federal Register containing such designation and such notice. If the designation has not been published in the Federal Register, the presiding officer shall file as an exhibit the order of the Secretary designating him to preside.

(b) To promote orderliness and clarity of the record, evidence shall be received with respect to the subject matter of the hearing in the following order, except as the presiding officer otherwise may permit:

(1) Evidence with respect to the proposal in general, including such matters as its historical background, the reason for the proposal, and its probable effect. No evidence shall be introduced at this stage of the hearing as to any specific provision of the proposal.

(2) Evidence with respect to specific terms of the proposal, which shall be read and considered section by section in a sequence to be determined by the presiding officer. Suggestions to add to, delete, or alter any portions of a given section of the proposal shall be made as consideration of such section is reached and, insofar as practicable, shall be submitted within a time to be specified by the presiding officer upon the identification of such statute, report, or document, determine whether the same shall be produced at the hearing and physically be made a part of the evidence as an exhibit or whether it shall
be incorporated into the evidence by reference. Where relevant and material matter offered in evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter shall be excluded in part. It shall be segregated as far as practicable, subject to the direction of the presiding officer.

§ 1.709 Oral and written arguments. (a) Unless the presiding officer shall issue an announcement at the hearing authorizing oral arguments before him, it shall not be permitted.

(b) The presiding officer shall announce at the hearing a reasonable period within which interested persons may file written arguments based solely upon the evidence received at the hearing, citing the page or pages of the transcript of the testimony where such evidence occurs.

§ 1.710 Filing the record of the hearing. As soon as practicable after the close of the hearing, the complete record of the hearing shall be filed in the office of the hearing clerk. The record of the hearing, comprising the transcript of the testimony, including any exhibits and together with any written arguments that may have been filed with the presiding officer.

§ 1.711 Copies of the record of the hearing. The Department will make provisions for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purposes. Any person desiring a copy of the hearing or of any part thereof shall be entitled to the same upon application to the hearing clerk and upon payment of the costs thereof. Suggested corrections to transcripts of the testimony shall be considered only if offered within a period to be fixed by the presiding officer of not more than 3 days following the completion of the testimony, for which purpose the record shall be kept open for such additional period. The presiding officer shall have authority to act upon such suggested corrections.

§ 1.712 Proposed order. The Secretary, within a reasonable time after the filing of the record of the hearing, will issue his proposed order, which shall be served upon the interested persons whose appearances were entered at the hearing by publication in the Federal Register or by mailing a copy of the proposed order to each of such persons by registered mail: Provided, however That if, after examination of the record of the hearing, the Secretary finds that no controversy with respect to the subject of the hearing exists between the persons who appeared thereat, and that such action will promote the purposes of the act, the Secretary may issue a final order in lieu of issuing a proposed order in accordance with this section.

§ 1.713 Exceptions. Within a reasonable time, which shall be specified in the proposed order but shall not exceed 20 days from the issuance of such order, any interested person whose appearance was filed at the hearing may file exceptions to the proposed order. The exceptions shall point out with particularity the alleged errors in said proposed order, and shall contain a specific reference to the page of the transcript of the testimony or the record thereof on which each exception is based. Such exceptions may be accompanied by a memorandum in brief in support thereof.

§ 1.714 Final order. The Secretary thereafter will issue his final order. A duplicate original thereof shall thereon be filed with the Architect of the United States and published in the Federal Register. A duplicate original thereof shall also be filed with the hearing clerk for public inspection.

PUBLIC NOTICE OF REGULATIONS

§ 1.715 Notice of proposed regulations. Public notice of the issuance of the foregoing rules of practice for hearings in §§ 1.701-1.714 shall be given by publishing the same in the Federal Register.

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

Sec.

3.2 Notice to packers and shippers of packed or shellac peanuts, and distributors of glandular preparations.

3.3 Notice to manufacturers, packers, and distributors of glandular preparations.

3.4 Notice to manufacturers, packers, and distributors of dog food, which contains mineral oil.

3.5 Notice to manufacturers, packers, and distributors of gauze bandages.

3.6 Notice to importers: Of Peruvian coca leaf.

3.7 Notice to manufacturers, packers, and distributors of veterinary preparations.

3.8 Notice to manufacturers, packers, and distributors of penicillin-containing drugs for veterinary use.

3.9 Notice to manufacturers, packers, and distributors of cast substitutes.

3.10 Notice to manufacturers and users in food products of monosodium glutamate.

3.11 Notice to manufacturers, packers, and distributors of orthodox hormone preparations.

3.12 Temperary permits for interstate shipment of canned or cured foods containing drugs varying from the requirements of definitions and standards of identity.

3.13 Suspension of a number of parts of regulations and sections of the code.

3.14 Notice to manufacturers and distributors of foods and drugs containing artificial sweeteners.

3.15 Notice to manufacturers and importers of antibacterial and antibiotic-containing drugs.

3.16 Notice to manufacturers, packers, and distributors of drugs for veterinary use.

3.17 Labeling of drugs.

3.18 Notice to manufacturers, packers, and distributors of packed or shellac peanuts, and distributors of glandular preparations.

3.19 Notice to manufacturers, packers, and distributors of packed or shellac peanuts, and distributors of glandular preparations.

3.20 Status of fluidized water and foods prepared with fluidized water under the Federal Food, Drug, and Cosmetic Act.

3.21 Notice to manufacturers and packers of food products of monosodium glutamate and other hydrolyzed vegetable protein products.

3.22 Subpoenas to appear at the hearing.

3.23 Notice to manufacturers and users in food products of monosodium glutamate and other hydrolyzed vegetable protein products.
in affecting the structure or any function or effect of some significant or measurable nature. Preparations incapable of exerting an active effect in the human body were subsequently marketed with disclaimers of the type suggested. The term "inert glandular materials" means preparations incapable of exerting an action or effect of some significant or measurable benefit in one way or another, i.e., in the diagnosis, cure, mitigation, treatment, or prevention of disease, or in affecting the structure or any function of the body.

Manufacturers have heretofore taken advantage of regulation (b) under section 502 (f) of the act (§ 1.106 (b) of this chapter) by presenting applications for use where the so-called "prescription only" legend was placed upon the labels. This regulation was amended, effective October 1, 1945, to provide that applications for use where the so-called "prescription only" legend was placed upon the labels shall not be exempt from the requirements of section 502 (f) (1) of the act that they bear adequate directions for use; and, accordingly, that their labeling must include, among other representations, disclaimers of the type suggested. The regulations enumerated in this chapter now authorizing the omission of directions for use, § 1.106 (b) (3) of this chapter, is the following: "Information adequate for the use of such drugs * * * must be given by physicians, dentists, or veterinarians, as the case may be, readily available." Obviously, information adequate for the use of a glandular preparation which is inert is not available to physicians, dentists, or veterinarians.

The Department of Health, Education, and Welfare is of the opinion that inert glandular materials may not be exempted from the requirements of section 502 (f) (1) of the act that they bear adequate directions for use; and, accordingly, that their labeling must include, among other representations, disclaimers of the type suggested. The regulations for parenteral use are therefore subject to the same comment as applies to those intended for oral administration.

§ 3.4 Notice to manufacturers, packers, and distributors of drugs intended for parenteral use containing mineral oil.

Recent investigations have revealed that most manufacturers have obtained the machinery needed for the individual wrapping of such bandages or have been promised early delivery of such machinery. It will be the purpose of the Department of Health, Education, and Welfare to recommend legal actions in instances where United States Pharmacopeia parenteral requirements are not met by July 1, 1948.

§ 3.6 Notice to importers of Peruvian canned fish. In collaboration with the United States Department of State and officials of the Government of Peru, the Food and Drug Administration of the Department of Health, Education, and Welfare has made a study in Peru of the canning of bonito and tuna packed for exportation to the United States. The fish known in Peru as bonito constitute a major portion of the pack. Representative specimens of Peruvian bonito have been identified as the species Sarda chilensis. This confirms previous information that the species of fish constituting the commercial bonito fishery in Peru is the same species of bonito that has been packed in this country in small quantities and sold as bonito, for many years.

Minor quantities of another bonito, Sarda velox, are apparently caught in Peruvian waters but do not enter the commercial pack at any significant degree. The bonitos, Sarda chilensis and Sarda velox, are not classified as tuna and under the provisions of the Federal Food, Drug, and Cosmetic Act have never been legally labeled as tuna, but must be labeled as "bonito" or "bonito fish.

Two species of tuna, "skipjack" (Katsuwonus pelamis) and "yellowfin" (Thunnus macropterus), are commercially packed in Peru and constitute a relatively small proportion of the Peruvian pack of canned fish exported to the United States.

Information developed during the investigations in Peru shows that the bonito (Sarda chilensis) can be readily distinguished from the tunas. Consequently no difficulty should be encountered by packers in keeping separate the fish in the two classifications and in properly labeling the canned product before shipment.

The provisions of the Federal Food, Drug, and Cosmetic Act require that importations of canned bonito and canned tuna, when offered for entry into the United States, must bear labels designating the product as "bonito" or as "tuna", as the case may be, and that unbranded or misbranded canned fish not legally labeled as bonito or tuna are subject to seizure and condemnation.

§ 3.7 Notice to manufacturers, packers, and distributors of fish in pet food. A number of pet foods have been developed to promote fattening, increase milk or egg production, or effect other physiological changes in farm animals. Many of these compounds contain as active ingredients substances the toxicity of which is known to be of a high order. For example, thiouracil, a very powerful agent, has been proposed for use to promote fattening. When such substances are added to food they render the food adulterated under section 402 (a) of the Federal Food, Drug, and Cosmetic Act.

The Department of Health, Education, and Welfare regards sections 402 (a) (2) and 406 of the act as clear enunciations of congressional intent to deny the chann
Results of treatment are no more than fair in mastitis caused by Streptococcus uberis and staphylococcus; poor in cases caused by corynebacteria. Mastitis caused by colon bacill not respond to penicillin according to reports. In cases of mastitis, streptococci, actinomycoses, bovis, erysipelas in turkey, superficial infections of the skin caused by penicillin-sensitive organisms. It should be remembered that proper use of effective therapy depends on an accurate diagnosis of the disease condition to be treated.

**Methods of administration**—(1) **By injection.** Deep intramuscular injection is the route of choice when using the parenteral forms of penicillin for systemic therapy. Subcutaneous injections are not to be used frequently, therefore usually avoided. When penicillin in oil or penicillin in oil and wax is injected care should be taken that the needle is not in the main vessel discharging the contents of the syringe.

(2) **By mouth.** Since penicillin is inactivated by gastric secretion, it cannot be given by mouth unless precautions are taken to maintain the drug in the stomach. This may be accomplished through the use of buffered penicillin tablets given at least 2 hours before and not less than 2 hours after eating. The therapeutic efficacy of these tablets will vary in different individuals and according to the amount of active penicillin absorbed. As a general rule, the amount of penicillin required for effective therapy when given by mouth is five times the amount required by injection. With the possible exception of small-animal practitioners, veterinarians will probably find it impractical to use penicillin in this form. Buffered penicillin tablets may be of value in some cases in which it is not possible to administer the drug by injection at the required intervals and in others after the disease has been brought under control by penicillin injections, and it is desirable to continue the use of the drug. The tablets may be given alone or as a supplement to parenteral therapy. In all serious conditions, however, parenteral administration is the recommended route.

**By topical application.** Topical application includes direct injection of penicillin suspended in suitable vehicles into udders through the teat canal, into abscesses, joint capsules, body cavities, the spinal canal, and direct application to the skin and eyes. The underlying purpose of this method is to insure effective therapeutic concentrations of penicillin in the local areas of infection. In many instances it may be used as an adjunct to parenteral injections. However, after parenteral injection, penicillin does not penetrate readily to the eyes, into spinal fluid, or, unless in extremely high unitage, into the milk. Therefore the topical method appears to be the only practical one of treating local infections involving the eyes, spinal canal, or udder.

**Dosage**—(1) **Systemic infections.** For therapy of systemic infections caused by most strains of penicillin-sensitive organisms, 0.2 units of body weight should be administered, preferably by intramuscular injection. Further information concerning this recommendation may be obtained by contacting your local distributor. To maintain effective therapeutic concentrations of the drug in the body fluids and tissues, the necessary amount of penicillin in oil and wax should be given every 12 hours. The indicated quantity of procaine penicillin in oil or of certain of the newer adjlatable repository penicillin products may be given as infrequently as once every 24 hours or longer. However, severe infections or infections caused by less sensitive organisms may require up to double the minimum dosage or more frequent injections. Since the objective of penicillin therapy is to bring the infection under control as quickly as possible, the minimum dosage or frequency of injection or both should be increased materially if this is known to be caused by sensitive organisms if no definite indication of clinical improvement is noticed 12 to 14 hours after the initial injection. (2) **Bovine Streptococcus agalactiae mastitis.** Effective treatment of udders infected with penicillin-sensitive organisms depends on maintaining therapeutically effective concentrations of penicillin in the area of infection. Available experimental data indicate that the following methods for introducing adequate amounts of the drug into infected quarters can be depended upon to overcome the infection in a majority (75 percent or more) of Streptococcus agalactiae mastitis cases:

- Buffered penicillin solutions (sodium, calcium, or crystalline penicillin dissolved in sterile distilled water)
- Inject 25,000 to 30,000 units under acricle condition through the teat canal into each infected quarter, given as infusions of 25,000 units each at intervals of 8 hours or once every 12 hours until five to seven infusions have been made. One repeat injection may be sufficient in the chronic form without indication.
- In cows producing up to 40 pounds of milk per day a total of 100,000 units per infected quarter administered as five infusions of 20,000 units each at intervals of 12 hours or as four injections of 25,000 units each at intervals of 24 hours. In cows producing more than 40 pounds of milk per day or in acute cases a total of 200,000 units per infected quarter is the minimum of 2,000 units per infected quarter, administered as four infusions of 50,000 units each at intervals of 24 hours. This may be desirable to slap one milking after the last injection in the series to provide a therapeutic concentration of penicillin in the treated quarters. Volume at the point of vehicle should be adequate to favor immediate distribution throughout udder and teat area. Usually 50 cc or more is adequate.
- Large udders: First day, 200,000 units per infected quarter; second and
third days, 100,000 units per infected quarter each day. Small to moderate-sized udders: First day, 100,000 units per infected quarter; second and third days, 50,000 units per infected quarter each day. All quarters infected with Staphylococcus albus and Staphylococcus aureus should be treated with 100,000 units under aseptic conditions through the test canal into each infected quarter. Repeat treatment if subsequent bacteriological examination shows infection to be still present.

(ii) Emulsified solutions (soluble salts of penicillin dissolved in oil and water emulsified with vegetable oil) should be treated with 100,000 units under aseptic conditions through the test canal into each infected quarter. Repeat treatment if subsequent bacteriological examination shows infection to be still present.

(iii) Bougies (25,000 or more units of sodium, calcium, potassium, or procaine penicillin in a milk-soluble base shaped in slender, elongated form to permit easy insertion into the milk cistern of the udder through the test canal) Aseptically insert one bougie into each infected quarter after each milking for as long as the infection persists.

(iv) Oil and wax suspensions (calcium or crystalline penicillin in refined peanut or sesame oil and white wax) and ointments (calcium or crystalline penicillin in an ointment base suitable for udder instillation) in view of the scarcity of information concerning this use of such products, basic directions for use may be different in individual cases. Adequacy of directions as a whole depends primarily on the penicillin potency of each product and the nature of supportive data.

§ 3.10 Notice to manufacturers and users in food products of monosodium glutamate. In the light of information now before the Food and Drug Administration on the manner of use of monosodium glutamate in foods, this Agency is not disposed to maintain the position previously expressed by it on April 11, 1940, in a trade correspondence letter designated as TC 233 that monosodium glutamate be designated as an artificial flavoring and added to foods on labels which it is added. Where it is used as an ingredient in a food for which a standard of identity has not been promulgated under the Federal Food, Drug, and Cosmetic Act, the Agency does not consider this to be a violation of the Federal Food, Drug, and Cosmetic Act. The interstate distribution of monosodium glutamate under section 201 (p) of the Federal Food, Drug, and Cosmetic Act. The interstate distribution of monosodium glutamate under section 201 (p) of the Federal Food, Drug, and Cosmetic Act. The interstate distribution of monosodium glutamate under section 201 (p) of the Federal Food, Drug, and Cosmetic Act. The interstate distribution of monosodium glutamate under section 201 (p) of the Federal Food, Drug, and Cosmetic Act. The interstate distribution of monosodium glutamate under section 201 (p) of the Federal Food, Drug, and Cosmetic Act. The interstate distribution of monosodium glutamate under section 201 (p) of the Federal Food, Drug, and Cosmetic Act.

(b) It is the purpose of the Department to permit such tests where they are necessary to the proper determination of the safety of an otherwise adequate investigation and where the interests of consumers are adequately safeguarded. The Department will therefore refrain from recommending regulatory procedures under the act on the charge that a food does not conform to an applicable definition, if the person who introduces the food into interstate commerce holds an effective permit from the Secretary providing specifically for those variations in respect to which the food fails to conform to the applicable definition and standard of identity.

(c) Any person desiring a permit may file with the Secretary a written application in triplicate containing as part thereof the following information:

Name and address of the applicant.

(2) A statement of whether or not the applicant is regularly engaged in producing the food involved.

(3) A reference to the applicable definition and standard of identity (citing applicable section of regulations).

(4) A full description of the proposed variation from the standard.

(5) The basis upon which the food so varying is believed to be wholesome and not deleterious.

(6) The amount of any new ingredient to be added; the amount of any ingredient, required by the standard, to be eliminated; any change of concentration or contemplation of a new ingredient by the standard; or any change in name that would more appropriately describe the new product under test. If such new ingredient is not a commonly known food ingredient, a description of its properties and basis for concluding that it is not deleterious or toxic.

(7) The purpose of effecting the variation.

(8) A statement of how the variation is of potential advantage to consumers.
(9) The labeling proposed to be used for the food so varying.

(10) The period during which the applicant desires to introduce such food into interstate commerce, with a statement of the reasons supporting the need for such period.

(11) The probable amount of such food that will be distributed.

(12) The areas of distribution.

(13) Food tampering at which such food will be manufactured.

(14) A statement of whether or not such food has been or is to be distributed in the State in which it was manufactured.

(15) If it has not been or is not to be so distributed, a statement showing why.

(16) If it has been or is to be so distributed, a statement of why it is deemed necessary to distribute such food in other States.

(d) The Secretary may require the applicant to furnish samples of the food varying from the standard and to furnish such additional information as may be deemed necessary for action on the application.

(e) If the Secretary concludes that the variation may be advantageous to consumers and will not result in failure of the food to conform to any provision of the act except section 403 (g) a permit shall be the applicant for interstate shipment of such food. The terms and conditions of the permit shall be those set forth in the application with such modifications or qualifications as the Secretary may deem necessary and state in the permit.

(f) The terms and conditions of the permit may be modified at the discretion of the Secretary or upon application of the permittee during the effective period of the permit.

(g) The Secretary may revoke a permit for cause, which shall include but not be limited to the following:

(1) That the permittee has introduced a food into interstate commerce contrary to the terms and conditions of the permit.

(2) That the application for a permit contains an untrue statement of a material fact.

(3) That the need therefor no longer exists.

(h) During the period within which any permit is effective, it shall be deemed to be included within the terms of any guaranty or undertaking otherwise effective pursuant to the provisions of section 303 (e) of the act.

(i) If an application is made for an extension of the permit, it shall be accompanied by a description of experiments conducted under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered necessary.

(See S. 401, 403, 42 Stat. 1046, 1047, 21 U. S. C. 341, 348)

§ 3.13 Supplying pharmacists with indications and dosage of drugs. (a) This Department is aware of statements that the regulations covering prescription drugs prevent the manufacturer from sending information and data he needs to indicate indications and dosage in exercising his important professional function of checking against possible mistakes in the prescription.

(b) The regulations emphasize the importance of the profession of pharmacy; they are not intended to deprive the pharmacist of information necessary to the discharge of his professional duty of insuring the integrity of the drugs he dispenses on prescription.

(c) To discourage attempts at self-medicating or mixing drugs, the pharmacist cannot safely and effectively use without the physician's guidance and which therefore should be dispensed only on the doctor's request, it is provided that the labeling of such drugs shall not bear indications or directions, except that the prescription package should bear the directions specified in the prescription. The law defines labeling as written, printed, or graphic matter accompanying the drug.

(d) The courts have given a broad interpretation to the definition of labeling, finding it to cover all as well as the printed or the like used to inform consumers what the drug is for and how it is to be used. The Department of Health, Education, and Welfare believes it would render a pharmacist for professional information, and not as a means of over-the-counter sales promotion, such as by displaying to prospective purchasers, as a legitimate means of making information necessary for professional use readily available. This Department has no intention of recommending any misleading advertising or use of such material for that professional purpose.

§ 3.14 Notice to manufacturers and distributors of foods and drugs containing artificial sweeteners. Chronic-toxicity studies conducted by the Department of Health, Education, and Welfare show that the artificial sweeteners dulcin (also known as sucral, or 4-ethoxyphenylurea, or paraphenetolcarbamide) and P-4000 (also known as N-propyul-2-amino-4-nitrobenzene) cause injury to rats when fed at relatively low levels for approximately 2 years. Consequently, the Secretary of Health, Education, and Welfare wishes to convey the impression to the pharmacist for his professional information, and not as a means of over-the-counter sales promotion, such as by display to prospective purchasers, as a legitimate means of making information necessary for professional use readily available. This Department has no intention of recommending any misleading advertising or use of such material for that professional purpose.

§ 3.15 Notice to manufacturers and distributors of foods and drugs containing antibiotic and antibiotic-containing preparations. Letters by the Department of Health, Education, and Welfare have revealed that a number of persons engaged in manufacturing and selling antibiotic and antibiotic-containing preparations are entering into interstate commerce shipments of these drugs that are unlabeled, or not fully labeled, and are not exempt from labeling under the terms and conditions as outlined in § 146.18 of this chapter. This practice has been based upon the belief that interstate shipments of antibiotic and antibiotic-containing drugs to purchasers in the export trade are not subject to certification.

When these drugs are introduced into interstate commerce contrary to the requirements of the act, they are declared to be misbranded. This section provides for the release of ox bile from condemned livers of slaughtered animals for use in the manufacture of certain drugs.

The Secretary of Health, Education, and Welfare has reviewed the animal drug industry's operation to this problem and has reached the conclusion that no hazard to public health will be involved in the release of such ox bile, after the addition of an inert sodium hydroxide to the bile, to give the mixture a sodium hydroxide content of not less than 5 percent, the mixture then being allowed to stand at least 24 hours. This Drug Enforcement Administration has issued a letter of violation of the provisions of the Federal Food, Drug, and Cosmetic Act such alkalized and aged ox bile, if labeled “Ox Bile and Sodium Hydroxide (or Ox Bile and Sodium Hydroxide not less than 5 percent by weight.) For manufacturing use only,” together with a statement of the quantity of ingredients in the commerce (in an example, “50 gallons”) and the name and address of the manufacturer, packer, or shipper.

Bile from the condemned livers of sheep and goats also may be released, under the same conditions as outlined in the preceding paragraph, except that the words “Sheep Bile” or “Gest Bile,”...
as the case may be, shall be substituted for the words "Ox Bile" upon the label. In the case of mixtures of bile from any two or all three of the sources mentioned, the label shall indicate the sources of such bile.

§ 3.17 Labeling of oleomargarine. The Federal Food, Drug, and Cosmetic Act was amended by the recently enacted legislation (64 Stat. 20) on colored oleomargarine. A new section numbered 407 was added. Among other things, the new section requires that there appear on the label of the package the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on such label, and a full and accurate statement of all the ingredients contained in such oleomargarine or margarine. It provides that these requirements "shall be in addition to and not in lieu of any of the other requirements of this Act."

(a) Under section 403 (g) of the Federal Food, Drug, and Cosmetic Act any article that is represented as or purports to be oleomargarine must conform to the definition and standard of identity for oleomargarine as promulgated under section 401 of the act. Where more than one type of oleomargarine is involved, the name specified in the statute should appear on the label, until the standard is amended.

(b) While under the provisions of the identity standard for oleomargarine only certain of the optional ingredients authorized by the standard are required to be declared on the label, section 407 requires, in the case of colored oleomargarine, "a full and accurate statement of all the ingredients contained in such oleomargarine or margarine." The following optional ingredients authorized by the identity standard for oleomargarine and the names by which we believe such ingredients, when present, should be declared in order to constitute "a full and accurate statement" are set forth below:

(1) The rendered fat, or oil, or stearin derived therefrom (any or all of which may be hydrogenated) of cattle, sheep, swine, or goats, or any combination of two or more of such articles—be it declared by the name of the specific animal fat, oil, or stearin, for example, "beef fat."

(2) Any vegetable food fat or oil, or oil or stearin derived therefrom (any or all of which may be hydrogenated) or any combination of two or more of such articles—to be declared as, for example, "cottonseed oil, soybean oil, peanut oil, and corn oil," listing the predominating oils of the mixture ahead of those which are present in much smaller quantities. If the oil or oils present are hydrogenated, the declaration should be, for example, "hydrogenated cottonseed oil" or "hydrogenated soybean oil" when one is hydrogenated and the other is not.

(3) The optional ingredients cream, milk, skim milk, or dried skim milk (nonfat dry milk solids or defatted milk solids) and any salt, flavor, or color should be declared by these terms.

(4) Artificial color and artificial flavor should be declared as such by the terms prescribed in the identity standard for oleomargarine. They need not be additionally declared by the names of the specific colors or flavors.

(5) The presence of sodium benzoate or benzaquin acid should be declared as prescribed by the identity standard for oleomargarine and when applied to comply with the definition and standard of identity for oleomargarine promulgated under section 401 of the act, it was the clear intent of Congress that any article which is represented as or purports to be oleomargarine and which fails to comply with the definition and standard of identity for oleomargarine is misbranded under section 403 (g), even though it may meet the new statutory definition if it fails to comply with the definition and standard of identity for oleomargarine heretofore has not applied to colored or uncolored oleomargarine sold within the same State in which manufactured. By the terms of the new section 407 colored oleomargarine or colored margarine which is sold in the case, or in a display in the store, or is presented as or purports to be oleomargarine or margarine or which fails to comply with the definition and standard of identity for oleomargarine is subject to the provisions of this act as if it had been introduced to interstate commerce.

(b) When placing the names of these foods on labels so as to comply with the requirements of section 403 (a), (d), and (g) of the act, all the words forming the name specified by the definition and standard of identity should be given equal prominence. This can readily be accomplished by printing the specified name of the food in letters of the same

similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter. Notwithstanding the difference between this definition and the definition and standard of identity for oleomargarine promulgated under section 401 of the act, it was the clear intent of Congress that any article which is represented as or purports to be oleomargarine and which fails to comply with the definition and standard of identity for oleomargarine is misbranded under section 403 (g), even though it may meet the new statutory definition if it fails to comply with the definition and standard of identity for oleomargarine.
A hearing to take evidence on these proposals will be called as soon as practicable. Pending such a hearing and the issuance of an order resulting therefrom, the Department of Health, Education, and Welfare will not recommend action against pasteurized process cheese foods or pasteurized process cheese spreads solely because they include skim milk milk. The regulations cannot be amended to insert definitions of optional cheese or dairy ingredients. Such foods must comply with other requirements of the existing regulations as well as the general provisions of the law.

§ 3.23 Purified monosodium glutamate

The statement of the Department of Health, Education, and Welfare announcing the proposed amendment of the regulations that it would permit the use of the term "purified monosodium glutamate" as an ingredient of foods and that it would recommend that the term be used on the label of the fabricated food product prior to distribution in interstate commerce.

The regulations establishing definitions and standards of identity for pasteurized process cheese food and pasteurized process cheese spread appear in §§ 19.765 and 19.776 of this chapter, respectively.

An application has been received from a substantial portion of the interested industry proposing to amend these regulations to permit skim milk cheese for manufacturing as an optional ingredient in these foods. Alternative ways of amending the regulations are suggested:

(1) To permit skim milk cheese for manufacturing as an optional ingredient under paragraph (c) of each of the sections; or

(2) To permit skim milk cheese for manufacturing as an optional dairy ingredient under paragraph (d) of each of the sections.

The glands are subjected to quick freezing promptly upon removal from the carcasses and maintained in a frozen state until they are ground and immersed in 95 percent to 100 percent acetone. The ground tissues remain in the acetone for a period of not less than 60 days. The mixture is filtered, and the residue is burned.

The glands are subjected to quick freezing promptly upon removal from the carcasses and maintained in a frozen state until they are ground and immersed in 95 percent to 100 percent acetone. The ground tissues remain in the acetone for a period of not less than 60 days. The mixture is filtered, and the residue is burned.

(1) (a) The facts submitted establish that there are three classes of products to be considered:

(i) Monosodium glutamate.

(ii) Hydrolyzed proteins (amino acid salts) from which monosodium glutamate has been removed.

(iii) Hydrolyzed proteins (amino acid salts) a by-product in the manufacture of monosodium glutamate.

(2) The statement of policy appearing in § 3.10 is reaffirmed. Monosodium glutamate is the common and usual name of the substance covered in said statement of policy. It may not be used as an artificial flavoring, but when used as an ingredient of food products should be so labeled as to conceal damage or inferiority or make the article appear better or of greater value than it is.

(c) Where the names of optional ingredients are required to appear on the label, the names of all ingredients should be given equal prominence. The names of the optional ingredients should appear prominently and conspicuously but should not be displayed with greater prominence than the name of the food. The word "contains" may precede the names of the optional ingredients, and when so used will not be as underlined or printed matter between name of food and name of optional ingredient required to be placed on the label.

(d) Where a manufacturer elects to include a label statement of fat and moisture content, the declaration shall be on the basis of the food as marketed. A fat declaration on a moisture-free basis is likely to be misleading, and should not be used in labeling.

§ 3.20 Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act

Under date of March 8, 1949, the Department of Health, Education, and Welfare announced (§ 3.20) that it would regard each salt substitute as a new drug and that it would require manufacturers of these products to file and become effective. Subsequent to the announcement, it has been quite generally emphasized, and is now possible to evaluate the safety of many of the ingredients used in salt substitutes. Alternative ways of labeling are suggested:

(1) The substance described in paragraph (a) of this section has long been designated as "hydrolyzed vegetable protein."

(2) The substance covered by paragraph (a) of this section should have a distinctive name, since one of its original constituents has been partially removed. Manufacturers have suggested that this substance be described as "hydrolyzed vegetable protein with reduced monosodium glutamate content." This designation appears acceptable.

(3) While the substances referred to in paragraphs (a) (2) and (3) of this section contain a number of amino acid salts as well as sodium chloride, monosodium glutamate is the ingredient that has been quite generally emphasized, and is best known to consumers under that name. No objection is offered under the Federal Food, Drug, and Cosmetic Act to the addition of a qualitative declaration on the labels of containers of such hydrolyzed vegetable protein or hydrolyzed vegetable protein with reduced monosodium glutamate content showing the percentage amounts of monosodium glutamate, the total of other amino acid salts, salt, and water, if in liquid form, all to be declared in the order of their decreasing percentages. If monosodium glutamate represents a smaller proportion of the substance than the other amino acid salts and salt (sodium chloride) it should be declared last in the list of ingredients.

(4) When the substances described in paragraphs (a) (2) and (3) of this section are used as ingredients in a fabricated food, either may be declared as "salt and hydrolyzed vegetable protein" (or "salt and hydrolyzed plant protein") on the label of the fabricated food product. Provided, That where salt is declared as a separate ingredient of the fabricated food, in compliance with section 403 (1) (2) of the act, the word "salt" need not be repeated in connection with the "hydrolyzed vegetable protein" (or "hydrolyzed plant protein") declaration.

§ 3.24 Notice to packers of comminuted tomato products

It has long been known that tomato rot may be caused by a number of different fungi. Fungi, bacterial diseases, virus diseases, and certain nonparasitic diseases. Only the fungi that are characterized by the presence of mold filaments, mold counts on comminuted tomato products are not increased by incorporating within the product tomato rot caused by bacteria, virus, or nonparasitic factors. Although high mold counts on these products reveal that...
large amounts of rotten material are present, low mold counts do not necessarily demonstrate absence of the type of rot caused by the auto-digestion diseases that are not charge caused by mold filaments.

Inspections of canneries engaged in the packing of comminuted tomato products show that most packers effectively trim, sort out, and discard rotten tomatoes from the raw stock. Some packers, however, do not properly eliminate rotten tomato material, and a few packers deliberately use rotten tomatoes in these foods. Provided counts are low. Some packers, on occasion, have mixed tomato products having a high mold count with tomato products containing little or no mold, so as to produce a blend with a low mold count.

Packers of comminuted tomato products who rely upon the mold count as the sole or primary control procedure, to the neglect of adequate sorting and trimming, may produce products with low mold counts which contain substantial amounts of rot.

It is the purpose of this announcement to advise all canners of tomato products that:

(a) Although high mold count is conclusive evidence of inclusion of substantial amounts of mold material, it is not the only way of establishing that comminuted tomato products contain decomposed tomato material.

(b) Where factory observations or other evidence show that comminuted tomato products contain rot not caused by mold, such rot, as well as that caused by mold, will be taken into account in applying the provisions of the Federal Food, Drug, and Cosmetic Act.

(c) Liquid preparations offered in multiple-dose containers should contain one or more suitable and harmless substances that will prevent the growth of micro-organisms, or should be so packaged as to volume and type of contents and use as to duration of use and necessary warnings as will afford adequate protection and minimize the hazard of injury resulting from contamination during use.

§ 3.28 Notice to manufacturers and repackers of ophthalmic solutions. (a) Investigations by pharmaceutical manufacturers, physicians, and the Food and Drug Administration have shown that liquid preparations for ophthalmic use contaminated with viable microorganisms have been responsible for serious eye injuries and, in some cases, complete loss of vision. The Food and Drug Administration has conducted a survey of medical opinion and has found that it is the consensus of informed persons that such preparations should be sterile. It is evident that liquid preparations offered or intended for ophthalmic use purport to be of such purity and quality as to be suitable for safe use in the eye. The Department of Health, Education, and Welfare concludes that such preparations fall below their prescribed standard of purity or quality and may be unsafe for use if they are not sterile. Accordingly, liquid preparations offered or intended for ophthalmic use which are not sterile may be regarded as adulterated within the meaning of section 402 (e) of the Federal Food, Drug, and Cosmetic Act, and further, may be deemed within the meaning of section 502 (j) of the act.

(b) Liquid ophthalmic preparations packed in multiple-dose containers should contain one or more suitable and harmless substances that will prevent the growth of micro-organisms, or should be so packaged as to volume and type of contents and use as to duration of use and necessary warnings as will afford adequate protection and minimize the hazard of injury resulting from contamination during use.

§ 3.29 Direct or indirect addition of antibiotic drugs to foods for human consumption. (a) The Food and Drug Administration has received inquiries concerning the use of antibiotic drugs as food preservatives. Consideration has been given to this question and the conclusion has been reached that such use constitutes a public-health hazard. Consumption of food so treated may cause sensitization of the consumer to such antibiotics and may result in the emergence of strains of pathogenic micro-organisms resistant to these drugs.

(b) The presence of antibiotic drugs in foods intended for human consumption, or the direct or indirect addition of such drugs to such foods, may be deemed an adulteration within the meaning of section 402 of the Federal Food, Drug, and Cosmetic Act (sec. 402, 52 Stat. 1044; 21 U. S. C. 342).

§ 3.30 Shipment of antibiotic drugs packaged in bulk containers. (a) The Food and Drug Administration has received inquiries from certain interested
manufacturers concerning their shipment of certified antibiotics, packaged in bulk containers, to hospitals and pharmacies for repackaging or for use in the manufacture of another drug on the order or prescription of a physician. The regulations promulgated under section 607 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 357) do not prohibit the shipment of certified bulk containers, and the provisions of such section have been interpreted by us to permit such shipment. However, under the provisions of § 146.4 (b) (2) (I) of this chapter, certification should be requested of each repacked batch and each repackager of another drug manufactured from such bulk drug, unless the repackaged drug or other drug has been made exempt from the certification requirements by regulation. The fact that the drug is to be repacked or manufactured on the order or prescription of a physician does not exempt it from the certification requirements of the act. Under the provisions of § 146.4 (b) (2) (II) of this chapter, it is only when the drug used to compound a prescription is in a container packaged for dispensing that certification of the drug so compounded is required.

(b) In the light of these provisions, unless the manufacturer and shipper of bulk containers of antibiotics is, with the consignee, an effective permit issued under § 146.22 of this chapter, if the drug is to be repacked, or under § 146.22 of this chapter if it is to be used in the manufacture of another drug, the shipper has the responsibility of seeing that certification of each repacked batch and of each batch of another drug manufactured from such drug is requested of each repackager of another drug.

§ 3.31 Label declaration of salt in frozen vegetables. (a) In a number of diseases or disease conditions it is important to restrict the intake of sodium. Sodium occurs in all natural foods, but added salt makes the most important contribution to the total sodium intake in the diet. Most fresh vegetables are of low sodium and consequently generally regard frozen vegetables as being free of added salt and suitable for use in low-sodium diets. While salt may not be added directly as a seasoning ingredient in freezing all vegetables, the use of salt brine in quality separation of such vegetables as peas and lima beans preparatory to freezing may contribute substantial amounts of salt to the finished article. The failure of the labels of frozen vegetables to declare the presence of salt has been the basis of complaints to the Food and Drug Administration.

(b) Section 403 (l) (2) of the Federal Food, Drug, and Cosmetic Act requires the label of a fabricated food to bear the common or usual name of each ingredient. The Department of Health, Education, and Welfare regards any frozen vegetable containing salt, added directly or indirectly, as misbranded under § 402 (I) (2) of the Federal Food, Drug, and Cosmetic Act unless its labels name salt as an ingredient.

§ 3.32 Label declarations of vitamin B<sub>12</sub> and folio acid in foods for special dietary use. (a) Section 125.3 (a) (2) of this chapter, issued under the authority of section 403 (l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 (l)) requires that if a food purports to be or is represented for special dietary use by man by reason of its content of a vitamin for which in human nutrition has not been established, the label of such food shall bear the statement "The need for ______ in human nutrition has not been established," the blank to be filled in with the name of such vitamin.

(b) Hereinfore this Department has considered vitamin B<sub>12</sub> and folio acid to be among those vitamins for which the need in human nutrition has not been established. However, recent scientific evidence shows that these vitamins are needed in human nutrition. The Department therefore considers the requirement of 125.3 (a) (2) quoted in paragraph (a) of this section as no longer applicable to food offered for special dietary use by reason of these vitamins.

§ 3.33 Status of foods containing added coumarin. Manufacturers of coumarin have reported pharmacological investigations showing coumarin's toxic properties. They have informed the Food and Drug Administration that it will no longer be sold for food use. The Federal Food, Drug, and Cosmetic Act requires food as adulterated when it contains any added poisonous or deleterious substance not required in the production or manufacture of the food, and when distributed in the United States. The Department of Health, Education, and Welfare regards the designation "Korean crab" as a suitable common name for the product when distributed in the United States. However, the provisions of the act prohibit the shipment of certified bulk containers, to hospitals and pharmacies for repackaging or for use in the manufacture of another drug on the order or prescription of a physician. The regulations promulgated under section 607 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 357) do not prohibit the shipment of certified bulk containers, and the provisions of such section have been interpreted by us to permit such shipment. However, under the provisions of § 146.4 (b) (2) (I) of this chapter, certification should be requested of each repacked batch and each repackager of another drug manufactured from such bulk drug, unless the repackaged drug or other drug has been made exempt from the certification requirements by regulation. The fact that the drug is to be repacked or manufactured on the order or prescription of a physician does not exempt it from the certification requirements of the act. Under the provisions of § 146.4 (b) (2) (II) of this chapter, it is only when the drug used to compound a prescription is in a container packaged for dispensing that certification of the drug so compounded is required.

(b) In the light of these provisions, unless the manufacturer and shipper of bulk containers of antibiotics is, with the consignee, an effective permit issued under § 146.22 of this chapter, if the drug is to be repacked, or under § 146.22 of this chapter if it is to be used in the manufacture of another drug, the shipper has the responsibility of seeing that certification of each repacked batch and of each batch of another drug manufactured from such drug is requested of each repackager of another drug.

§ 3.34 Labeling of imported crabmeat. (a) For many years canned crabmeat has been imported into the United States from Japan. Such imports have consisted of crabmeat designated as "Korean crabmeat." There have been limited importations of articles designated as "Korean crabmeat" and "Snow crabmeat." Two closely allied species of crab found in Japan for export to the United States, under the designation "Korean crabmeat." These species are Paralithodes camtschatica (taraba-gani) and Paralithodes platypus (hamashin-gani). A third species of crab, Paralithodes breviceps, has been labeled either as "Korean crabmeat" or "Hamashin crabmeat" when imported for export to the United States. The Department of Health, Education, and Welfare considers the term "Korean crabmeat" as an acceptable common name for the product prepared from any one of the three species Paralithodes camtschatica, Paralithodes platypus, and Paralithodes breviceps. The Department also considers the name "Hamashin crabmeat" as an alternative common name for the product prepared from Paralithodes breviceps.

(b) Prior to World War II, there was a limited pack of crabmeat from the species Erasmus esbenicelli at canneries located on the coast of Korea, but only a small quantity of this product was imported into the United States. To distinguish the product from the various species of Paralithodes and to connote its geographic origin, the article was designated by the name "Erasmus crab." For the past several years there has been a limited amount of the species Erasmus esbenicelli packed in Japan or on Japanese factory ships operating in the Sea of Japan for export to the United States. The Department of Health, Education, and Welfare regards the label designations '"Korean crab" as suitable common names for the product when distributed in the United States. However, recent scientific evidence shows that these vitamins are needed in human nutrition. The Department therefore considers the designation "Korean crab" as an acceptable common name for the product when distributed in the United States.

(c) There has also been a limited pack of Chionoecetes opilio (zuwai-gani) offered for entry into the United States. The Department of Health, Education, and Welfare regards the label designations "Korean crabs" as suitable common names for the product when distributed in the United States.

(d) Section 403 (l) (1) of the Federal Food, Drug, and Cosmetic Act requires that the label of a food for which there is no definition and standard of identity shall bear the common or usual name of the food, if any there be. No definition and standard of identity has been established for crabmeat under the act. The Department of Health, Education, and Welfare regards the label designations for canned crabmeat prepared from the various species of crab as stated in paragraphs (a), (b), and (c) of this section as satisfactory.

§ 3.35 Labeling of drug preparations containing significant proportions of wintergreen oil. (a) Because methyl salicylate (wintergreen oil) manifests no toxicity in the minute amounts in which it is used as a flavoring, it is mistakenly regarded by the public as harmless even when taken in substantially larger amounts. Actually, it is quite toxic when taken in quantities of a teaspoonful or more. Wintergreen oil and preparations containing it have caused a number of deaths through accidental ingestion by both adults and children. Children are particularly attracted to the odor and are likely to swallow these products when left within reach.

(b) To safeguard against fatalities from this cause, the Department of Health, Education, and Welfare will regard as misbranded under the provisions

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of the Federal Food, Drug, and Cosmetic Act any drug containing more than 5 percent methyl salicylate (wintergreen oil) the labeling of which fails to warn that use otherwise than as directed therein may be dangerous and that the article shall exhibit the following precautionary statement: "A warning should be used by children to prevent accidental poisoning.

(c) This statement of interpretation in no way exempts methyl salicylate (wintergreen oil) from the requirements of the Federal Food, Drug, and Cosmetic Act for the issuance, amendment, or repeal of standards for foods from complying in all other respects with the requirements of the Federal Food, Drug, and Cosmetic Act.

(See. 502, 52 Stat. 1051; 21 U. S. C. 352)

3.36 Procedure for establishing food standards under the Federal Food, Drug, and Cosmetic Act. The procedure prescribed in the Federal Food, Drug, and Cosmetic Act for the issuance, amendment, or repeal of standards for foods has recently been modified by Congress. The new amendment permits any interested person and furnishes reasons for the issuance, amendment, or repeal of standards for foods to petition the Secretary of Health, Education, and Welfare to institute action.

(a) If the petitioner shows that he is an interested person and furnishes reasonable grounds for his proposal, it is the duty of the Secretary to publish the proposal and afford opportunity for other interested persons to comment. After a study of all the facts available and of the comments received, the Secretary will act upon the proposal and publish an order, to which objection may be taken by interested persons who would be adversely affected. Thus the issues in controversy are single out for a public hearing.

(b) Practical administration of the law requires that the Secretary show merit before any proposal is published. In passing on proposals submitted by petitioners for initiating action, it will be the policy of the Department of Health, Education, and Welfare to consider that reasonable grounds have been furnished when:

(1) The proposal includes or is accompanied by a statement of the facts that the petitioner asserts he is in a position to substantiate by evidence in the event the proceedings lead to a public hearing.

(2) The facts declared furnish substantial support for the proposal and warrant a conclusion that the proposal is reasonable.

(3) The proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Opportunity will be given to amend petitions regarded as inadequate.

(See. 401, 52 Stat. 1016, as amended, 65 Stat. 54; 21 U. S. C. 341)

3.37 Confidentiality of information contained in new-drug applications.

(a) The Federal Food, Drug, and Cosmetic Act provides, in section 506 (b), that any person may file with the Secretary of Health, Education, and Welfare an application for a new drug, which shall include, among other things, a full list of the articles used as components and a full statement of the composition of such drug. These requirements apply to all components or ingredients of a new drug, whether or not they are therapeutically active. Fulfillment of these requirements may be met by submitting a full statement of the chemical or common or usual name and of the quantity of each component or ingredient of the drug. Such requirements may also be met through the inclusion in the new-drug application of a properly authorized reference to a previous application or other Food and Drug Administration file containing the relevant information.

(b) The Food and Drug Administration treats information in new-drug applications and of the Federal Food, Drug, and Cosmetic Act makes it an offense to divulge to unauthorized persons any information acquired from a new-drug application concerning any method or process that is a trade secret. Basic manufacturers sometimes submit data to the Food and Drug Administration in the form of so-called master files for the purpose of establishing the safety of ingredients that may be used in new drugs and authorize specified applicants to refer to the data in support of their own new-drug applications. Manufacturers may regard some of the data in such files as trade secrets and request the Food and Drug Administration to treat such information as confidential. The Food and Drug Administration will preserve the confidentiality of such data to the extent that it may properly do so.

(See. 505, 52 Stat. 1042; 21 U. S. C. 351, 352)

3.38 Declaration of quantity of contents on labels for canned oysters. (a) For many years packers of canned oysters in the Gulf area of the United States have labeled their output with a declaration of the drained weight of oysters in the container. In other areas, packers have marketed canned oysters with a declaration of the total weight of the contents of the container. Investigation reveals that under present-day practice consumers generally do not discard the liquid packing medium, but use it as a part of the food. Section 403 (c)(1) of the Federal Food, Drug, and Cosmetic Act and the regulations thereunder require in packages of canned oysters to bear an accurate label statement of the quantity of food in the container.

(b) It is concluded that compliance with the label declaration of quantity of contents requirement will be met by an accurate declaration of the total weight of the contents of the can. The requirements of § 3.36 of this chapter, § 3.37 of this chapter, and § 3.32 of this chapter apply to the labeling of containers for canned oysters and specifying the quantity of contents requirement for those canned oysters falling to meet that standard will remain unaffected by this interpretation.

(See. 403, 52 Stat. 1047; 21 U. S. C. 343)

3.39 Use of vegetable fat in products which are imitations of ice cream. There is currently being marketed in interstate commerce a frozen product made in semblance of ice cream, but containing vegetable fats in complete or partial substitution for milk fat. In some cases the product is marketed under a fanciful designation. Such a product is now regarded as an imitation of ice cream, and thus amenable to the provision of the Federal Food, Drug, and Cosmetic Act requiring the label to bear the name "Imitation Ice Cream," with words in the form size and prominence, regardless of whether a fanciful designation is used.

(See. 402, 403; 52 Stat. 1047; 21 U. S. C. 343, 345)

3.40 Pesticide chemicals; dates on which statute becomes fully effective. (a) The pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (68 Stat. 511) is scheduled to become fully effective on July 22, 1955. However, the Secretary of Health, Education, and Welfare may extend the effective date on a product-by-product basis for a time not to exceed 12 months on a finding that conditions exist that necessitate the extension of such additional period.

(See. 401, 402, 52 Stat. 1042, 1053; 21 U. S. C. 351, 352)

(b) The Department of Health, Education, and Welfare is prepared to consider requests for an extension of the effective date of the pesticide chemicals amendment, and the following criteria, among others, will be used in evaluating and acting upon such requests:

(1) There should not be an extension of the effective date of the amendment for uses of pesticide chemicals for which tolerances have already been established.

(2) The effective date of the amendment should be extended for a pesticide

(See. 403, 52 Stat. 1047; 21 U. S. C. 343)
chemical only upon a finding, based on a study of the available data, that the chemical and its toxicity, that the interests of public health will not be jeopardized by the extension.

(3) There should be evidence about the amount and methods of use, or on food from use of a pesticide chemical and about its chronic toxicity before an extension is granted.

(4) Extension should not be granted for a pesticide chemical which causes alarming symptoms in test animals (cancer or blood disorders, for example) in any dosage, unless experimental data show a level of feeding to test animals that is safe.

(5) Where a tolerance has been set for residues of a pesticide chemical on one or more raw agricultural commodities under the Food, Drug, and Cosmetic Act, and the other criteria of this statement of policy are met, the effective date may be extended for other uses of the pesticide chemical.

(6) Extension should be granted only for uses of a pesticide chemical registered with the Department of Agriculture under the Federal Insecticide, Fungicide, and Rodenticide Act, and the other criteria of this statement of policy are met, the effective date may be extended for other uses of the pesticide chemical.

(7) Extension should be granted only to the end of the 1955 growing season, because longer extensions would result in confusion during the 1956 growing season. The principal growing season in the United States ends by October 31.

(8) Notice of the decisions of the Department on requests for extensions will be published in the Federal Register.

(9) Each request for an extension should be addressed to the Commissioner of Food and Drugs and should give:

(1) The name and chemical composition of the pesticide chemical for which extension is requested.

(2) A list of uses for which extension is requested and evidence that these uses were registered under the Federal Insecticide, Fungicide, and Rodenticide Act prior to May 1, 1955.

(10) Extensions should be granted only for pesticide uses that leave no residues that are expected to remain in the raw agricultural commodity will not be considered adulterated within the meaning of the act even though it is marketed after the growing season, provided the commodity bearing such residues would have been legal in interstate commerce during the 1955 growing season.

(11) The Department believes that extension beyond October 31, 1955, would lead to confusion in 1956. It recommends that States prepare spray schedules for the 1956 growing season which direct (1) pesticide uses that leave no residues will be legal at time of harvest or (2) the use only of pesticides for which tolerances have been established or exemptions granted under the Federal Food, Drug, and Cosmetic Act.

§ 3.34 Pesticide chemicals: extended dates on which statute shall become fully effective. (a) The amendment in clause (2) of section 402 (a) of the Federal Food, Drug, and Cosmetic Act shall become effective on the dates specified for the following pesticide chemicals:

(1) The effective date for Aralene (2-fluorotoluene) isospropyl-2-chloroethyl sulfide shall be September 30, 1955, unless a tolerance is established for Aralene before that date, in which case the effective date shall be the date on which such tolerance is published in the Federal Register.

(b) Extension should be granted only if:

(1) Evidence about the amounts of residues that are expected to remain in the raw agricultural commodity will not jeopardize the public health.

(2) A statement of the reason(s) a tolerance or exemption from the requirement of a tolerance has not been requested.

(3) In order that decisions on requests for extensions may be published before July 31, 1955, requests and supporting data should be received by June 27, 1955.

(4) Use during the 1955 growing season of a pesticide chemical for which extension is granted may yield a raw agricultural commodity which bears residues of the chemical. In such case, the raw agricultural commodity will not be considered adulterated within the meaning of this act even though it is marketed after the growing season, provided the commodity bearing such residues would have been legal in interstate commerce during the 1955 growing season.
Beans (including black-eyed peas and soybeans),
Beets (garden variety), turnips, and rutabagas (including tops),
Beets, sugar (including tops),
Broccoli, Brussels sprouts, kohlrabi.
Cabbage and cauliflower.
Carrots, horseradish, peanuts, and radishes (including tops).
Celeriac.
Collards, kale, mustard greens, spinach, and Swiss chard.
Corn, grain (including sweet, field, and popcorn),
Corn fodder or forage.
Cucumbers and summer squash.
Eggplant, peppers, and pimientos.
Endive (escarole), lettuce, salatilly.
Melons (including cantaloupes, muskmelons, watermelons), pumpkins, and winter squash.
Okra.
Parsley and watercress.
Peanuts.
Peas and cowpeas (including forage),
Potatoes and sweetpotatoes.
Tomatoes.
Grains (including oats, rye, barley, wheat, rice),
Buckwheat.
Grain forage.
Nuts (including pecans, almonds, hazelnuts, walnuts, hickory nuts).
Legumes for forage (including clovers, alfalfa, soybean hay, peanut hay, lespedeza).
Grass crops (pasture and range grass, timothy, grass hay).
Mint, spearmint, and peppermint.
Sorghum.
Sorghum forage.
Endrin:
Cabbage.
Sugar beets.
EPN (O-ethyl-O-paranitrophenyl benzene thioephosphonate).
Grapes.
Nuts (including pecans, walnuts, and almonds).
Tomatoes.
Olives.
Onions.
Cottonseed.
Sugar beets.
Ethylene dichloride: As grain and soil fumigant.
Ethylene dichloride: As grain fumigant.
Perbam: Almonds.
Heptachlor:
Alfalfa, clover, and sweet clover.
Beets, including sugar beets.
Cabbage, Brussels sprouts, kohlrabi, and cauliflower.
Corn.
Cotton.
Pasture and range grass.
Onions.
Peanuts.
Pears.
Sweetpotatoes.
Turnips.
Hydricyanic acid: As a fumigant for grains, dried peas and beans, and cut meats.
Karathane (2,6-dinitro-6-caprylphenyl crotonate)
Apples.
Pears.
Almonds.
Cantaloup.
Cucumbers.
Squash.
Karmex DW (3-(3,4-dichlorophenyl)-1,1-dimethyl urea) Cottonseed.
Karmex W (3-(parachlorophenyl)-1,1-dimethyl urea)
Pineapples.
Asparagus.
Onions.
Sugarcane.
Lindane:
Cranberries.
Watermelons.
Grain (from treating storage bins),
Meat.
Walnuts.
Forage crops (alfalfa, clover),
Sweetpotatoes and yams.
Malathion:
Alfalfa.
Apples.
Apricots.
Avocados.
Barley.
Beans.
Beets.
Blueberries.
Broccoli.
Brussels sprouts.
Cabbage.
Cauliflower.
Celery.
Cherries.
Citrus.
Cranberries.
Cucumbers.
Currants.
Dandelions.
Dates.
Dewberries.
Eggplant.
Gooseberries.
Grapes.
Guava.
Kale.
Kohlrabi.
Leek.
'Nance.
Potatoes.
Plums.
Peaches.
Pears.
Peanuts.
Pecans.
Peas.
Beets.
Pineapples.
Flours.
Pineapples.
Raspberries.
Rutabagas.
Spinach.
Squash.
Strawberries.
Broccoli.
Brussels sprouts.
Cabbage.
Cauliflower.
Celery.
Cranberries.
Cucumbers.
Dates.
Dewberries.
Eggplant.
Gooseberries.
Grapes.
Guava.
Kale.
Kohlrabi.
Leek.
'Nance.
Potatoes.
Plums.
Peaches.
Pears.
Peanuts.
Pecans.
Peas.
Beets.
Pineapples.
Flours.
Raspberries.
Rutabagas.
Spinach.
Squash.
Strawberries.
Broccoli.
Brussels sprouts.
Cabbage.
Cauliflower.
Cranberries.
Cucumbers.
Dates.
Dewberries.
Eggplant.
Gooseberries.
Grapes.
Guava.
Kale.
Kohlrabi.
Leek.
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Potatoes.
Plums.
Peaches.
Pears.
Peanuts.
Pecans.
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Beets.
Pineapples.
Flours.
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Rutabagas.
Spinach.
Squash.
Strawberries.
Broccoli.
Brussels sprouts.
Cabbage.
Cauliflower.
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Dates.
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Flours.
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Strawberries.
Broccoli.
Brussels sprouts.
Cabbage.
Cauliflower.
Cranberries.
Cucumbers.
Dates.
Dewberries.
Eggplant.
Gooseberries.
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Guava.
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Kohlrabi.
Leek.
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Peaches.
Pears.
Peanuts.
Pecans.
Peas.
Beets.
Pineapples.
Flours.
Raspberries.
Rutabagas.
Spinach.
Squash.
Strawberries.
Broccoli.
Brussels sprouts.
Cabbage.
Cauliflower.
Cranberries.
Cucumbers.
Dates.
Dewberries.
Eggplant.
Gooseberries.
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Guava.
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Raspberries.
Rutabagas.
Spinach.
Squash.
Strawberries.
Broccoli.
Brussels sprouts.
Cabbage.
Cauliflower.
Cranberries.
Cucumbers.
Dates.
Dewberries.
Eggplant.
Gooseberries.
Grapes.
Guava.
Kale.
Kohlrabi.
Leek.
'Nance.
Potatoes.
Plums.
Peaches.
Pears.
Peanuts.
Pecans.
Peas.
Beets.
Pineapples.
The extensions prescribed in paragraph (a) of this section apply only to the extent that tolerances or exemptions under section 408 of the Federal Food, Drug, and Cosmetic Act shall not have been established prior to the effective dates as extended.

§ 3.42 Pesticide chemicals; additional extended dates on which statute shall become fully effective; denial of requests for extensions. (a) Conditions exist which necessitate the following extensions. The amendment in clause (2) of section 402 (a) of the Federal Food, Drug, and Cosmetic Act shall become effective on the dates specified for the following pesticide chemicals:

(1) Effective date October 31, 1955: Alkyl dimethyl benzyl ammonium chloride: On apples.

(2) Effective date January 22, 1956: Dieldrin: On citrus.

(b) Extension is not granted for the following indicated uses of the listed pesticide chemicals. Conditions do not exist that necessitate extension for these uses.

Use of Salicylate Preparations by Children, (2) Effective date January 22, 1956:

(a) Conditions exist that tolerances or exemptions under section 408 of the Federal Food, Drug, and Cosmetic Act shall not have been established prior to the effective dates as extended.

§ 3.43 Labeling of drug preparations containing salicylates. (a) Because salicylate preparations enjoy widespread use as analgesics and such articles are ordinarily toxic in the amounts required for producing an analgesic action, they are frequently regarded by the public as harmless. Actually, salicylates are capable of causing injury and even death when consumed in excessive quantities. Salicylate preparations have caused a number of deaths through accidental misuse by both adults and children, which might have been avoided had the users been aware of their potential hazards.

(b) On the basis of a study and conclusions by the Medical Advisory Panel on the Accidental Ingestion and Misuse of Salicylate Preparations by Children, under date of February 14, 1955, and in the interest of protecting the public health, the following recommendations are made concerning the labeling which should be employed for salicylate preparations containing aspirin, salicylamide, salicylic acid and its salts, and other salicylic acid derivatives used as analgesics, except as provided in paragraph (b) of this section.

(1) The labeling recommendations in paragraph (b) of this section are applicable only to preparations containing aspirin, salicylamide, salicylic acid and its salts, and other salicylic acid derivatives used as analgesics, except as provided in paragraph (b) of this section.

(2) The recommendations in this paragraph, the labeling recommendations of paragraph (b) of this section do not apply to the following preparations:

(a) Salicylate preparations used as analgesics and such articles are capable of causing injury and even death when consumed in excessive amounts. Salicylate preparations, however, have been widely prescribed in the treatment of conditions in children in the form of aspirin and other salicylates.

(c) The labeling recommendations in paragraph (b) of this section are applicable only to preparations containing aspirin, salicylamide, salicylic acid and its salts, and other salicylic acid derivatives used as analgesics, except as provided in paragraph (b) of this section.

§ 3.44 Pesticide chemicals; further extended dates on which statute shall become fully effective. The amendments in clause (2) of section 402 (a) of the Federal Food, Drug, and Cosmetic Act shall not have been established prior to the dates specified for the pesticide chemicals named in this section. The extensions prescribed in this section apply only to the extent that tolerances or exemptions from the requirements of section 408 of the Federal Food, Drug, and Cosmetic Act shall not have been established prior to the effective dates as extended.

(a) Effective date January 22, 1956:

(b) Effective date February 14, 1956:
Copper carbonate, base: On peans.
DIT: In meat.
Ethylene dibromide: As a fumigant.
Ethylene oxide: A grain fumigant, on citrus and strawberries.
Ethylene oxide: On spices.
Malathion: On fruits and vegetables.
Oxotan (p-chlorophenyl parachlorobenzene sulfonate) On citrus.
Sodium-coprophene tetrahydrate: On apples and pears.
Sodium-o-phenylphenate: On citrus.
Trichloroethylene: As a grain fumigant, on citrus and strawberries.
(See, 402, 408, 68 Stat. 511, 517; 21 U. S. C. 512, 354(a)).

§ 3.45 Sterilization of drugs by irradiation. There is a current interest in the sterilization of drugs by means of radiation. Prior to the marketing of a drug sterilized by such means, it is necessary in the interest of public health to establish by adequate investigations that the irradiation treatment does not cause the drug to become unsafe or otherwise unsuitable for use. According to the regulations, including injections, ophthalmic solutions, surgical sutures, and surgical dressings sterilized by means of irradiation are regarded as new drugs within the meaning of section 201 (p) of the Federal Food, Drug, and Cosmetic Act. An effective new-drug application pursuant to section 505 of the act is therefore a prerequisite to interstate shipment of such articles, except as provided by section 505 (1). (Sec. 201, 505, 62 Stat. 1042, 1052; 21 U. S. C. 321, 335)

PART 4—OFFICIAL RECORDS AND INFORMATION

§ 4.1 Disclosure of official records and information. (a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health, Education, and Welfare—except as otherwise specifically authorized in accordance with paragraph (c) of this section or except in the discharge of his official duties under the laws administered by the Food and Drug Administration—shall produce or disclose to any person, or before any tribunal, directly or indirectly, whether sworn or unsworn, or under the law, or otherwise, any record (including any file, letter, application, report, work sheet, or other paper or document) pertaining to the functions of the Food and Drug Administration, or any information acquired from any such record or otherwise acquired in the discharge of his official duties, except in the case of a subpoena or otherwise, as otherwise specifically authorized in accordance with paragraph (c) of this section or except in the discharge of his official duties, or as otherwise specifically authorized in accordance with paragraph (c).

(b) Whenever a subpoena or a subpoena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health, Education, and Welfare, the person served may object upon proper showing of any such record or the giving of any such information, such officer or employee will, unless otherwise specifically authorized in accordance with paragraph (c), appear in response thereto and respectfully decline to produce the record or information specified therein, on the ground that disclosure of such record or information is prohibited by this section.

(c) A person who desires the disclosure of any such record or information may make written request therefor, verified by oath, directed to the Commissioner of Food and Drugs, setting forth his interest in the matter sought to be disclosed and specifically designating the use to which such records or information will be put in the event of compliance with such request; Provided, That a written request for records made by a health, food or drug officer, prosecuting attorney or member of the judiciary of any State, Territory, or political subdivision thereof, setting forth his capacity, official capacity not be verified by oath. It is determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that disclosure of any such record or information for the use specifically designated will not result in revealing confidential matters the request will be granted, and if testimony relating thereto is required one or more employees of the Food and Drug Administration will be designated and directed to appear, in person or by a subpoena or a subpoena duces tecum, and testify with respect thereto.

§ 9.1 Definitions.
9.2 General specification for straight colors.
9.3 List of straight colors and specifications for their certification for use in food, drugs, and cosmetics.
9.4 List of straight colors and specifications for their certification for use in drugs and cosmetics.
9.5 List of straight colors and specifications for their certification for use in externally applied drugs and cosmetics.
9.6 Mixtures which may be certified.
9.7 Sampling, storage, and packaging.
9.8 Request for certification.
9.9 Certification.
9.10 Limitations of certificates.
9.11 Labelling.
9.12 Records of distribution.
9.13 Authority to refuse certification service.
9.14 Procedure for admitting color to listing.
9.15 Fees.


§ 9.1 Definitions. For the purposes of this part:
(a) The term "coal-tar color" means articles which (1) are composed of or contain any substance derived from coal tar, or any substance so related in its chemical structure to a constituent of coal tar as to be capable of derivation from such constituent; and (2) when added or applied to a food, drug, cosmetic, or the human body or any part thereof, are capable (alone or through reaction with other substances) of imparting color thereto.
(b) The term "straight color" means a coal-tar color listed in §§ 9.3, 9.4, or 9.5, and includes such impurities and substrates as are contained in such color.
(c) The term "mixture" means a coal-tar color made by mixing two or more straight colors, or one or more straight colors and one or more dilluents.
(d) The term "diluent" means any component of a coal-tar color, except a straight color.
(e) The term "pure dye" means the coal-tar dye containing any one coal-tar color, exclusive of any intermediate or other impurity, or of any diluent or substratum contained therein.
(f) The term "substratum" means the substance on which the pure dye in a lake is extended.
(g) The term "alumina" means a suspension in water of precipitated aluminum hydroxide.
(h) The term "blanc fixe" means a suspension in water of precipitated barium sulfate.
(i) The term "gloss white" means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.
(j) The term "mixed oxides" means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.
(k) The term "batch" means a quantity of coal-tar color which is set apart and held as a unit for purposes of obtaining certification of such quantity.
(l) The term "batch number" means the number assigned to a batch by the person who requests certification thereof.
(m) The term "lot number" means an identifying number or symbol assigned to a batch by the Food and Drug Administration.
(n) The term "externally applied drugs and cosmetics" means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.
(o) The authorization contained in this part for the certification of coal-tar colors shall not be considered to authorize the certification of any coal-tar color for use in any article which is applied to the area of the eye. A coal-tar color used in any such article which is so applied shall be considered to be from a batch, or batches, which have been certified for other uses.
(p) The term "area of the eye" means the area, enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyelid, the skin below the eyebrow, the eyelids and the eyelashes, the conjunctival sac of the eye, the eyebrow, and the soft aricular tissue that lies within the purview of the information below.
(q) The definitions and interpretations of terms contained in section 501 of the act shall be applicable also to such terms when used in this part.
§ 9.2 General specifications for straight colors. No batch of a straight color listed in §9.3, §9.4, or §9.5 shall be certified under this part unless:

(a) It is made from impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such section for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

1. In the case of a straight color listed in §9.3:
   - Lead (as Pb), not more than 0.001 percent.
   - Arsenic (as As₂O₃), not more than 0.00014 percent.
   - Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

2. In the case of a straight color listed in §9.4 or §9.5:
   - Lead (as Pb), not more than 0.002 percent.
   - Arsenic (as As₂O₃), not more than 0.0003 percent.
   - Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(c) In the case of a straight color which contains no barium salt listed in §9.4 or §9.5—soluble barium (in dilute HCl) (as BaCl₂), not more than 0.05 percent.

§ 9.3 List of straight colors and specifications for their certification for use in food, drugs, and cosmetics. A batch of a straight color listed in this section may be certified, in accordance with the provisions of the regulations in this part, for use in food (subject to the restrictions prescribed by paragraph (c) of this section) drugs, and cosmetics, if such batch conforms to the requirement of §9.2 and to the specifications in this section set forth for such color.

FD&C Green No. 1

SPECIFICATIONS

Monosodium salt of 4-{[4-(N-ethyl-p-sulfobenzamino)-diphenylmethyl]yl}-(4-sulfonfocyanomethyl)glycine.

Volatile matter (at 135° C), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.3 percent.

Chlorides and sulfates of sodium, not more than 0.3 percent.

Mixed oxides, not more than 0.1 percent.

FD&C Green No. 2

SPECIFICATIONS

Disodium salt of 4-{[4-(N-ethyl-p-sulfobenzamino)-diphenylmethyl]yl}-(4-sulfonfocyanomethyl)glycine.

Volatile matter (at 135° C), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

FD&C Yellow No. 1

SPECIFICATIONS

Disodium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C), not more than 10.0 percent.

Water insoluble matter, not more than 0.1 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 0.1 percent.

Mixed oxides, not more than 0.1 percent.

FD&C Yellow No. 2

SPECIFICATIONS

Diiodosodium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.3 percent.

Chlorides and sulfates of sodium, not more than 0.4 percent.

Mixed oxides, not more than 0.3 percent.

FD&C Yellow No. 3

SPECIFICATIONS

1-Phenylazo-2-naphthylamine.

Volatile matter (at 85° C), not more than 0.2 percent.

Sulfated ash, not more than 0.2 percent.

Water soluble matter, not more than 0.2 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 10.0 percent.

FD&C Yellow No. 4

SPECIFICATIONS

1-0-Toluidino-2-naphthylamine.

Volatile matter (at 85° C), not more than 0.2 percent.

Sulfated ash, not more than 0.2 percent.

Water soluble matter, not more than 0.2 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

FD&C Yellow No. 5

SPECIFICATIONS

Triiodosodium salt of 6-carboxy-6-hydroxy-1-pseudo-cumol-diphenylmethyl-2-pyridone.

Volatile matter (at 135° C), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

Mixed oxides, not more than 0.5 percent.

FD&C Yellow No. 6

SPECIFICATIONS

Disodium salt of 1-p-coumaroyl-2-naphthol-3, 4-dicarboxylic acid.

Volatile matter (at 135° C), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

Mixed oxides, not more than 0.5 percent.

FD&C Red No. 1

SPECIFICATIONS

Disodium salt of 1-p-coumaroyl-2-naphthol-3, 4-dicarboxylic acid.

Volatile matter (at 135° C), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.3 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

Mixed oxides, not more than 0.5 percent.

FD&C Red No. 2

SPECIFICATIONS

Triiodosodium salt of 6-carboxy-6-hydroxy-1-pseudo-cumol-diphenylmethyl-2-pyridone.

Volatile matter (at 135° C), not more than 12.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

Mixed oxides, not more than 0.5 percent.

FD&C Red No. 3

SPECIFICATIONS

Disodium salt of 6-carboxy-6-hydroxy-1-pseudo-cumol-diphenylmethyl-2-pyridone.

Volatile matter (at 135° C), not more than 12.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

Mixed oxides, not more than 0.5 percent.
**FD&C Red No. 4**

**SPECIFICATIONS**

Discosodium salt of 2-[(sulfuro-2,4-xyllylazo)-1-naphthol-4-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water, insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Blue No. 1**

**SPECIFICATIONS**

Discosodium salt of 4-[4-[(N-ethyl-p-sulfobenzamino) -phenyl] - (2-sulfoniumphenyl)]-metbylene]-[1-(N-ethyl-N-p-sulfobenzyl)-1,2-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 1.0 percent.

Sodium acetate, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Blue No. 2**

**SPECIFICATIONS**

Discosodium salt of 5,5'-indigotindisulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Sulfonated dyes, not more than 8.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**FD&C Violet No. 1**

**SPECIFICATIONS**

Monosodium salt of 4-[4-[(N-ethyl-p-sulfobenzamino) -phenyl] - (4-sulfoniumphenyl)]-metbylene]-[1-(N-ethyl-N-p-sulfobenzyl)-1,2-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.6 percent.

p-Dimethylaminobenzenc acid, not more than 8.0 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

**LAKES**

Any lake made by extending on a substratum of alumina, a salt prepared from one of the water soluble straight colors hereinbefore listed in this paragraph by combining such color with the basic radicle aluminum or calcium.
Federal Register

D&C Yellow No. 10

**SPECIFICATIONS**

Dissodium salt of disulfonic acid of 2-(2-quinolyl)-1,3-indandione.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 65.0 percent.

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D&C Yellow No. 11

**SPECIFICATIONS**

2-[(2-Quinolyl)-1,3-indandione.

Volatile matter (at 135° C.), not more than 1.0 percent.

Sulfated ash, not more than 1.0 percent.

Water insoluble matter, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 63.0 percent.

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D&C Red No. 5

**SPECIFICATIONS**

Disodium salt of 1-xyllylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 63.0 percent.

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D&C Red No. 6

**SPECIFICATIONS**

Monosodium salt of 4-(o-sulfo-p-tolyazo)-3-hydroxy-2-naphtholic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 63.0 percent.

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D&C Red No. 7

**SPECIFICATIONS**

Calcium salt of 4-(o-sulfo-p-tolyazo)-3-hydroxy-2-naphtholic acid.

Volatile matter (at 135° C.), not more than 8.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Chlorides and sulfates (as calcium salts), not more than 6.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 8

**SPECIFICATIONS**

Monosodium salt of 1-(4-chloro-o-sulfo-5-tolyazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

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Other extracts (Isopropyl ether), not more than 0.5 percent.

Lake Red O Amino, not more than 0.2 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

D&C Red No. 9

**SPECIFICATIONS**

Barium salt of 1-(4-chloro-o-sulfo-5-tolyazo)-2-naphtholic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Lake Red O Amino, not more than 0.2 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 10

**SPECIFICATIONS**

Calcium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalencsulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

Chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 11

**SPECIFICATIONS**

Barium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalencsulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Tobias acid, not more than 0.2 percent.

Chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 12

**SPECIFICATIONS**

Calcium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalencsulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Tobias acid, not more than 0.2 percent.

Chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 13

**SPECIFICATIONS**

Barium salt of 1-(4-chloro-o-sulfo-5-tolyazo)-2-naphtholic acid.

Volatile matter (at 125° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 14

**SPECIFICATIONS**

Monosodium salt of 1-o-carboxy-phenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 15

**SPECIFICATIONS**

Calcium salt of 1-o-carboxyphenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 16

**SPECIFICATIONS**

1-o-Phenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 17

**SPECIFICATIONS**

1-o-Phenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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D&C Red No. 18

**SPECIFICATIONS**

Calcium salt of 1-o-carboxyphenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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1-o-Phenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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1-o-Phenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 65.0 percent.

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1-o-Phenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.
**RULES AND REGULATIONS**

**SPECIFICATIONS**

**D&C Red No. 19**

3-Ethochloride of 9-o-carboxyphenyl-6-di-
ethy lamino-3-ethoxanthone.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (from alkali solution), not more than 0.5 percent.

Dialyl-m-aminophenol, not more than 2.0 percent.

Mixed oxides, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

D&C Red No. 20

3-Ethoacetate of 9-o-carboxyphenyl-6-di-
ethy lamino-3-ethoxanthene.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts (from acid solution), not more than 0.5 percent.

Dialyl-m-aminophenol, not more than 0.2 percent.

Sodium acetate, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 92.0 percent.

D&C Red No. 21

2,4,5,7-Tetrabromo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkali solution), not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.25 percent.

Permitted range of organically combined bromine in pure dye, 47.0-51.5 percent.

Pure dye (as determined gravimetrically), not less than 92.0 percent.

D&C Red No. 22

Disodium salt of 9-o-carboxyphenyl-2,4,5,7-tetrachloro-6,8-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chloride in pure dye, 28.0-32.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Red No. 23

Disodium salt of 2,4,5,7-tetrabromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 16.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.03 percent.

Permitted range of organically combined bromine in pure dye (free from water or alcohol of crystallization), 43.0-48.0 percent.

Pure dye (as determined gravimetrically), not less than 80.0 percent.

D&C Red No. 24

Disodium salt of 2,4,5,7-tetrachloro-5,8-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkali solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chloride in pure dye, 28.0-32.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Red No. 25

Disodium salt of 9-o-carboxyphenyl-2,4,5,7-tetrachloro-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chloride in pure dye, 28.0-32.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 26

Disodium salt of 9-o-carboxyphenyl-2,4,5,7-tetrachloro-6,8-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chloride in pure dye, 28.0-32.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Red No. 27

Disodium salt of 2,4,5,7-tetrabromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chloride in pure dye, 28.0-32.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 28

Disodium salt of 2,4,5,7-tetrachloro-12,13,14,15-tetrachloro-6,8-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkali solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chloride in pure dye, 28.0-32.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 29

Disodium salt of 8-amino-2-phenylazo-1-naphthalene-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

- Aniline, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 30

Calcium salt of 3-hydroxy-4-phenylazo-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts (isopropyl ether), not more than 0.5 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Red No. 31

Disodium salt of 8-amino-2-phenylazo-1-naphthalene-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 32

Disodium salt of 2,4,5,7-tetrachloro-12,13,14,15-tetrachloro-6,8-fluorandiol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Red No. 33
D&C Red No. 34

SPECIFICATIONS

Copper salt of -(-sulfato-2-pyridylazo)-
-3-hydroxy-2-naphthol acid.
Sulfated ash (at 135°C), not more than 2.0 percent.
Sulfated ash, not more than 1.5 percent.
Ether extracts, not more than 0.5 percent.
Oxides of iron and aluminum, not more than 1.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

D&C Red No. 35

SPECIFICATIONS

1-(o-Nitro-p-tolylazo)-2-naphthol.
Volatile matter (at 135°C), not more than 2.0 percent.
Sulfated ash, not more than 1.5 percent.
Matter insoluble in toluene, not more than 1.5 percent.
Ether extracts, not more than 0.5 percent.
Mixed oxides, not more than 0.5 percent.

D&C Red No. 36

SPECIFICATIONS

1-(o-Chloro-p-nitrophenylazo)-2-naphthol.
Volatile matter (at 135°C), not more than 5.0 percent.
Sulfated ash, not more than 1.0 percent.
Matter insoluble in toluene, not more than 1.0 percent.
Beta-Naphthol, not more than 0.2 percent.

D&C Red No. 37

SPECIFICATIONS

Ethyl esterate of 9-o-carboxyphenyl-6-diethy lamino-3-ethylamino-3-leucanthone.
Volatile matter (at 260°C), not more than 2.0 percent.
Sulfated ash, not more than 3.0 percent.
Matter insoluble in benzene, not more than 0.5 percent.
Diethyl-m-aminophenol, not more than 0.2 percent.
Stearic acid (not part of the dye), not more than 5.0 percent.
Pure dye (as determined by titration with titanium trichloride) not less than 90.0 percent.

D&C Red No. 38

SPECIFICATIONS

8-Hydroxy-5-(m-nitrophenyl)-4-(o-nitro-
p-tolylazo)-2-naphthamide.
Volatile matter (at 135°C), not more than 5.0 percent.
Sulfated ash, not more than 1.5 percent.
Matter insoluble in nitrobenzene, not more than 0.5 percent.
Ether extracts, not more than 0.2 percent.

D&C Red No. 39

SPECIFICATIONS

o-[p-(p-0-dihydroxy-dibethylamino)-phenylazo]-benezidinediazotized.
Volatile matter (at 100°C), not more than 2.0 percent.

Matter insoluble in carbon disulfide, not more than 1.5 percent.
Ether extract (petroleum ether), not more than 0.5 percent.
N.N.N'(p0-dihydroxy-dibutylamino)-aniline, not more than 0.2 percent.
Sulfated ash, not more than 1.5 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

D&C Orange No. 3

SPECIFICATIONS

Dichromate salt of 1-phenylazo-2-naphthol-
6,8-dianisole acid.
Volatle matter (at 135°C), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts, not more than 0.5 percent.
Aniline, not more than 0.2 percent.
Chlorides and sulfates of sodium, not more than 8.0 percent.
Mixed oxides, not more than 1.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Orange No. 4

SPECIFICATIONS

Monosodium salt of 1-p-sulphophenylazo-2-
naphthol.
Volatle matter (at 135°C), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts, not more than 0.5 percent.
Beta-Naphthol, not more than 0.2 percent.
Chlorides and sulfates of sodium, not more than 8.0 percent.
Mixed oxides, not more than 1.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Orange No. 5

SPECIFICATIONS

4,5-Dibromo-3,6-Diureindol.
Volatle matter (at 135°C), not more than 5.0 percent.
Inconelate matter (alkaline solution), not more than 1.0 percent.
Ether extracts (from alkaline solution), not more than 0.5 percent.
Sodium chloride, not more than 3.0 percent.
Mixed oxides, not more than 1.0 percent.
Free bromine, not more than 0.5 percent.
Permuted range of organically combined bromine in pure dye, 8.3-28.0 percent.
Pure dye (as determined gravimetrically), not less than 10.0 percent.

D&C Orange No. 6

SPECIFICATIONS

Dichromate salt of 4,5-dibromo-9-o-carboxy-
phenyl-6-hydroxy-3-leucanthone.
Volatile matter (at 135°C), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts, not more than 0.5 percent.
Chlorides and sulfates of sodium, not more than 5.0 percent.
Mixed oxides, not more than 1.0 percent.
Free bromine, not more than 0.5 percent.
Permuted range of organically combined bromine in pure dye, 28.0-32.0 percent.
Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 7

SPECIFICATIONS

Dipentacarboxylate salt of 4,5-dibromo-9-o-carboxy-
phenyl-6-hydroxy-3-leucanthone.
Volatile matter (at 135°C), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.

Matter insoluble in carbon disulfide, not more than 1.5 percent.
Ether extract (petroleum ether), not more than 0.5 percent.
Chlorides and sulfates of sodium, not more than 5.0 percent.
Mixed oxides, not more than 1.0 percent.
Free bromine, not more than 0.5 percent.
Permuted range of organically combined bromine in pure dye, 0.5-0.10 percent.
Pure dye (as determined gravimetrically), not less than 35.0 percent.

D&C Orange No. 8

SPECIFICATIONS

4,5-Dichloro-3,6-Diureindol.
Volatle matter (at 135°C), not more than 5.0 percent.
Inconelate matter (alkaline solution), not more than 1.0 percent.
Ether extracts (from alkaline solution), not more than 0.5 percent.
Chlorides and sulfates of sodium, not more than 3.0 percent.
Mixed oxides, not more than 1.0 percent.
Free chlorine, not more than 0.5 percent.
Permuted range of organically combined chlorine in pure dye, 16.0-16.4 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 33.0 percent.

D&C Orange No. 9

SPECIFICATIONS

Dichromate salt of 9-o-carboxyphenyl-4,5-
dichloro-3,6-dihydroxy-3-leucanthone.
Volatle matter (at 135°C), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts (from alkaline solution), not more than 0.5 percent.
Chlorides and sulfates of sodium, not more than 3.0 percent.
Mixed oxides, not more than 1.0 percent.
Free chlorine, not more than 0.5 percent.
Permuted range of organically combined chlorine in pure dye, 14.5-17.5 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 33.0 percent.

D&C Orange No. 10

SPECIFICATIONS

4,5-Dilodo-3,6-Diureindol.
Volatle matter (at 135°C), not more than 0.0 percent.
Inconelate matter (alkaline solution), not more than 1.0 percent.
Ether extracts (from alkaline solution), not more than 0.5 percent.
Sodium chloride, not more than 3.0 percent.
Mixed oxides, not more than 1.0 percent.
Free iodine, not more than 0.5 percent.
Permuted range of organically combined iodine in pure dye, 41.5-42.5 percent.
Pure dye (as determined gravimetrically), not less than 63.0 percent.

D&C Orange No. 11

SPECIFICATIONS

Dichromate salt of 9-o-carboxy phenyl-4,5-
dilodo-3,6-dihydroxy-3-leucanthone.
Volatle matter (at 135°C), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts (from alkaline solution), not more than 0.5 percent.
Chlorides and sulfates of sodium, not more than 3.0 percent.
Mixed oxides, not more than 1.0 percent.
Free iodine, not more than 0.5 percent.
Permuted range of organically combined iodine in pure dye, 41.0-42.0 percent.
Pure dye (as determined gravimetrically), not less than 63.0 percent.

D&C Orange No. 12

SPECIFICATIONS

Dipentacarboxylate salt of 9-o-carboxyphenyl-
4,5-dilodo-3,6-dihydroxy-3-leucanthone.
D&C Orange No. 13

**SPECIFICATIONS**

- **Dia-mmonium salt of 9-0-carboxyphenyl-5-hydroxy-4,5-dilodo-3-isoxanthone.**
- **Volatilize matter (at 135° C.), not more than 10.0 percent.**
- **Sulfatd ash, not more than 1.0 percent.**
- **Water insoluble matter, not more than 1.0 percent.**
- **Ether extracts, not more than 0.5 percent.**
- **Chlorides and sulfates of potassium, not more than 0.5 percent.**
- **Mixed oxides, not more than 1.0 percent.**
- **Free iodine, not more than 0.05 percent.**
- **Permitted range of organically combined iodine in pure dye, 38.5-40.5 percent.**
- **Pure dye (as determined gravimetrically), not less than 85.0 percent.**

D&C Blue No. 4

**SPECIFICATIONS**

- **Di-ammonium salt of 6-p-sulfophenylazo-2-(2,4-xylylazo)-1,8-resorcinol.**
- **Volatilize matter (at 135° C.), not more than 10.0 percent.**
- **Sulfatd ash, not more than 1.0 percent.**
- **Water insoluble matter, not more than 1.0 percent.**
- **Ether extracts, not more than 0.5 percent.**
- **Chlorides and sulfates of ammonium, not more than 0.5 percent.**
- **Mixed oxides, not more than 1.0 percent.**
- **Free bromine, not more than 0.05 percent.**
- **Permitted range of organically combined iodine in pure dye, 38.5-40.5 percent.**
- **Pure dye (as determined gravimetrically), not less than 85.0 percent.**

D&C Orange No. 14

**SPECIFICATIONS**

- **4,5,15-Tribromo-2,7-dicarboxy-3-fluorodiol.**
- **Volatilize matter (at 135° C.), not more than 2.0 percent.**
- **Sulfatd ash, not more than 1.0 percent.**
- **Insoluble matter (alkaline solution), not more than 0.1 percent.**
- **Solvatble matter (in 1 percent aqueous hydrochloric acid), not more than 2.0 percent.**
- **Free bromine, not more than 0.02 percent.**
- **Permitted range of organically combined bromine in pure dye 36.0-40.0 percent.**
- **Pure dye (as determined gravimetrically), not less than 85.0 percent.**

D&C Orange No. 15

**SPECIFICATIONS**

- **1,2-Anthraquinonemethyl.**
- **Volatilize matter (at 135° C.), not more than 2.0 percent.**
- **Water soluble matter, not more than 1.5 percent.**
- **Sulfatd ash, not more than 1.0 percent.**
- **Insoluble matter (alkaline solution), not more than 1.0 percent.**
- **Sodium chloride, not more than 1.0 percent.**
- **Mixed oxides, not more than 1.0 percent.**
- **Pure dye (as determined gravimetrically), not less than 95.0 percent.**
- **Melting point, not less than 285° C.**

D&C Orange No. 16

**SPECIFICATIONS**

- **4,5-Dibromo-3,7-dilodo-3,5-fluorodiol.**
- **Volatilize matter (at 135° C.), not more than 5.0 percent.**
- **Insoluble matter (alkaline solution), not more than 1.0 percent.**
- **Ether extracts (alkaline solution), not more than 0.1 percent.**
- **Sodium chloride, not more than 3.0 percent.**
- **Mixed oxides, not more than 1.0 percent.**
- **Free halogen, not more than 0.06 percent.**
- **Permitted range of organically combined bromine in pure dye, 22.0-23.0 percent.**
- **Pure dye (as determined gravimetrically), not less than 90.0 percent.**

D&C Orange No. 17

**SPECIFICATIONS**

- **1-(2,4-Dinifluorophenylazo)-2-naphthal.**
- **Volatilize matter (at 135° C.), not more than 5.0 percent.**

**RULES AND REGULATIONS**

- **Sulfatd ash, not more than 1.0 percent.**
- **Water insoluble matter, not more than 1.0 percent.**
- **Ether extracts, not more than 0.5 percent.**
- **Chlorides and sulfates of potassium, not more than 0.5 percent.**
- **Mixed oxides, not more than 1.0 percent.**
- **Free iodine, not more than 0.05 percent.**
- **Permitted range of organically combined iodine in pure dye, 38.5-40.5 percent.**
- **Pure dye (as determined gravimetrically), not less than 85.0 percent.**

D&C Blue No. 8

**SPECIFICATIONS**

- **Calcium salt of 4-[4-(N-ethylbenzylamino)-6-hydroxy-4-sulfo-niumphenyl]-methyleney-4(1H)-benzyl-cyclohexadilene.**
- **Volatilize matter (at 135° C.), not more than 10.0 percent.**
- **Water insoluble matter, not more than 1.0 percent.**
- **Ether extracts, not more than 0.5 percent.**
- **Chlorides and sulfates (as calcium salts), not more than 0.5 percent.**
- **Benzylthiophenylamine, not more than 0.2 percent.**
- **Water insoluble matter, not more than 1.0 percent.**
- **Ether extracts, not more than 0.5 percent.**
- **Combined nitrogen (as calculated from organically combined nitrogen), not less than 97.0 percent.**

D&C Black No. 1

**SPECIFICATIONS**

- **Disodium salt of 3-amino-2-p-nitrophenylazo-2-phenylazo-1-naphthol-3,6-disulfonic acid.**
- **Volatilize matter (at 135° C.), not more than 10.0 percent.**
- **Water insoluble matter, not more than 1.0 percent.**
- **Ether extracts, not more than 0.5 percent.**
- **Sulfatd ash, not more than 1.0 percent.**
- **Combined nitrogen or sulphur), not less than 10.0 percent.**
- **Water insoluble matter, not more than 1.0 percent.**
- **Ether extracts, not more than 0.5 percent.**
- **Chlorides and sulfates of sodium, not more than 10.0 percent.**
- **Mixed oxides, not more than 1.0 percent.**
- **Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.**

D&C Violet No. 2

**SPECIFICATIONS**

- **1-Hydroxy-4-p-toluidino-anthraquinone.**
- **Volatilize matter (at 135° C.) not more than 2.0 percent.**
- **Sulfatd ash, not more than 1.0 percent.**
- **Water insoluble matter, not more than 1.0 percent.**
- **Ether extracts, not more than 0.5 percent.**
- **Combined nitrogen or sulphur), not less than 10.0 percent.**
- **Water insoluble matter, not more than 1.0 percent.**
- **Ether extracts, not more than 0.5 percent.**
- **Chlorides and sulfates of sodium, not more than 10.0 percent.**
- **Mixed oxides, not more than 1.0 percent.**
- **Pure dye (as calculated from organically combined nitrogen), not less than 95.0 percent.**

**TAKES**

Any lake, other than those listed in § 135.8, made by extending on a substratum of alumina, basic felspar, glass white, clay, titanium dioxide, zinc oxide, talc, resin, aluminum benzoate, or any combination of two or more of these, (1) one of the straight colors (except lakes) listed in § 135.3 or hereinafter listed in this paragraph, which color is a salt in which is combined the basic radicle sodium, potassium, aluminum, barium, calcium, strontium, or chromium; or (2) a salt prepared from one of the straight colors (except lakes) listed in § 135.5, or hereinafter listed in this paragraph, by combining such color with the basic radicle so-
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Ethere extracts, not more than 0.5 percent. Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.

Intermediate tests, not more than 0.2 percent.

(b) Each lake made as prescribed under the caption “Lakes” in paragraph (a) of this section shall be considered to be a straight color or to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared, except that if such name contains the symbol “FD&C” such symbol shall be changed to “D&C”.

(2) The name of the basic radicle combined in such color; and

(3) The word “Lake”.

For example, the name of a lake prepared by extending the color D&C Red No. 9 upon a substratum is “D&C Red No. 9—Barium Lake” and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum other than alumina is “D&C Green No. 1—Aluminum Lake”.

§ 5.61 *List of straight colors and specifications for their certification for use in externally applied drugs and cosmetics.*

(a) A batch of a straight color listed in this section may be certified, in accordance with the provisions of this part, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of § 5.92 and to the specifications set forth in this section for such color.

**SPECIFICATIONS**

Monosodium salt of 4-alkylphenylazo-diphenylamine.

Volatile matter (at 135°C), not more than 10.0 percent. Water insoluble matter, not more than 10.0 percent.

Chloroform soluble matter, not more than 0.8 percent. Sulfated ash, not more than 6.0 percent. Water insoluble matter, not more than 10.0 percent.

Ethere extracts, not more than 0.6 percent. Sodium chloride, not more than 6.0 percent. Pure dye (as determined by titration with 100% trichloroacetic acid), not less than 90% percent.

**SPECIFICATIONS**

Dicyanidium salt of 5,6-dichloro-2-(3,6-dichloro-3-carboxyphenyl)-2-hydroxy-2,4,5,7-tetraol.-3-acetanilide.

Volatile matter (at 135°C), not more than 10.0 percent. Water insoluble matter, not more than 10.0 percent.

Chloroform soluble matter, not more than 0.5 percent. Sodium chloride, not more than 6.0 percent. Pure dye (as determined by titration with 100% trichloroacetic acid), not less than 90% percent.

**SPECIFICATIONS**

Dicyanidium salt of 4-m-sulfophenylazo-di-amidophenyazo-1-naphthol - 5,6 - disulfenate acid.

Volatile matter (at 135°C), not more than 10.0 percent. Water insoluble matter, not more than 10.0 percent.

Chloroform soluble matter, not more than 0.5 percent. Sodium chloride, not more than 6.0 percent. Pure dye (as determined by titration with 100% trichloroacetic acid), not less than 90% percent.

**SPECIFICATIONS**

Tritriazolium salt of 1-(4-chloro-6-sulfophenylazo-2-naphtho)-4-sulfophenylpyrazole.

Volatile matter (at 135°C), not more than 10.0 percent. Water insoluble matter, not more than 10.0 percent.

Ethere extracts, not more than 0.5 percent. Sodium chloride, not more than 6.0 percent. Pure dye (as determined by titration with 100% trichloroacetic acid), not less than 90% percent.

**SPECIFICATIONS**

Monosodium salt of 1-(4-chloro-6-carboxyphenyl)-5-5-p-tolylazo-3-(p-tolylsulfonoxy)-phenylazo-pyrazole.

Volatile matter (at 135°C), not more than 5.0 percent. Water insoluble matter, not more than 10.0 percent.

Ethere extracts, not more than 0.5 percent. Sodium chloride, not more than 6.0 percent. Pure dye (as determined by titration with 100% trichloroacetic acid), not less than 90% percent.
**RULES AND REGULATIONS**

**Specifications**

**Monosodium salt of 5,4-dihydroxy-2-anthrachinonsulfonic acid.**

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 0.50 percent.

Mixed oxides, not more than 1.0 percent.

Free acid as H₂SO₄, not more than 0.01 percent.

Pure dye (by spectrophotometric determination), not less than 92.0 percent.

**Ext D&C Red No. 7**

**Specifications**

Monosodium salt of 4-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

 Ether extracts, not more than 0.5 percent. 

 beta-Naphthol, not more than 0.2 percent. 

 Chlorides and sulfates of sodium, not more than 0.50 percent. 

 Mixed oxides, not more than 1.0 percent. 

 Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent. 

**Ext D&C Blue No. 3**

**Specifications**


Volatile matter (at 135° C.), not more than 10.0 percent. 

Water insoluble matter, not more than 1.0 percent. 

 Ether extracts, not more than 0.5 percent. 

 Benzyltrimethylamine, not more than 0.3 percent. 

 Chlorides and sulfates of sodium, not more than 8.0 percent. 

 Mixed oxides, not more than 1.0 percent. 

 Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent. 

**Ext D&C Blue No. 4**

**Specifications**

Disodium salt of 4,8-diamino-1,5-dihydroxy-2-anthraquinone disulfonic acid. 

Volatile matter (at 135° C.), not more than 10.0 percent. 

Water insoluble matter, not more than 1.0 percent. 

 Ether extracts, not more than 0.5 percent. 

 Chlorides and sulfates of sodium, not more than 10.0 percent. 

 Mixed oxides, not more than 1.0 percent. 

 Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent. 

**Ext D&C Blue No. 5**

**Specifications**

1,4-Bis (amidino) - anthraquinone. 

Volatile matter (at 100° C.), not more than 2.0 percent. 

Insoluble matter in carbon tetrachloride, not more than 1.0 percent. 

Sulfated ash, not more than 0.5 percent. 

Pure dye (as calculated from organically combined sulfur or nitrogen), not less than 80.0 percent. 

**Ext D&C Black No. 1**

**Specifications**

Disodium salt of 8-anilino-5-[4-(5-sulfo-p-tolylazo) -1-naphthylazo]-1-naphthalene-4-sulfonic acid. 

Volatile matter (at 135° C.), not more than 10.0 percent. 

Water insoluble matter, not more than 1.0 percent. 

 Ether extracts, not more than 0.5 percent. 

 Chlorides and sulfates of sodium, not more than 0.3 percent. 

 Sulfated ash, not more than 0.5 percent. 

 Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent. 

**Ext D&C Green No. 1**

**Specifications**

Ferric salt of 6-sodiumsulfo-1-isocitroso-1,2-naphthoquinone. 

Volatile matter (at 135° C.), not more than 10.0 percent. 

Water insoluble matter, not more than 1.0 percent. 

 Ether extracts, not more than 0.5 percent. 

 Chlorides and sulfates of sodium, not more than 5.0 percent. 

 Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent. 

**Ext D&C Violet No. 1**

**Specifications**

Disodium salt of 1,5-bis(o-sulfo-p-toluino)-anthraquinone.
Volatile matter (at 135° C.), not more than 10.0 percent.
Water insoluble matter, not more than 1.0 percent.
Ether extracts, not more than 0.5 percent.
α-Toluidine, not more than 0.2 percent.
Caleides and sulfates of sodium, not more than 8.0 percent.
Mixed oxides, not more than 1.0 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 99.9 percent.

**Specifications**

- **EXT D&C Violet No. 2**
  - Monosodium salt of 1-hydroxy-4-(o-sulfo-p-toluene)-anthraquinone.
  - Volatile matter (at 135° C.), not more than 10.0 percent.
  - Water insoluble matter, not more than 1.0 percent.
  - Ether extracts, not more than 0.5 percent.
  - p-Toluidine, not more than 0.2 percent.
  - Chlorides and sulfates of sodium, not more than 8.0 percent.
  - Mixed oxides, not more than 1.0 percent.
  - Pure dye (as determined by titration with titanium trichloride), not less than 99.9 percent.

- **EXT D&C Orange No. 1**
  - Pure dye (as determined gravimetrically), not more than 4.0 percent.
  - Mixed oxides, not more than 1.0 percent.
  - Ether extracts, not more than 0.5 percent.
  - p-Toluidine, not more than 0.2 percent.
  - Chlorides and sulfates of sodium, not more than 8.0 percent.
  - Pure dye (as determined by titration with titanium trichloride), not less than 99.9 percent.
  - Melting point, not less than 210° C.

- **EXT D&C Orange No. 2**
  - Pure dye (as determined gravimetrically), not more than 4.0 percent.
  - Ether extracts (alkaline solution), not more than 0.5 percent.
  - p-Toluidine, not more than 0.2 percent.
  - Chlorides and sulfates of sodium, not more than 8.0 percent.
  - Pure dye (as determined by titration with titanium trichloride), not less than 99.9 percent.

- **EXT D&C Orange No. 3**
  - Pure dye (as determined gravimetrically), not less than 99.9 percent.

- **EXT D&C Orange No. 4**
  - Pure dye (as determined gravimetrically), not less than 10.0 percent.

**§ 9.6 Mixtures which may be certified.**

(a) A batch of a mixture which contains no straight color listed in §9.4 or §9.5 may be certified in accordance with §9.6 if it is submitted in accordance with the provisions of the regulations in this paragraph, for use in food (subject to the restrictions prescribed in paragraph (d) of this section) drugs, and cosmetics, if:

  (1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture.

(b) Each diluent in such batch of mixture is harmless and suitable for use therein.

(c) No mixture which contains a lake listed in §9.3 shall be certified for any use in foods except external application to shell eggs.

**§ 9.7 Sampling, storage, and packaging.**

(a) A sample of a coal-tar color which is to accompany a request for certification submitted in accordance with §9.6 shall be taken from the batch covered by such request only after such batch has been so thoroughly mixed as to be of uniform composition throughout. Immediately after such sample is taken it shall be closed in a package of such kind as to prevent change in the composition of such sample. Such package shall be labeled to show conspicuously the name and post office address of the person submitting such request, the name of such color, and the batch number and quantity of such batch.

(b) Immediately after such sample is taken such batch shall be stored in containers of such kind as to prevent change in the composition of such color or closed in packages for shipment or delivery, and so held until such batch is certified or certification thereof is refused. If such batch is certified and at the time of certification such batch or any part thereof is so stored such storage shall be maintained until such batch or part is:

(1) Closed in such packages.

(2) Used by the person who obtained such certification as an ingredient in a batch of a mixture on which such person obtained such certification in accordance with §9.6, or

(3) Used by such person in coloring a food, drug, or cosmetic, in accordance with the use for which such batch was certified or certification thereof is refused.

(c) The package in which a coal-tar color is closed for shipment or delivery shall be of such kind as to prevent change in the composition of such color, and shall be so closed or sealed that such package cannot be opened without destroying such package or seal.
(d) For the purposes of this part an unavoidable change in the moisture content of a coal-tar color caused by ordinary and customary exposure that occurs in good storage packing, and distribution practice, shall not be considered to be a change in the composition of such color.

§ 9.8 Requests for certification. (a) A request for certification of a batch of a coal-tar color shall be addressed to the Food and Drug Administration, Department of Health, Education and Welfare, Washington 25, D.C. A request for certification of such color shall be addressed to the person who submitted as part of his request statements showing:

(1) Whether or not he manufactured such color, and if he did not, the name and post office address of the manufacturer thereof;

(2) The name of such color, as listed in § 9.3, § 9.4, or § 9.5, and the batch number and quantity of such batch;

(3) In the case of a lake, the purpose whereby such lake is made, including the name or names of the substrata present and the quantity thereof used for such lake.

Such request shall be accompanied by a ¼-pound sample taken from such batch and representing thereof, and by payment of the fee prescribed by § 9.15 (a) (1) Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such batch complies with the requirements laid down by § 9.9 (a) for the issuance of a certificate; and

(2) Showing the lot number of such previously certified batch, the name of such repacked color, and the batch number and quantity of such batch;

(3) In the case of a lake, the purpose whereby such lake is made, including the name or names of the substrata present and the quantity thereof used for such lake.

§ 9.9 Certification. (a) If the Food and Drug Administration determines, after such investigation as it considers to be necessary, that:

(1) A request submitted in accordance with § 9.8 appears to contain no untrue statement of a material fact;

(2) In the case of a straight color, such color conforms to the specifications set forth therefor in §§ 9.2, 9.3, 9.4, and 9.5;

(3) In the case of a mixture containing a diluent, such diluent is harmless and suitable for use therein;

(4) The batch covered by such request otherwise appears to comply with this part, the Food and Drug Administration shall issue a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by § 9.10, shall be from a batch that has not been certified in accordance with this part, the Food and Drug Administration, or the batch number and quantity of such batch;

(5) In such case such mixture contains a diluent permitted by § 9.6 (a) (3) only because such mixture is for use in coloring shell eggs or such diluent does not become a component of a food colored by such mixture, specifying the name of the food for which such mixture is used;

(6) Describing fully the process of mixing, with special reference to the precautions taken to render such batch uniform in composition.

Such request shall be accompanied by a ¼-pound sample taken from such batch containing 2 percent or less of pure dye, a ¼-pound sample taken from such batch and accurately representative thereof, and by payment of the fee prescribed by § 9.15 (a) (1) Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such mixed batch complies with the requirements laid down by § 9.9 (a) for the issuance of a certificate.

(b) A person who requests the certification of a batch made by repacking a coal-tar color from a batch previously certified under this part, shall submit as part of his request statements:

(1) To the effect that he made the batch covered by such request by repacking such color, and that such color has not changed in composition in any manner whatever since such previous certification; and

(2) Showing the lot number of such previously certified batch, the name of such repacked color, and the batch number and quantity of such batch.

§ 9.10 Limitations of certificates. (a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and coal-tar color from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with this part.

(b) If, between the time a sample of coal-tar color accompanies a request for certification is taken and the time a certificate covering the batch of such color is received by the person to whom it is issued, any such color becomes changed in composition in any manner whatever, such certificates shall not be effective with respect to such changed color, and such changed color shall be considered to be from a batch that has not been certified in accordance with this part.

(c) If, at any time after a certificate is received by the person to whom it is issued, any color from such batch covered by such certificate becomes changed in composition in any manner whatever, such certificate shall expire with respect to such changed color. After such expiration such color shall be considered to be from a batch that has not been certified in accordance with this part; except that such color shall not be so considered for the purposes of certifying a batch of a mixture in which such color was used as an ingredient, if such change resulted solely from such use.

(d) A certificate shall expire with respect to any coal-tar color covered thereby if the package in which such color was closed for shipment or delivery is opened, unless opened solely for repacking by the person to whom such certificate was issued. After such expiration such color shall be considered to be from a batch that has not been certified in accordance with this part; except that such color shall not be so considered:

(1) When such color is used, subject to the restrictions prescribed by paragraphs (f) (g) and (h) of this section, in coloring a food, drug, or cosmetic;

(2) For the purpose of certifying a batch made by repacking such color; or

(3) For the purpose of certifying a batch of a mixture in which such color is used as an ingredient.

(e) A certificate shall not be effective with respect to a package of coal-tar color, and such color shall be considered to be from a batch that has not been certified in accordance with this part, if such package is shipped or delivered under a label which does not bear all words, statements, and other information required by § 9.11 to appear thereon.

(f) If a mixture from a batch containing a diluent permitted by § 9.6 (a) (3) only because such diluent does not become a component of a food colored by such mixture is used in coloring an other food, such mixture so used shall be considered to be from a batch that has not been certified in accordance with this part.

(g) If coal-tar color from a batch which was certified for use in drugs and

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cosmetics only is used in coloring a food; such color so used shall be considered to be from a batch that has not been certified in accordance with this part.

(b) If a coal-tar color from a batch containing any lake listed in §3.3 is used in coloring any food except drugs and cosmetics, such color so used shall be considered to be from a batch that has not been certified in accordance with this part.

(c) If a coal-tar color from a batch containing any lake listed in §3.3 is used in coloring any food except drugs and cosmetics, such color so used shall be considered to be from a batch that has not been certified in accordance with this part.

(d) If a coal-tar color from a batch containing any lake listed in §3.3 is used in coloring any food except drugs and cosmetics, such color so used shall be considered to be from a batch that has not been certified in accordance with this part.

§9.11 Labeling. (a) The label on each package of coal-tar color from a batch containing any lake listed in §3.3 shall contain the following information: (1) The name of such color; (2) the lot number; and, (3) the name of such color as provided in paragraph (b) of this section; and,

(b) The statement of the percentage of pure dye in such color as provided in paragraph (b) of this section.

§9.12 Records of distribution. (a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the coal-tar color from such batch, including, but not limited to, the name and address of the person receiving the color or the batch, the date and the amount of such disposal, the name and description of the intermediate and other article of commerce used in the color or the batch, and the name and description of the intermediate and other article of commerce in which the color or the batch was used. (b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by each person from such batch and the date and kind of such use;

(2) The date and quantity of each shipment or delivery from such batch, including the name and address of the person to whom such shipment or delivery was made.

§9.13 Authority to refuse certification. When it appears to the Secretary of Health, Education, and Welfare that a person has:

(a) Obtained a certificate through fraud or misrepresentation of a material fact;

(b) Failed to keep the records required to be kept by §9.12;

(c) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks and other articles of commerce used in the color or the batch, shall keep, and otherwise to check the correctness of such records, as required by such section.

(d) After the records required to be kept by paragraph (a) of this section have been made available to the Secretary of Health, Education, and Welfare, the Secretary may immediately suspend the certification covering such color, and the certificate of a coal-tar color to listing in §9.3, §9.4, or §9.5 shall be accompanied by:

(1) Full reports of investigations which are adequate to show whether or not such color is harmless and suitable for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, as the case may be;

(2) A full statement of the percentage and composition of the pure dye and all intermediates and other impurities contained in such color;

(3) A full statement showing the identity, purity, and quantity or proportion of each intermediate and other article used as a component of such color, and all steps in the process used for the manufacture of such color;

(4) A full description of practical and accurate methods of analysis for the qualitative determination of the pure dye and all intermediates and other impurities contained in such color;

(5) A full description of practical and accurate methods for the identification of such color in food, drugs, and cosmetics colored therewith, and in drugs and cosmetics colored therewith;

(6) A 5-pound sample of such color (unless the Food and Drug Administration finds that such color is harmless and suitable for use in food, drugs, and cosmetics, or in externally applied drugs and cosmetics, as the case may be).

(7) The advance deposit prescribed by §9.15 (b) (3)

(b) If the Secretary determines, after such investigation as he considers to be necessary, that:

(1) Such color is harmless and suitable for use in foods, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics;

(2) Practical and accurate methods of analysis exist for the quantitative determination of the pure dye and all intermediates and other impurities contained in such color;

(3) Practical and accurate methods exist for the identification of such color in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith, the Secretary for the purpose of listing such color in §9.3, §9.4, or §9.5, shall proceed with a proposed amendment to this part as prescribed by section 701 (e) of the act.

(c) If the Secretary, after such investigation as he considers to be necessary, determines that such color does not comply with the requirements laid down by paragraph (b) of this section with respect to procedure for the purpose of listing such color in §9.3, §9.4, or §9.5, the Secretary shall give notice thereof to the applicant, stating the respects in which such color does not comply.

§9.15 Fees. (a) The fee for the services provided by the regulations in this part, in the case of each request for certification submitted in accordance with §9.3, shall be one hundred ($100) dollar for the first pound of the batch covered by such request; but no such fee shall be less than $75.00.
(3) The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 9.8 (c) or (d) shall be:

Weight of batch: Fee
100 pounds or less... $6.00.
Over 100 pounds $6.00, plus 4 cents for each pound in excess of 100 pounds.
Over 200 pounds... $25.00, plus 1 cent for each pound in excess of 200 pounds.

(b) (1) The fee for the services provided by this part, in the case of each application for the admission of an coal color, shall be the cost incurred by the Department in making the investigations contemplated by § 9.14 (b) and (c).

(2) Each such application shall be accompanied by an advance deposit of $500 to cover such fee, and thereafter advance deposits of the same amount (unless the Food and Drug Administration authorizes deposit in other amount) shall be made whenever necessary to prevent arrearages in payment of such fee. Any excess advance deposit so made shall be returned to the applicant after the close of such investigation.

(c) All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of the Treasurer of the United States, and shall be forward to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D. C. All such deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D. C., unconfer upon making appropriate records of them which will be transmitted to the Chief Disbursements Officer, Division of Disbursement, Treasury Department, for deposit to the special account “Certification and Inspection Services, Food and Drug Administration.”

(d) Whenever in the judgment of the Commissioner the ratio between fees collected (wholeness of costs, drawings and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make rata-ble refunds to those persons to whom the services were rendered and charged, except that no refund shall be made where the computed ratable amount for the elapsed period is less than $5.00.

Subchapter B—Food and Food Products

PART 10—GENERAL REGULATIONS RELATING TO DEFINITIONS AND STANDARDS FOR FOOD

Sec. 10.1 General regulation.
10.2 General methods for water capacity and fill of containers.
10.3 General statements of substandard quality and substandard fill of containers.


§ 10.1 General regulation. (a) The definitions and interpretations of terms contained in section 201 of the act shall be applicable also to such terms when used in regulations promulgated under the act.

(b) If a regulation prescribing a definition and standard of identity for a food has been promulgated under section 401 of the act and the name therein specified for the food is used in any other regulation under section 401 or any other provision of the act, such name means the food which conforms to such definition and standard, except as otherwise specifically provided in such other regulation.

(c) No provision of any regulation prescribing a definition and standard of identity or standard of quality or fill of container under section 401 of the act shall be construed as in any way affecting the concurrent applicability of the regulations and the therewithout relation to adulteration and misbranding. For example, all regulations under section 401 contemplate that the food and all articles used as components or ingredients thereof shall not be poisonous or deleterious and shall be clean, sound, and fit for food. A provision in such regulations for the use of coloring or flavoring does not authorize such use under circumstances or in a manner whereby damage or inferiority is concealed or whereby the food is made to appear better or of greater value than it is.

10.2 General methods for water capacity and fill of containers. For the purposes of regulations promulgated under section 401 of the act:

(a) The term “general method for water capacity of containers” means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Wash, dry, and weigh the empty container.

(3) Fill the container with distilled water at 68° Fahrenheit to ¾ inch vertical distance below the top level of the container, and weigh the container thus filled.

(4) Subtract the weight found in subparagraph (2) from the weight found in subparagraph (3) of this paragraph. The difference shall be considered to be the weight of water required to fill the container.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in subparagraphs (2)–(4) of this paragraph, except that under subparagraph (3) fill the container to the level of the top thereof.

10.3 General statements of substandard quality and substandard fill of container. For the purposes of regulations promulgated under section 401 of the act:

(a) The term “general statement of substandard quality” means the statement “Below Standard In Quality Food—Not High Grade” printed in two lines of Cheltenham bold condensed caps. The words “Below Standard In Quality” constitute the first line, and the second immediately follows. If the quantity of the contents of the container is less than 1 pound, the type of the first line is 12-point, and of the second, 8-point. If such quantity is 1 pound or more, the type of the first line is 14-point, and of the second, 10-point. If the statement is enclosed within lines, not less than 6 points in width, forming a rectangle. Such statement, with enclosing lines, is considered to be easily seen under customary conditions of purchase.

(b) The term “general statement of substandard fill” means the statement “Below Standard In Fill” printed in Cheltenham bold condensed caps. If the quantity of the contents of the container is less than 1 pound, the statement is in 12-point type; if such quantity is 1 pound or more, the statement is in 14-point type. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle; but if the statement specified in paragraph (a) of this section is also used, both statements (one following the other) may be enclosed within the same rectangle. Such statement or statements, with enclosing lines, are on a strongly contrasting, un-
form background, and are so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation may be, conspicuously as to be easily seen under customary conditions of purchase.

Part 14—Cacao Products; Definitions and Standards of Identity

Sec.

14.1 Cacao nibs, cocoa nibs, cracked cocoa; identity; label statement of optional ingredients.

14.2 Chocolate liquor, chocolate, baking chocolate, bitter chocolate, coating chocolate, cocoa, vanilla, vanilla flavor, chocolate coating; identity; label statement of optional ingredients.

14.3 Breakfast cocoa, high fat cocoa; identity; label statement of optional ingredients.

14.4 Cocoa, medium fat cocoa; identity; label statement of optional ingredients.

14.5 Low-fat cocoa; identity; label statement of optional ingredients.

14.6 Sweet chocolate, sweet chocolate coating; identity; label statement of optional ingredients.

14.7 Milk chocolate, sweet milk chocolate, milk chocolate coating, sweet milk chocolate coating; identity; label statement of optional ingredients.

14.8 Semi-sweet chocolate, milk semi-sweet chocolate coating, semi-sweet milk chocolate coating; identity; label statement of optional ingredients.

14.9 Buttersweet chocolate, buttermilk chocolate coating; identity; label statement of optional ingredients.

14.10 Malted milk chocolate, milk chocolate, dairy product chocolate coatings; identity; label statement of optional ingredients.

14.11 Sweet chocolate and vegetable fat (other than cocoa fat) coating; identity; label statement of optional ingredients.

14.12 Sweet cocoa and vegetable fat (other than cocoa fat) coating; identity; label statement of optional ingredients.

14.13 Sweet cocoa and vegetable fat (other than cocoa fat) coating; identity; label statement of optional ingredients.


§ 14.1 Cacao nibs, cocoa nibs, cracked cocoa; identity; label statement of optional ingredients. (a) Cacao nibs, cocoa nibs, cracked cocoa is the food prepared by heating cacao beans or cacao nibs, or any mixture of two or more of these, after part of the cacao fat has been removed from ground cacao nibs. It may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combination of ingredients specified in subparagraphs (1), (2), or (3) of this paragraph which imparts a flavor that imitates the flavor of chocolate, milk, or butter:

(1) Ground spice.
(2) Ground vanilla beans; any natural food flavoring, oil, oleoresin, or extract.
(3) Vanillin, ethyl vanillin, or other artificial food flavoring.
(4) Butter, milk fat, dried malted milk extract, ground coffee, ground nuts.
(5) Salt.

Any optional ingredient used with the cacao beans or cocoa nibs from which such chocolate liquor is prepared, or used with any cocoa added in preparing such chocolate liquor, shall be considered to be an optional ingredient used with such chocolate liquor. The optional ingredients specified for use with cacao nibs in § 14.1 (a) may be used in combination with chocolate liquor; but for each 100 parts by weight of cacao nibs used in preparing the chocolate liquor, the total quantity of such allalns used shall not exceed the neutralizing value (calculated from the respective combining weights of such allalns used) than 3 parts by weight of anhydrous potassium carbonate. The finished chocolate liquor contains not less than 11.75 percent by weight (calculated to an alkali-free basis) if they or the cocoa beans from which they were prepared have been processed with alkali as determined by the method prescribed under "Shell in Cacao Nibs—Tentative" beginning on page 202 (Ed. note, 8th edition, 1955, secs. 12.3-12.13 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th ed., 1950, p. 195, secs. 12.3-12.13 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th ed., 1950).

(b) When cocoa nibs or the cocoa beans from which they are prepared are processed, in whole or in part, with any optional alkali ingredient specified in paragraphs (1), (2), or (3) of this paragraph which imparts a flavor that imitates the flavor of chocolate, milk, or butter, the label shall bear the statement "Process with Alkali". In lieu of the word "Alkali" in such statement the specific common name of the optional alkali ingredient used may be used. Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such statement shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(1) When the food is seasoned with an optional ingredient specified in subparagraph (a) (1) of this section the label shall bear the statement "Spiced,
(2) "Spiced Added," "With Added Spice,
(3) or "Spiced, Spiced Added,
(4) or "Spiced Added__", the blank being filled in with the specific common name of the spice used.

(2) When the food is seasoned with an optional ingredient specified in paragraph (a) (2) of this section, the label shall bear the statement "Flavored,
(3) "Flavored Added,
(4) or "Flavored With __", the blank being filled in with the specific common name of the flavoring used.

(3) If the food is seasoned with an optional ingredient specified in paragraph (a) (3) of this section, the label shall bear the statement "Artificial Flavoring Added,
(4) or "Artificial Flavoring With__", the blank being filled in with the specific common name of the artificial flavoring used.

(4) When the food is seasoned with an optional ingredient specified in paragraph (a) (4) of this section, the label shall bear the statement "Seasoned With__", the blank being filled in with the specific common name of the substance used as seasoning.

(5) When any optional alkali ingredient specified in § 14.1 (a) is used, the label shall bear the statement "Process with Alkali"; but in lieu of the word "Alkali" in such statement the specific common name of the optional alkali ingredient used may be used.

Label statements prescribed in subparagraphs (1) to (4) inclusive of this paragraph may be omitted, for example, "With Added Cinnamon, Vanilla, and Ethyl Vanillin, an Artificial Flavoring.

§ 14.3 Breakfast cocoa, high fat cocoa; identity; label statement of optional ingredients. (a) Breakfast cocoa, high fat cocoa is the food prepared by pulverizing the residual material remaining after part of the cocoa fat has been removed from ground cacao nibs. It may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combination of ingredients which imparts a flavor that imi-
tates the flavor of chocolate, milk, or butter.

(1) Ground spice.
(2) Ground vanilla beans; any natural food flavoring, oil, oleoresins, or extract.
(3) Vanillin, ethyl vanillin, or other artificial food flavoring.
(4) Salt.

Any optional ingredient used with the cocoa beans, cocoa nibs, or ground cocoa nibs from which the breakfast cocoa is prepared shall be considered to be an optional ingredient used with such breakfast cocoa. The optional alkali ingredients specified for use with cocoa nibs in §14.1 (a) may be used as optional ingredients with breakfast cocoa; but for each 100 parts by weight of cocoa nibs used in preparing the breakfast cocoa, the total quantity of such alkalis used is not greater in neutralizing value (calculated from the respective combing weights of such alkalis used) than 3 parts by weight of anhydrous potassium carbonate. The finished breakfast cocoa contains not less than 22 percent of cocoa fat, as determined by the method prescribed under "Fat Method I—Official" beginning on page 202 of the 8th edition, 1985, p. 198, sec. 12.22 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 8th Ed., 1940.

(b) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing the optional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter:

(1) When the food is seasoned with an optional ingredient specified in paragraph (a) (1) of this section, the label shall bear the statement "Spiced," "Spice Added," "With Added Spice," "Spiced With ———," or "With Added ———," the blank being filled in with the specific common name of the spice used.

(2) When the food is flavored with an optional ingredient specified in subparagraph (a) (2) of this section, the label shall bear the statement "Flavored," "Flavoring Added," "With Added Flavoring," "Flavoring With ———," "Flavoring ———," or "With Added ———," the blank being filled in with the specific common name of the flavoring used.

(3) When the food is flavored with an optional ingredient specified in paragraph (a) (3) of this section, the label shall bear the statement "Artificially Flavored," "Artificial Flavoring Added," "With Artificial Flavoring," "Artificially Flavored With ———," or "With ———, Artificial Flavoring," the blank being filled in with the specific common name of the artificial flavoring used.

(4) When any optional alkali ingredient specified in §14.1 (a) is used, the label shall bear the statement "Processed With Alkali" but in lieu of the word "Alkali" in the preceding statement the specific common name of the optional alkali ingredient may be used.

Label statements prescribed by subparagraphs (1) to (4), inclusive, of this paragraph may be combined, as for example, "With Added Cinnamon, Vanilla, and Ethyl Vanillin, an Artificial Flavouring."

§14.4 Cocoa, medium fat cocoa; identity; label statement of optional ingredients.

Cocoa, medium fat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for breakfast cocoa by §14.3, except that it contains less than 10 percent of cocoa fat, as determined by the method referred to in §14.3 (a).

§14.5 Low-fat cocoa; identity; label statement of optional ingredients.

Low-fat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for breakfast cocoa by §14.3, except that it contains less than 10 percent of cocoa fat, as determined by the method referred to in §14.3 (a).

§14.6 Sweet chocolate, sweet chocolate coating; identity; label statement of optional ingredients.

(a) Sweet chocolate, sweet chocolate coating is the solid or semisolid mass of ingredients of which are intimately mixed and ground, prepared from chocolate liquor (with or without the addition of cacao fat) sweetened with one of the optional saccharine ingredients specified in paragraph (b) of this section. It may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combination of ingredients which imparts a flavor that imitates the flavor of chocolate, milk, or butter:

(1) Ground spice, ground vanilla beans, or other natural food flavoring, oil, oleoresins, or extract, ground coffee, ground nut meats, honey, molasses, brown sugar, mable sugar, dried malted barley, salt.

(b) The optional saccharine ingredients referred to in paragraph (a) of this section are:

(1) Sugar, or partly refined cane sugar, or both.
(2) Any mixture of dextrose and sugar or partly refined cane sugar or both in which the weight of the solids of the dextrose used is not more than one-third of the total weight of the solids of all the saccharine ingredients used.
(3) Any mixture of dried corn sirup or dried glucose sirup and sugar or partly refined cane sugar or both in which the weight of the solids of the dried corn sirup or of the dried glucose sirup used is not more than one-fourth of the total weight of the solids of all the saccharine ingredients used.
(4) Any mixture of dextrose and dried corn sirup or dried glucose sirup and sugar or partly refined cane sugar or both in which three times the weight of the solids of the dextrose used plus four times the weight of the solids of the dried corn sirup or of the solids of the dried glucose sirup used is not more than the total weight of the solids of all the saccharine ingredients used.
(5) (a) The term "dextrose" means the anhydrous refined monosaccharide obtained from hydrolysis of starch;
(b) The term "dried corn sirup" means the product obtained by drying incompletely hydrolyzied cornstarch; its solids contain not less than 58 percent by weight of reducing sugars.
(6) The term "dried glucose sirup" means the product obtained by drying "glucose sirup." "Glucose sirup" is a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 46 percent by weight of reducing sugars calculated as anhydrous dextrose.

(d) "Semisweet chocolate," "bitter-sweet chocolate," "semisweet chocolate coating," and "bittersweet chocolate coating" are alternate names for sweet chocolate which contains not less than the minimum quantity of chocolate liquor prescribed for bittersweet chocolate by paragraph (a) of this section.

(1) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing the op-
tional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter:

(1) When the food is flavored with an optional ingredient specified in paragraph (a) (2) of this section, the label shall bear the statement “Artificially Flavored.” “Artificial Flavoring,” or “With Added Emulsifier,” the blank being filled in with the specific common name of the optional ingredient used.

(2) When any optional ingredient specified in § 14.1 (a) is used the label shall bear the statement “Processed With Alkali,” but in lieu of the word “Alkali” in such statement the specific common name of the optional alkali ingredient may be used.

Label statements prescribed by subparagraphs (1) and (2) of this paragraph may be combined, as for example, “With Added Emulsifier and Ethyl Vanillin, an Artificial Flavoring.”

§ 14.7 Milk chocolate, sweet milk chocolate, milk chocolate coatings, sweet milk chocolate coating; identity, label statement of optional ingredients. (a) Milk chocolate, sweet milk chocolate, milk chocolate coating specified in milk chocolate coating is the solid or semiplastic foec the ingredients of which are intimately mixed and ground, prepared from chocolate liquor (with or without the addition of cocoa fat) and one or more of the optional dairy ingredients specified in paragraph (b) of this section, sweetened with one of the optional succharine ingredients specified in § 14.8 (b) and (c).

(b) It may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combination of ingredients which imparts a flavor that imitates the flavor of chocolate, milk, or butter:

- Ground spice, ground vanilla beans, any natural food syrup, all-cloves or extract, ground coffee, ground nut meats, honey, molasses, brown sugar, maple sugar, dried malted cereal extract, salt.
- Vanillin, ethyl vanillin or other artificial food flavoring.

One or a mixture of both of the following optional emulsifying ingredients may be added in a total quantity not more than 0.5 percent of the weight of the finished food product or mixture may be added in combination with a vegetable food fat carrier, such combination containing not less than 60 percent by weight of the emulsifying ingredient or mixture used:

- Lecithin, with or without related natural phosphatides.
- Monoglycerides and diglycerides of fat-forming fatty acids in combination with monosodium phosphate derivatives thereof.

If chocolate liquor with any optional ingredient specified in § 14.2 (a) is used, such ingredient shall be considered to be an optional ingredient used with the milk chocolate. The finished milk chocolate contains not less than 3.65 percent by weight of milk fat, not less than 12 percent by weight of milk solids, and not less than 10 percent by weight of chocolate liquor as calculated by subtracting from the weight of chocolate liquor used the weight of cocoa fat therein and the weights of optional and accompanying ingredients, if any, multiplying the remainder by 2.2, dividing the result by the weight of the finished milk chocolate, and multiplying the quotient by 100.

(b) The optional dairy ingredients referred to in paragraph (a) of this section are milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk, butter, milk fat, cream, skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, and nonfat dry milk solids; but in any such ingredient or combination of two or more of such ingredients used, the weight of nonfat milk solids is not more than 2.43 times and not less than 1.20 times the weight of milk fat therein.

(1) Wherever the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section shall be the optional ingredient used in label immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter:

- When the food is flavored with an optional ingredient specified in paragraph (a) (2) of this section, the label shall bear the statement “Artificially Flavored.” “Artificial Flavoring,” or “With Added Emulsifier,” the blank being filled in with the specific common name of the artificial flavoring used.
- When an optional ingredient specified in paragraph (a) (3) or (4) of this section is used, the label shall bear the statement “Emulsifier Added” or “With Added Emulsifier.”
- When any optional alkali ingredient specified in § 14.1 (a) is used the label shall bear the statement “Processed With Alkali,” but in lieu of the word “Alkali” in such statement the specific common name of the optional alkali ingredient may be used.

Label statements prescribed by subparagraphs (1) and (2) of this paragraph may be combined, as for example, “With Added Emulsifier and Ethyl Vanillin, an Artificial Flavoring.”

§ 14.8 Slim milk chocolate, sweet slim milk chocolate, slim milk chocolate coating, sweet slim milk chocolate coating; identity, label statement of optional ingredients. (a) Slim milk chocolate, sweet slim milk chocolate, slim milk chocolate coating, sweet slim milk chocolate coating conform to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for milk chocolate by § 14.5, except that:

(1) The dairy ingredients used are limited to sweet cream buttermilk, concentrated sweet cream buttermilk, dried sweet cream buttermilk, or any combination of two or all of these.

(2) The finished buttermilk chocolate contains less than 3.66 percent by weight of milk fat and, instead of milk solids, it contains not less than 12 percent by weight of sweet cream buttermilk solids.

§ 14.9 Buttermilk chocolate, buttermilk chocolate coating; identity, label statement of optional ingredients. (a) Buttermilk chocolate, buttermilk chocolate coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for milk chocolate by § 14.5, except that:

(1) The dairy ingredients used are limited to sweet cream buttermilk, concentrated sweet cream buttermilk, dried sweet cream buttermilk, or any combination of two or all of these.

(2) The finished buttermilk chocolate contains less than 3.66 percent by weight of milk fat and, instead of milk solids, it contains not less than 12 percent by weight of sweet cream buttermilk solids.

§ 14.10 Mixed dairy product chocolate, mixed dairy product chocolate coating; identity, label statement of optional ingredients. (a) The articles for which definitions and standards of identity are prescribed are the foods each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for milk chocolate by § 14.5, except that:

(1) The dairy ingredient used in each such article is a mixture of two or more of the following four components:

- Any dairy ingredient or combination of such ingredients specified in § 14.7 (b) which is within the limits of the ratios specified therein for nonfat milk solids to milk fat.
- One or more of the five slim milk ingredients specified in § 14.8.
- One or more of the three sweet cream buttermilk ingredients specified in § 14.7.
- One or more of the five buttermilk ingredients specified in § 14.8.

(b) The designation of each of the components used in any such mixture is more than 2.43 times the quantity of one component and less than 2.43 times the quantity of another component, if any, of the weight of milk constituent solids in such mixture.

§ 14.11 Malted milk.

(2) Each of the finished articles may contain less than 3.66 percent by weight of milk fat and, instead of milk solids, it contains not less than 12 percent by weight of milk constituent solids of the components used. The quantity of each component used in any such mixture is limited to one-third of the weight of milk constituent solids contributed by that component used in largest proportion. When each mixture is of such composition that (i) and (ii) of subparagraph (1) the quantity of nonfat milk solids in such mixture is more than 2.43 times the quantity of milk fat therein. For the purposes of paragraphs (b) and (c) of this section, the designation of each of the components listed above is respectively “Milk,” “Slim Milk,” “Buttermilk,” and “Malted Milk.”

(b) The following designation is “Chocolate” or “Chocolate coating” preceded by the designations prescribed by paragraph (a) of this section for each component of the dairy ingredients used, as the designations appearing in the order of predominance, if any, of the weight of milk constituent solids in each such mixture.
component. (For example, “Milk and Skim Milk Chocolate.”)

§ 14.11 Sweet chocolate and vegetable fat (other than cacao fat) coating; identity; label statement of optional ingredients. (a) Sweet chocolate and vegetable fat (other than cacao fat) coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for sweet chocolate by § 14.6, except that:

(1) In its preparation is added one or any combination of two or more vegetable food oils or vegetable food fats, other than cacao fat, which oil, fat, or combination may be hydrogenated and which has a melting point lower than that of cacao fat.

(2) The requirement of § 14.6 (a) that the milk constituent solids be less than 12 percent by weight does not apply.

(b) The provisions of this section shall not be construed as applicable to any article by reason of the addition thereto of a vegetable food fat other than cacao fat as a carrier of emulsifying ingredients, as authorized and within the limit prescribed by § 14.6 (a).

§ 14.12 Sweet cocoa and vegetable fat (other than cacao fat) coating; identity; label statement of optional ingredients. (a) Sweet cocoa and vegetable fat (other than cacao fat) coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for sweet chocolate by § 14.6, except that:

(1) In its preparation is added one or any combination of two or more vegetable food fats or vegetable food stearins, other than cacao fat, which oil, fat, stearin, or combination has a melting point higher than that of cacao fat. Any such oil or fat may be hydrogenated.

(2) The requirement of § 14.6 (a) that the milk constituent solids be less than 12 percent by weight does not apply.

Part 15—CEREAL FLOURS AND RELATED PRODUCTS; DEFINITIONS AND STANDARDS OF IDENTITY

Subpart A—Wheat Flour and Related Products

Sec. 15.1 Flours, white flour, wheat flour, plain flour; identity; label statement of optional ingredients.

15.10 Enriched flour; identity; label statement of optional ingredients.

15.20 Bromated flour; identity; label statement of optional ingredients.

15.30 Enriched bromated flour; identity; label statement of optional ingredients.

15.40 Durum flour; identity.

15.50 Self-rising flour, self-rising white flour, enriched self-rising flour; identity; label statement of optional ingredients.

15.60 Enriched self-rising flour; identity; label statement of optional ingredients.

15.70 Phosphated flour, phosphated white flour; identity; label statement of optional ingredients.

15.80 Whole wheat flour, graham flour, entire wheat flour; identity; label statement of optional ingredients.

15.90 Bromated whole wheat flour; identity; label statement of optional ingredients.

15.100 Whole durum wheat flour; identity; label statement of optional ingredients.

15.110 Crushed wheat, coarse ground wheat; identity.

15.120 Cracked wheat; identity.

15.130 Fat, vegetable fat.

15.140 Enriched farina; identity; label statement of optional ingredients.

15.150 Semolina; identity.

Subpart B—Corn Flour and Related Products

Sec. 15.50 Corn flour, white corn flour, yellow corn flour; identity.

15.510 Yellow corn flour; identity.

15.520 Malted corn flour; identity.

15.530 Malted white corn flour, degerminated white corn meal, degerminated white flour; identity.

15.540 Degerminated corn flour, degerminated corn meal; identity.

15.550 Degerminated yellow corn meal, degerminated yellow corn flour, degerminated yellow flour; identity.

15.560 Semolina; identity.

15.570 Self-rising yellow corn flour; identity.

15.580 White corn flour; identity.

15.590 Yellow corn flour; identity.

15.610 Grits, corn grits, hominy grits; identity.

15.620 Enriched corn grits; identity; label statement of optional ingredients.

15.630 Corn meal; identity.

15.640 White corn meal; identity.

15.650 Yellow corn meal; identity.

15.660 Semolina; identity.

15.670 Enriched corn grits, corn meal; identity; label statement of optional ingredients.

15.680 Semolina; identity.

§ 15.1 Flours, white flour, wheat flour, plain flour; identity; label statement of optional ingredients. (a) Flour, white flour, wheat flour, plain flour is the food prepared by grinding and bolting cleaned wheat other than durum wheat and red durum wheat, having a moisture basis not more than 14 percent by weight of one or any mixture of two or more of the following: potassium alum, calcium sulfate, magnesium carbonate, sodium aluminum sulfate, di-calcium phosphate, tricalcium phosphate, starch, calcium carbonate.

(b) When any optional bleaching ingredient is used, the word "bleached" shall immediately and conspicuously as to be easily seen under customary conditions of purchase, the word "bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of trade-mark or brand, other written, printed, or graphic matter which is also a part of such trade-mark or brand, may so intervene if the word "bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:


(2) Protein is 5.75 times the nitrogen as determined by the method prescribed in such book on page 29, under "Kjeldahl-Gunning-Arnold Method—Official." (Ed. note: 8th Ed., 1955, p. 15, "Improved Kjeldahl method for nitrate-free samples," sec. 2.23.)

(3) Moisture is determined by the method prescribed in such book on page 211, under "Vacuum Oven Method—Official." (Ed. note: 8th Ed., 1955, p. 200, sec. 13.2, 13.3.)

§ 15.10 Enriched flour; identity; label statement of optional ingredients. Enriched flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 15.1, except that:
(a) It contains in each pound not less than 2.0 milligrams and not more than 2.5 milligrams of thiamine, not less than 1.2 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, not less than 13.0 milligrams and not more than 16.5 milligrams of iron (Fe), and not more than 1.2 milligrams and not more than 2.0 milligrams of thiamine, not less than 1.2 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, not less than 13.0 milligrams and not more than 16.5 milligrams of iron (Fe).

(b) Calcium may be added in such quantity that each pound of the finished enriched flour contains not less than 500 milligrams and not more than 625 milligrams of calcium (Ca) except that enriched flour may be acidified with monocalcium phosphate irrespective of the minimum limit for calcium (Ca) prescribed in this paragraph;

(c) It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ; and

(d) In determining whether the cash content complies with the requirements of this section allowance is made for cash resulting from any added iron salts of iron or calcium.

Iron and calcium may be added only in forms which are harmless and assurable. The substances referred to in paragraphs (a) and (b) of this section may be added in a harmless carrier which does not impair the enriched flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.

§ 15.20 Bromated flour: identity; label statement of optional ingredients. Bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 15.1, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished bromated flour, and is added only to flours whose baking qualities are improved by such addition.

§ 15.30 Enriched bromated flour: identity; label statement of optional ingredients. Enriched bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for enriched flour by § 15.10, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished enriched bromated flour, and is added only to enriched flours whose baking qualities are improved by such addition.

§ 15.40 Durum flour: identity. (a) Durum flour is the food prepared by grinding and bolting cleaned durum wheat. One of the cloths through which such flour is bolted has openings not larger than 0.30 mm and not smaller than 0.15 mm. (b) It contains in each pound not less than 2.5 milligrams of thiamine, not less than 1.2 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, not less than 13.0 milligrams and not more than 16.5 milligrams of iron (Fe) or sodium bicarbonate, and the acid-reacting substance calcium phosphate irrespective of the minimum limit for calcium (Ca) prescribed in this paragraph; and

and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 1.5 percent. Its moisture content is not more than 14 percent. (b) For the purposes of this section, ash and moisture are determined by the methods therefor referred to in § 15.1.

§ 15.50 Self-rising flour, self-rising white flour, self-rising wheat flour: identity; label statement of optional ingredients. (a) Self-rising flour, self-rising white flour, self-rising wheat flour, is an intimate mixture of flour, sodium bicarbonate, and the acid-reacting substance monocalcium phosphate or sodium acid pyrophosphate or both. It is seasoned with salt. When it is tested by the method prescribed in paragraph (c) of this section allowance is made for ash resulting from any added iron salts of iron or calcium.

It contains in each pound not less than 1.5 milligrams of thiamine, not less than 1.2 milligrams and not more than 2.0 milligrams of riboflavin, and the acid-reaction substance is made of flour containing 0.5 percent of carbon dioxide is evolved. The acid-reaction substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of each acid-reaction substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of flour used. Subject to the conditions and restrictions prescribed by § 15.1. Optional ingredients specified in such section may be added as optional ingredients. If the flour used in making the self-rising flour is bleached, the optional bleaching ingredient is also an optional ingredient of the self-rising flour.

(b) (1) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." (2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately precede or follow such name, without intervening written, printed, or graphic matter; except that such name is a part of a trade-mark or brand, other phrase or word appearing in graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) The method referred to in paragraph (a) of this section is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, beginning on page 100 (Ed. note, 8th edition, 1955, p. 127, secs. 17.2, 11.3) under "Gasometric Method with Chittick's Apparatus—Official," except that the following procedure is substituted for the procedure specified therein under "6—Determination." Weigh 17 grams of the official sample into flask A, add 25-20 glass beads (4-6 mm. diameter) and connect this flask with the apparatus (fig. 2A). Open stopcock C and by means of the leveling bulb B bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1-2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask 45 cc. of sulfuric acid (1:5) to prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times. Rotate and vigorously agitate the decomposition flask for three minutes or mix the contents. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in weight of carbon dioxide recovered in the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 2. Place this number in the formula and solve as specified in the standard specifications.
less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D'.

(c) It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ.

(d) When added as dicalcium phosphate, such dicalcium phosphate is also considered to be an acid-reducing substance; and, when added as carbonate, the method set forth in §15.70 (c) does not apply as a test for carbon dioxide evolved; but in such case the quantity of carbonate, which does not impair the enriched self-rising flour is not less than 0.5 percent of the weight thereof.

Iron and calcium may be added only in forms which are harmless and assumable. The substances referred to in paragraphs (a) and (b) of this section may be added in a harmless carrier which does not impair the enriched self-rising flour. Such carrier is used only in the quantity necessary to effect an intimate mixture of such substances with the flour.

§15.70 Phosphated flour phosphated white flour phosphated wheat flour—identity; label statement of optional ingredients. Phosphated flour, phosphated white flour, phosphated wheat flour, conforms to the definition and standard of identity, and is subject to the requirements for label declaration of optional ingredients, prescribed for flour by §15.1, except that:

(a) Monocalcium phosphate is added in a quantity not less than 0.25 percent and not more than 0.75 percent of the weight of the finished phosphated flour; and

(b) In determining whether the ash content complies with the requirements of this section allowance is made for the added monocalcium phosphate.

§15.80 Whole wheat flour graham flour entire wheat flour—identity; label statement of optional ingredients.

(a) Whole wheat flour, graham flour, entire wheat flour, is the food prepared by so grinding cleaned wheat other than durum wheat flour, that when tested by the method prescribed in paragraph (c) (2) of this section, not less than 90 percent passes through a No. 8 sieve and not less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted wheat flour so used is not more than 0.5 percent, and the quantity of malted barley flour so used is not more than 0.25 percent. The moisture content of whole wheat flour is not more than 15 percent. Unless such addition conceals damage or impairs the quality of the whole wheat flour or makes it appear better or of greater value than it is, the optional bleaching ingredients chloride dioxide, chlorite, or chlorite, may be added in quantity not more than sufficient for bleaching and artificial aging effects.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intermingle with the above-mentioned juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:


(2) The method referred to in paragraph (a) of this section is as follows: Use No. 8 and No. 20 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and wire frames in "Standard Specifications for Sieves," published by the Association of Official Agricultural Chemists of the United States Department of Commerce, National Bureau of Standards, for No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 gm. of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-half of a revolution each time in the same direction, after each 25 strokes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.

§15.90 Bromated whole wheat flour—identity; label statement of optional ingredients. Whole durum wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by §15.80, except that potassium bromate is added in a quantity not exceeding 75 parts to each million parts of finished bromated whole wheat flour.

§15.100 Whole durum wheat flour—identity; label statement of optional ingredients. Whole durum wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by §15.80, except that cleaned durum wheat instead of cleaned wheat other than durum wheat and red durum wheat, is used in its preparation.

§15.110 Crushed wheat, coarse ground wheat; identity. Crushed wheat, coarse ground wheat, is the food prepared by so crushing cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in §15.80 (c) (2) not less than 50 percent passes through a No. 8 sieve and less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, page 353 (Ed. note: 8th edition, 1955, p. 367, secs. 22.2, 22.3), under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."

§15.120 Grits; identity. Grits is the food prepared by so crushing or cutting into angular fragments cleaned wheat other than durum wheat and red durum wheat, that, when tested by the method prescribed in §15.80 (c) (2) not less than 60 percent passes through a No. 8 sieve and not more than 20 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered.

§15.130 Farina; identity. Farina is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat, to such fineness that, when tested by the method prescribed in paragraph (b) (2) of this section, it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 6.0 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section:

(1) Ash and moisture are determined by the methods therefor referred to in §15.1 (c).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 20 and No. 100 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published by the Association of Official Agricultural Chemists of the United States Department of Commerce, National Bureau of Standards, for No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Pour 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-half of a revolution each time in the same direction, after each 25 strokes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.
§ 15.140 Enriched farina; identity; label statement of optional ingredients.
(a) Enriched farina conforms to the definition and standard of identity prescribed for farina by § 15.130, except that:

(1) It contains in each pound not less than 2.0 milligrams and not more than 2.5 milligrams of thiamine, not less than 1.5 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, and not less than 13.0 milligrams of iron (Fe).

(2) Vitamin D may be added in such quantity that each pound of the finished enriched farina contains not less than 250 U. S. P. units of the optional ingredient vitamin D.

(3) Calcium may be added in such quantity that each pound of the finished enriched farina contains not less than 500 milligrams of the optional ingredient calcium (Ca).

(4) It may contain not more than 8 percent by weight of the optional ingredient wheat germ or partly defatted wheat germ.

(5) It may contain not less than 0.5 percent and not more than 1 percent by weight of the optional ingredient disodium phosphate.

(b) In determining whether the ash content complies with the requirements of this section allowance is made for ash resulting from any added iron or salts of iron and disodium phosphate, or from any added wheat germ or partly defatted wheat germ.

Iron and calcium may be added only in forms which are harmless and assinilated.

§ 15.150 White corn meal; identity. (a) White corn meal is the food prepared by grinding and bolting cleaned durum wheat to such fine size that, when tested by the method prescribed in § 15.130 (b) (2) it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.92 percent. Its moisture content is not more than 15 percent.

(b) For the purpose of this section, ash and moisture are determined by the methods therefor referred to in § 15.1. (c) SUBPART B—COIN FLOUR AND RELATED PRODUCTS

§ 15.500 White corn meal; identity. (a) White corn meal is the food prepared by grinding and bolting cleaned durum wheat to such fine size that, when tested by the method prescribed in paragraph (b) (2) of this section not less than 95 percent passes through a No. 12 sieve, not less than 50 percent through a No. 28 sieve, but not more than 35 percent through a No. 72 grites gauze. Its moisture content is not more than 15 percent. In its preparation corn meal may be separated and discarded, or reground and recombined with all or part of the material from which they were separated, but in any such case the crude fiber content of the finished corn meal is not less than 1.2 percent and not more than than that of the cleaned corn from which it was ground, and its fat content does not differ more than 0.5 percent from that of the crude fiber and fat in all the foregoing provisions relating thereto are on a moisture-free basis.


(2) The method referred to in paragraph (a) of this section is as follows:

Use No. 12 and No. 28 sieves, having standard 8-inch diameter, full-holes frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the Bureau of Standards, United States Department of Commerce. A sieve with frame of the same dimensions as the No. 12 and 28 and fitted with 72 XXXX grits gauze may be used as the third sieve. It is referred to hereafter as the No. 72 sieve. The 72 XXXX grits gauze has openings equivalent in size with those of No. 70 woven-ware cloth, complying with specifications for standard cloth, United States Department of Commerce. A sieve with frame of the same dimensions as the No. 12 and 28 and fitted with 72 XXXX grits gauze has openings equivalent in size with those of No. 70 woven-ware cloth, complying with specifications for standard cloth, United States Department of Commerce. A sieve with frame of the same dimensions as the No. 12 and 28 and fitted with 72 XXXX grits gauze may be used as the third sieve. It is referred to hereafter as the No. 72 sieve. The 72 XXXX grits gauze has openings equivalent in size with those of No. 70 woven-ware cloth, complying with specifications for standard cloth, United States Department of Commerce.

(c) When the method prescribed in § 15.500 (b) (2), except that the No. 28 sieve shall be No. 25 sieve, not less than 95 percent passes through a No. 20 sieve, not less than 50 percent through a No. 25 sieve, but not more than 25 percent through a No. 12 sieve, and not more than 15 percent of the No. 12 sieve shall be 1.5 milligrams and not more than 2.5 milligrams of thiamine, not less than 20.0 milligrams of niacin or niacinamide, and not less than 14.0 milligrams of iron (Fe), its moisture content is not more than 15 percent. Its ash content is not more than 0.92 percent. Its fat content is not more than 15 percent. Its crude fiber content is not more than 15 percent. Its weight occurs in any sieve during a 1-minute shaking. The amount of sample passing through No. 12 sieve shall be determined by subtracting from 100 percent, the percent of material remaining on No. 12 sieve.

(d) It contains not less than 1.2 percent and not more than 20.0 percent through a No. 28 sieve shall be determined by adding the parents remaining on the No. 72 sieve and the percent in pan. The percent in the pan shall be corrected as the percent percentage through a No. 72 XXXX grits gauze.

§ 15.505 Bolted white corn meal; identity. (a) Bolted white corn meal is the food prepared by so grinding and sizing cleaned white corn that:

(1) Its crude fiber content is less than 1.5 percent but its fat content is not less than 2.23 percent; and

(2) When washed with water, not more than 25 percent of material is not more than 15 percent. Its moisture content is not more than 15 percent. Its ash content is not more than 0.92 percent. Its fat content is not more than 15 percent. Its crude fiber content is not more than 15 percent. Its weight occurs in any sieve during a 1-minute shaking. The amount of sample passing through No. 12 sieve shall be determined by subtracting from 100 percent, the percent of material remaining on No. 12 sieve. The percent in the pan shall be corrected as the percent percentage through a No. 72 XXXX grits gauze.

§ 15.505 Bolted yellow corn meal; identity. Bolted yellow corn meal conforms to the definition and standard of identity prescribed by § 15.500 for white corn meal except that bright yellow corn is used instead of cleaned white corn.

§ 15.505 Bolted yellow corn meal; identity. Bolted yellow corn meal conforms to the definition and standard of identity prescribed by § 15.502 for bolted white corn meal except that bright yellow corn is used instead of cleaned white corn.
yellow corn is used instead of cleaned white corn.

§ 15.504 Degerminated white corn meal, degermed white corn meal; identity. (a) Degerminated white corn meal, degermed white corn meal, is the food prepared by grinding cleaned white corn and removing bran and germ so that:

(1) On a moisture-free basis, its crude fiber content is not less than 1.2 percent and its fat content is less than 2.25 percent; and

(2) When tested by the method prescribed in § 15.500 (b) (2) except that a No. 20 standard sieve is used instead of a No. 12 sieve, not less than 95 percent passes through a No. 20 sieve, not less than 45 percent through a No. 25 sieve, and not more than 25 percent through No. 75 XXXX grits gauge. Its moisture content is not more than 15 percent.

(b) For the purposes of this section, moisture, fat and crude fiber are determined by methods therefor referred to in § 15.500 (b) (1).

§ 15.505 Degerminated yellow corn meal, degermed yellow corn meal; identity. Degerminated yellow corn meal, degermed yellow corn meal, conforms to the definition and standard of identity prescribed by § 15.504 for degerminated white corn meal except that cleaned yellow corn Is used instead of cleaned white corn.

§ 15.506 Self-rising white corn meal, identity. (a) Self-rising white corn meal is an intimate mixture of white corn meal, sodium bicarbonate, and the acid-reacting substance monocalcium phosphate. It is seasoned with salt. When it is tested by the method prescribed in paragraph (b) of this section, not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of white corn meal.

(b) The method referred to in paragraph (a) of this section is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," beginning on page 268 (Ed. note, 8th edition, 1955, p. 127, secs. 7.2, 7.3) under "Gasometric Method (2) with Chittick's Apparatus—Official," except that the following procedure is substituted for the procedure specified therein under "17.6—Determination".

Weigh 17 grams of the official sample into flask A, (35 to 40 mm. glass beads 6.3 mm. diameter) and connect this flask with the apparatus (fig. 25). Open stopcock C and by means of the leveling bulb B bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand for an hour in order that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1-4-5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the burette. Mix and then gently agitate the decomposition flask for 3 minutes to mix the contents intimately. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the burette and tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition) observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 44.30 (Ed. note, 8th edition, 1955, sec. 42.29)—Reference Tables for Pressure and Temperature—Observe the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

Prepare the synthetic sample with 16.2 grams of corn meal, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U. S. P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91. Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample.

§ 15.507 Self-rising yellow corn meal; identity. Self-rising yellow corn meal conforms to the definition and standard of identity prescribed by § 15.506 for self-rising white corn meal except that yellow corn meal is used instead of white corn meal.

§ 15.508 White corn flour; identity. (a) White corn flour is the food prepared by so grinding and sifting cleaned white corn, with removal of corn bran and germ, that:

(1) On a moisture-free basis its crude fiber content is not more than 1.2 percent and its fat content is not more than 2.25 percent; and

(2) When tested by the method prescribed in paragraph (b) of this section, not less than 95 percent passes through a No. 20 sieve but not more than 20 percent through a No. 25 sieve.

(b) (1) For the purposes of this section, moisture, fat, and crude fiber are determined by methods therefor referred to in § 15.500 (b) (1).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 10 and No. 25 sieves, having standard 8-inch diameter full-height frame, complying with the specifications for wire cloth and sieve frame in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the Bureau of Standards, United States Department of Commerce. Attach cone to a suction flask. Wash with 150 ml. of petroleum ether applied in a small stream without suction, while gently stirring the sample with a small glass rod. Apply suction for 2 minutes after washing is completed, then shake the cone for 2 minutes with a vigorous horizontal motion, striking the side against the hand, and then weigh. The decrease in weight of sample, calculated as percent by weight of sample shall be considered the mode of residue.

For the purpose of this section, not less than 0.12 percent and more than 0.30 percent of the residue is to be considered as ash, as determined by the ashing method prescribed in § 15.500 (b) (2) for degerminated corn meal, degermed corn meal, self-rising yellow corn meal; or by the ashing method prescribed in § 15.500 (b) (2) for synthetically prepared corn meal; or by the ashing method prescribed in § 15.500 (b) (2) for synthetic corn meal.

§ 15.510 Grits, corn grits, hominy grits; identity. (a) Grits, corn grits, hominy grits, is the food prepared by so grinding and sifting cleaned white corn, with removal of corn bran and germ, that:

(1) On a moisture-free basis its crude fiber content is not more than 1.2 percent and its fat content is not more than 2.25 percent; and

(2) When tested by the method prescribed in paragraph (b) of this section, not less than 95 percent passes through a No. 20 sieve but not more than 20 percent through a No. 25 sieve.

(b) (1) For the purposes of this section, moisture, fat, and crude fiber are determined by methods therefor referred to in § 15.500 (b) (1).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 10 and No. 25 sieves, having standard 8-inch diameter full-height frame, complying with the specifications for wire cloth and sieve frame in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the Bureau of Standards, United States Department of Commerce. Attach cone to a suction flask. Wash with 150 ml. of petroleum ether applied in a small stream without suction, while gently stirring the sample with a small glass rod. Apply suction for 2 minutes after washing is completed, then shake the cone for 2 minutes with a vigorous horizontal motion, striking the side against the hand, and then weigh. The decrease in weight of sample, calculated as percent by weight of sample shall be considered the mode of residue.

For the purpose of this section, not less than 0.12 percent and more than 0.30 percent of the residue is to be considered as ash, as determined by the ashing method prescribed in § 15.500 (b) (2) for degerminated corn meal, degermed corn meal, self-rising yellow corn meal; or by the ashing method prescribed in § 15.500 (b) (2) for synthetically prepared corn meal; or by the ashing method prescribed in § 15.500 (b) (2) for synthetic corn meal.
Section 15.511 Yellow grits, yellow corn grits, yellow hominy grits; identity. Yellow grits, yellow corn grits, yellow hominy grits, conforms to the definition and standard of identity prescribed by § 15.510 for grits except that cleaned yellow corn is used instead of cleaned white corn.

§ 15.512 Quick grits, quick cooking grits; identity. (a) Quick grits, quick cooking grits are the foods, each of which conforms to the definition and standard of identity prescribed for grits by §§ 15.510 or 15.511, except that in process of preparation the grits are lightly steamed and slightly compressed so as to fracture the particles.

(b) The name of each kind of grits is “Quick” or “Quick cooking” followed by the name of the kind of grits used which is prescribed in the definition and standard of identity therefor.

§ 15.513 Enriched corn meals; identity. (a) Enriched corn meals are the foods, each of which conforms to the definition and standard of identity prescribed for a kind of corn meal by §§ 15.550 to 15.557, inclusive, except that:

(1) It contains in each pound not less than 2.0 mg. and not more than 3.0 mg. of thiamine, not less than 1.2 mg. and not more than 1.8 mg. of riboflavin, not less than 16 mg. and not more than 24 mg. of niacin or niacinamide, not less than 13 mg. and not more than 26 mg. of iron (Fe).

(2) It may contain in each pound not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D; and

(3) It may contain in each pound not less than 500 mg. and not more than 750 mg. of calcium (Ca). Iron and calcium may be added only in forms which are harmless and assimilable. The vitamins referred to in paragraph (1) of this subparagraph may be added in harmless substances to render them insoluble in water if the water-insoluble products are assimilable. The substances referred to in this subparagraph and in subparagraphs (1) and (2) of this paragraph may be added in a harmless carrier; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the kind of corn grits used. Dried yeast in quantities not exceeding 1.5 percent by weight of the enriched food may be used. When the finished food is tested by the method prescribed in paragraph (c) of this section it complies with the requirements set forth therein.

(b) The name of each kind of enriched corn grits is the word “Enriched” followed by the name of the kind of corn meal used which is prescribed in the definition and standard of identity therefor.

§ 15.514 Enriched corn grits; identity. (a) Enriched corn grits are the foods, each of which conforms to the definition and standard of identity prescribed for grits, yellow grits, or quick cooking grits by §§ 15.510 to 15.512, inclusive, except that:

(1) It contains in each pound not less than 2.0 mg. and not more than 3.0 mg. of thiamine, not less than 1.2 mg. and not more than 1.8 mg. of riboflavin, not less than 16 mg. and not more than 24 mg. of niacin or niacinamide, not less than 13 mg. and not more than 26 mg. of iron (Fe).

(2) It may contain in each pound not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D; and

(3) It may contain in each pound not less than 500 mg. and not more than 750 mg. of calcium (Ca). Iron and calcium may be added only in forms which are harmless and assimilable. The vitamins referred to in paragraph (1) of this subparagraph may be added in harmless substances to render them insoluble in water if the water-insoluble products are assimilable. The substances referred to in this subparagraph and in subparagraphs (1) and (2) of this paragraph may be added in a harmless carrier; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the kind of corn grits used. Dried yeast in quantities not exceeding 1.5 percent by weight of the enriched food may be used. When the finished food is tested by the method prescribed in paragraph (c) of this section it complies with the requirements set forth therein.

(c) The method referred to in paragraph (b) of this section is “Vacuum Oven Method—Official.”

§ 15.515 Statement of optional ingredients. (a) Macaroni products are the class of foods each of which is prepared by drying formed units of dough made from semolina, durum flour, farina, flour, or any combination of two or more of these, with water and with or without one or more of the optional ingredients specified in subparagraphs (1) to (8), inclusive, of this paragraph:

(1) Egg white, frozen egg white, dried egg white, or any two or all of these, in such quantity that the solids thereof are not less than 0.5 percent and not more than 2.0 percent of the weight of the finished food.

(2) Dicalcium phosphate, in a quantity not less than 0.5 percent and not more than 1.0 percent of the weight of the finished food.

(3) Onions, celery, garlic, bay leaf, or any two or more of these, in a quantity which seasons the food.

(4) Salt, in a quantity which seasons the food.

(5) Gum gluten, in such quantity that the protein content of the finished food is not more than 15 percent by weight.


(b) Macaroni is the macaroni product the units of which are tubular and not more than 0.11 inch but not more than 0.27 inch in diameter.

(c) Spaghetti is the macaroni product the units of which are tube-shaped or cord-shaped (not tubular) and more than 0.06 inch but not more than 0.11 inch in diameter.

(d) Vermicelli is the macaroni product the units of which are cord-shaped (not tubular) and not more than 0.06 inch in diameter.

(e) The name of each food for which a definition and standard of identity is prescribed by this section is “Macaroni... 

Section 16—ALIMENTARY PASTES; DEFINITIONS AND STANDARDS OF IDENTITY

Sec. 16.3 Whole wheat macaroni products; identity; label statement of optional ingredients.

16.4 Wheat and egg macaroni products; identity; label statement of optional ingredients.

16.5 Vegetable macaroni products; identity; label statement of optional ingredients.

16.6 Noodle products; identity; label statement of optional ingredients.

16.7 Wheat and egg noodle products; identity; label statement of optional ingredients.

16.8 Vegetable noodle products; identity; label statement of optional ingredients.

16.9 Enriched macaroni products; identity; label statement of optional ingredients.

16.10 Enriched noodle products; identity; label statement of optional ingredients.

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(b) the (c), or (d) respectively, of this section.

The milk ingredients referred to in paragraph (a) (1) of this section are concentrated milk, evaporated milk, dried milk, and a mixture of butter with skim milk and/or other milk solids in such mixture is not more than 2.275 times the weight of milk fat therein.

§ 16.3 Whole wheat macaroni products; identity; label statement of optional ingredients. (a) Whole wheat macaroni products are the class of food each of which conforms to the definition of identity and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 16.1 (a) and (f) (2) and (3) except that:

(1) Whole wheat flour or whole durum wheat flour or both are used as the sole wheat ingredient; and

(b) Whole wheat macaroni is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 16.1 (b)

(c) Whole wheat spaghetti is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 16.1 (c)

(d) Whole wheat vermicelli is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 16.1 (d)

(e) The name of each food for which a definition and standard of identity is prescribed by this section. "Whole Wheat Macaroni Product", "Whole Wheat Spaghetti", "Whole Wheat Vermicelli", and "Whole Wheat Macaroni Product", respectively, of this section.
shape and size prescribed for macaroni by §16.1 (b).
(c) Vegetable spaghetti is the vegetable macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by §16.1 (c).
(d) Vegetable vermicelli is the vegetable macaroni product, the units of which conform to the specifications of shape and size prescribed for vermicelli by §16.1 (d).
(e) The name of each food for which a definition and standard of identity is prescribed in paragraph (a) of this section is "Macaroni Product," the blank being filled in with the name whereby the vegetable used is designated in paragraph (a) of this section; or alternatively, the name is "Soybean Macaroni," "Soy Spaghetti," or "Soy Vermicelli," as the case may be, when the units of the food comply with the requirements of paragraph (b) (c) or (d), respectively, of this section.
(f) When any ingredient specified in paragraph (a) of this section is used, the label of the noodle product shall bear the statement "Seasoned with ________," the blank being filled in with the common name of the ingredient; or in the case of bay leaves the statement "Spiced," "Spice added," or "Spiced with bay leaves.
(g) Wherever the name of the food appears on such label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the ingredients used shall follow the blank preceded in each instance by or followed by, or in part preceded and in part followed, such name without intervening written, printed, or other graphic matter.
§16.6 Noodle products; identity; label statement of optional ingredients.
(a) Noodle products are the class of food each of which is prepared by drying formed units of dough made from semolina, durum flour, farina, flour, or any combination of two or more of these, with liquid eggs, frozen eggs, dried eggs, egg yolks, frozen yolks, dried yolks, or any combination of two or more of these, with or without water and with or without one or more of the optional ingredients specified in subparagraphs (1) to (3) inclusive:
(1) Onions, celery, garlic, bay leaf, or any two or more of these, in a quantity which seasons the food.
(2) Salt, in a quantity which seasons the food.
(3) Gum gluten, in such quantity that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour or any combination of these, used does not exceed 13 percent of the weight of the finished food.

(b) Noodles, egg noodles, is the noodle product the units of which are ribbon-shaped.
(c) Egg macaroni is the noodle product the units of which are tube-shaped and more than 0.11 inch but not more than 0.27 inch in diameter.
(d) Egg spaghetti is the noodle product the units of which are tube-shaped or cord-shaped (not tubular) and more than 0.12 inch but not more than 0.11 inch in diameter.
(e) Egg vermicelli is the noodle product the units of which are cord-shaped (not tubular) and not more than 0.06 inch in diameter.
(f) The name of each food for which a definition and standard of identity is prescribed by this section is "Noodle Product," "Noodles," or "Egg Noodles," "Egg Macaroni," "Egg Spaghetti," or "Egg Vermicelli," as the case may be, when the units of the food are of the shapes and sizes specified in paragraph (b) (c) (d), or (e), respectively, of this section.
(g) When any ingredient specified in paragraph (a) of this section is used, the label of the noodle product shall bear the statement "Seasoned with ________," the blank being filled in with the common name of the ingredient; or in the case of bay leaves the statement "Spiced," "Spice added," or "Spiced with bay leaves.
(h) Wherever the name of the food appears on such label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the ingredients used shall follow the blank preceded in each instance by or followed by, or in part preceded and in part followed, such name without intervening written, printed, or other graphic matter.

§16.7 Wheat and soy noodle products; identity; label statement of optional ingredients.
(a) Wheat and soy noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for noodle products by §16.6 (a) and (g), except that soy flour is added in a quantity not less than 12.5 percent of the combined weight of the wheat and soy ingredients used (the soy flour used is made from heat-processed, dehulled soybeans, with or without the removal of fat therefrom).
(b) Wheat and soy noodles, wheat and soy egg noodles, is the wheat and soy noodle product the units of which are ribbon-shaped.
(c) Wheat and soy macaroni is the wheat noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni by §16.6 (c).
(d) Wheat and soy spaghetti is the wheat noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti by §16.6 (d).
(e) Wheat and soy vermicelli is the wheat noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli by §16.6 (e).
(f) The name of each food for which a definition and standard of identity is prescribed by this section is "Wheat and Soy Noodle Product," "Wheat and Soy Noodles," "Wheat and Soy Egg Noodle Product," "Wheat and Soybean Macaroni," "Wheat and Soybean Egg Noodle Product," "Wheat and Soy Noodle Product," "Wheat and Soy Egg Noodle Product," "Wheat and Soybean Noodle Product," or "Wheat and Soybean Egg Noodle Product," as the case may be, when the units of the food comply with the requirements of paragraph (b) (c) (d), or (e), respectively, of this section.
(g) When any ingredient specified in paragraph (a) of this section is used, the label of the noodle product shall bear the statement "Seasoned with ________," the blank being filled in with the common name of the ingredient; or in the case of bay leaves the statement "Spiced," "Spice added," or "Spiced with bay leaves.
(h) Wherever the name of the food appears on such label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the ingredients used shall follow the blank preceded in each instance by or followed by, or in part preceded and in part followed, such name without intervening written, printed, or other graphic matter.

§16.8 Vegetable noodle products; identity; label statement of optional ingredients.
(a) Vegetable noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for noodle products by §16.6 (a) and (g), except that tomato (or any red variety), artichoke, beet, carrot, parsley, or spinach is added in such quantity as to be seen under customary conditions of purchase.
(b) Vegetable noodles, vegetable egg noodles, is the vegetable noodle product the units of which are ribbon-shaped.
(c) Vegetable egg macaroni is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni by §16.6 (c).
(d) Vegetable egg spaghetti is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti by §16.6 (d).
(e) Vegetable egg vermicelli is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli by §16.6 (e).
(f) The name of each food for which a definition and standard of identity is prescribed by this section is "Vegetable Noodle Product," "Vegetable Noodles," or "Vegetable Egg Noodle Product," as the case may be, when the units of the food comply with the requirements of paragraph (b) (c) (d), or (e), respectively, of this section.
(g) When any ingredient specified in paragraph (a) of this section is used, the label of the noodle product shall bear the statement "Seasoned with ________," the blank being filled in with the common name of the ingredient; or in the case of bay leaves the statement "Spiced," "Spice added," or "Spiced with bay leaves.
(h) Wherever the name of the food appears on such label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the ingredients used shall follow the blank preceded in each instance by or followed by, or in part preceded and in part followed, such name without intervening written, printed, or other graphic matter.
§ 16.9 Enriched macaroni products; identity; label statement of optional ingredients. (a) Enriched macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 16.1, except that:

1. Each such food contains in each pound not less than 8 mg. of thiamine, not less than 1.7 mg. and not more than 2.2 mg. of riboflavin, not less than 27 mg. and not more than 34 mg. of niacin or niacinamide, and not less than 13 mg. and not more than 16.5 mg. of iron (Fe).

2. Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 250 U. S. P. units and not more than 1000 U. S. P. units of vitamin D.

3. Each such food may also contain as an optional ingredient added calcium in such quantity that each pound of the finished food contains not less than 500 mg. and not more than 625 mg. of calcium (Ca).

4. Each such food may also contain as an optional ingredient partially defatted wheat germ but the amount thereof does not exceed 5 percent of the weight of the finished food.

5. Each such food may be supplied, wholly or in part, with the prescribed quantity of any substance referred to in subparagraphs (1) (2) and (3) of this paragraph through the use of dried yeast, partially defatted wheat germ, enriched farina or enriched flour, or through the direct additions of any of the substances prescribed in subparagraphs (1), (2) and (3).

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in subparagraphs (1) and (2) of this paragraph may be added in a harmless carrier which does not impair the enriched macaroni product, but is not used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished enriched macaroni product.

(b) Enriched macaroni is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 16.1 (a).

(c) Enriched spaghetti is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 16.1 (c).

(d) Enriched vermicelli is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 16.1 (d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Enriched Macaroni," alternatively, the name is "Enriched Macaroni Product."
the combination of such preparation and the shortening. For the purposes of this section the lecithin may include related phosphatides derived from the corn or soybean meal from which the lecithin was obtained.

(2) Milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed partly skimmed milk, sweetened condensed skim milk, nonfat dry milk solids, or any combination of two or more of these; but the total quantity thereof is not more than 2 parts for each 100 parts by weight of flour used.

(3) Malt flour, malted barley flour, malted wheat flour, malted rice flour, malt extract, whole or in part defatted wheat germ, or partly defatted wheat germ; the term "enriched flour" as used in this section, the term "flour," and any quantity added, is not more than 0.25 part for each 100 parts by weight of flour used.

(12) Potassium bromate, potassium iodate, calcium peroxide, or any combination of two or more of these; but the total quantity thereof (including the quantity of such preparation in any phosphated flour used) is not more than 0.0075 part for each 100 parts by weight of flour used.

(13) (1) Monocalcium phosphate, but the total quantity thereof, including the quantity in any phosphated flour used and any quantity added, is not more than 0.75 part by weight for each 100 parts by weight of flour used.

(ii) A vinegar, in a quantity equivalent in acid strength to not more than 1 pint of 100-grain distilled vinegar for each 100 pounds of flour used; or

(iii) Calcium propionate, sodium propionate, or any mixture of these, but the total quantity thereof is not more than 0.32 part for each 100 parts by weight of flour used.

(iv) Sodium diacetate, but the quantity thereof is not more than 0.4 part for each 100 parts by weight of flour used; or

(v) Lactic acid, in such quantity that the pH of the finished bread is not less than 4.5.

(14) Spices, with which may be included spice oil and spice extract.

Each of such foods contains not less than 65 percent of total solids, as determined by the method prescribed by the Official Methods of Analysis of the Association of Official Agricultural Chemists; the seventh edition, 1955, page 209, section 13.70, under "Total Solids in Enriched Bread." (Ed. note. Ed. 6th ed., 1955, p. 222, sec. 13.72.) except that if the baked unit weighs 1 pound or more one entire unit is used for the determination, and if the baked unit weighs less than 1 pound, such number of entire units as weigh 1 pound or more is used for the determination.

(b) Bread, white bread is baked in units each of which weighs one-half pound or more after cooling. Rolls, white rolls, and buns, white buns are baked in units each of which weighs less than one-half pound after cooling.

(c) When any optional ingredient permitted by paragraph (a) (2) of this section is used, except a vinegar and except monocalcium phosphate, in a quantity less than 0.25 part for each 100 parts by weight of flour, the label shall bear the statement "**added to retard spoilage,**" the blank being filled in with the name by which the ingredient used is designated in such paragraph.

(d) When an optional ingredient permitted by paragraph (a) (10) of this section is used, the label shall bear the statement "**spice**" or "**spice added**" or "**spice is included**" or "**it contains spice**" or "**spice in the bread**" or "**spice is used in the manufacture of this bread**" in such language and in such size and form that the same shall be easily read and understood by the consumer.

(e) Wherever the name of the food appears on a label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements specified in this paragraph shall immediately and conspicuously precede or follow such name, and shall appear in type, characters, figures, or symbols of the same type, size, and form, and shall be of the same weight or density for each or every description or representation of food and shall be of the same general character, whether written, printed, or graphically matter.

§ 17.2 Enriched bread and enriched rolls or enriched buns; identity; label statement of optional ingredients. (a) Each of the foods milk bread, milk rolls, milk buns, white bread, white rolls, and white buns, as defined in such paragraph, is subject to the requirements for label statement of optional ingredients, prescribed for bread by § 17.1 (a) and (c), except that:

(1) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 150 United States Pharmacopeia units and not more than 750 United States Pharmacopeia units of vitamin D.

(2) Each such food may also contain as an optional ingredient added harmless calcium salts in such quantity that each pound of the finished food contains not less than 200 milligrams and not more than 800 milligrams of calcium (Ca).

(3) Each such food may also contain as an optional ingredient added harmless phosphates in such quantity that each pound of the finished food contains not less than 200 milligrams and not more than 800 milligrams of phosphorus (P).

(4) Each such food may also contain as an optional ingredient added harmless chlorine (Cl) in such quantity that each pound of the finished food contains not less than 200 milligrams and not more than 800 milligrams of chlorine (Cl).

(5) Enriched flour may be used, in whole or in part, instead of flour.

(6) The limitation prescribed by § 17.1 (a) (2) on the quantity and composition of milk and dairy ingredients does not apply.

As used in this section, the term "flour," unless otherwise defined, includes unenriched flour and unphosphated flour; the term "enriched flour" includes enriched bromated flour. The prescribed quantity of any substance referred to in subparagraphs (1), (2), (3), and (4) of this section may be supplied, or any amount less than the prescribed quantity of enriched flour; through the direct addition of such substance under the conditions permitted by § 15.10 of this chapter and as part of the ingredients in the preparation of enriched flour; through the use of any ingredient containing such substance, which ingredient is required or permitted by § 15.1 (a) (2) within the limits, if any, prescribed by such section, as modified by subparagraph (6) of this paragraph; through the use of wheat germ; or through any two or more of such methods.

(b) Enriched bread is baked in units each of which weighs one-half pound or more after cooling. Enriched rolls or enriched buns are baked in units each of which weighs less than one-half pound after cooling.

§ 17.3 Milk bread and milk rolls or milk buns; identity; label statement of optional ingredients. (a) Each of the foods milk bread, milk rolls, milk rolls, milk buns, as defined in such paragraph, is subject to the requirements for label statement of optional ingredients, prescribed for bread by § 17.1 (a) and (c), except that:

(1) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 150 United States Pharmacopeia units and not more than 750 United States Pharmacopeia units of vitamin D.

(2) Each such food may also contain as an optional ingredient added harmless calcium salts in such quantity that each pound of the finished food contains not less than 200 milligrams and not more than 800 milligrams of calcium (Ca).

(3) Each such food may also contain as an optional ingredient added harmless phosphates in such quantity that each pound of the finished food contains not less than 200 milligrams and not more than 800 milligrams of phosphorus (P).

(4) Each such food may also contain as an optional ingredient added harmless chlorine (Cl) in such quantity that each pound of the finished food contains not less than 200 milligrams and not more than 800 milligrams of chlorine (Cl).

(5) Enriched flour may be used, in whole or in part, instead of flour.

(6) The limitation prescribed by § 17.1 (a) (2) on the quantity and composition of milk and dairy ingredients does not apply.

As used in this section, the term "flour," unless otherwise defined, includes unenriched flour and unphosphated flour; the term "enriched flour" includes enriched bromated flour. The prescribed quantity of any substance referred to in subparagraphs (1), (2), (3), and (4) of this section may be supplied, or any amount less than the prescribed quantity of enriched flour; through the direct addition of such substance under the conditions permitted by § 15.10 of this chapter and as part of the ingredients in the preparation of enriched flour; through the use of any ingredient containing such substance, which ingredient is required or permitted by § 15.1 (a) (2) within the limits, if any, prescribed by such section, as modified by subparagraph (6) of this paragraph; through the use of wheat germ; or through any two or more of such methods.

(b) Enriched bread is baked in units each of which weighs one-half pound or more after cooling. Enriched rolls or enriched buns are baked in units each of which weighs less than one-half pound after cooling.

§ 17.5 Milk bread and milk rolls or milk buns; identity; label statement of optional ingredients. (a) Each of the foods milk bread, milk rolls, milk buns, as defined in such paragraph, is subject to the requirements for label statement of optional ingredients, prescribed for bread by § 17.1 (a) and (c), except that:

(1) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 150 United States Pharmacopeia units and not more than 750 United States Pharmacopeia units of vitamin D.

(2) Each such food may also contain as an optional ingredient added harmless calcium salts in such quantity that each pound of the finished food contains not less than 200 milligrams and not more than 800 milligrams of calcium (Ca).

(3) Each such food may also contain as an optional ingredient added harmless phosphates in such quantity that each pound of the finished food contains not less than 200 milligrams and not more than 800 milligrams of phosphorus (P).

(4) Each such food may also contain as an optional ingredient added harmless chlorine (Cl) in such quantity that each pound of the finished food contains not less than 200 milligrams and not more than 800 milligrams of chlorine (Cl).

(5) Enriched flour may be used, in whole or in part, instead of flour.

(6) The limitation prescribed by § 17.1 (a) (2) on the quantity and composition of milk and dairy ingredients does not apply.
ingredients, prescribed for bread and rolls by § 17.1 (a) and (c), except that:

(1) Milk is used as the sole moistening ingredient in preparing the dough; or in lieu of milk one or more of the dairy ingre-dients prescribed for bread and rolls by § 17.1 (a) and (c) are used, with or without water, in a quantity containing not less than 8.2 parts by weight of milk solids for each 100 parts of flour used (including any bromated flour or phosphated flour used)

(2) No ingredient permitted by § 17.1 (a) (3) is used.

(b) Milk rolls or milk buns are baked in units each of which weighs less than one-half pound after cooling.

The dough is made with whole wheat bread, whole wheat rolls, graham rolls, entire wheat rolls, or whole wheat buns, graham buns, or whole wheat buns with skim milk, and may contain milk, milk solids, or parts of same, or more of these ingredients in such proportion that the weight of non-fat milk solids in such mixture is not more than 2.3 times and not less than 1.2 times the weight of the milk fat therein.

§ 17.4 Raisin bread and raisin rolls or raisin buns; identity; label statement of optional ingredients. (a) Each of the foods raisin bread, raisin rolls, raisin buns conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for bread and rolls or buns by § 17.1 (a) and (c) except that:

(1) Not less than 50 parts by weight of seed or seeder raisins are used for each 100 parts by weight of flour used (including any bromated flour or phosphated flour used)

(2) Water extract of raisins may be used, but not to replace raisins.

(3) The baked units may bear 100% or refrigeration.

(4) The limitation prescribed by § 17.1 (a) (2) on the quantity and composition of dairy ingredients does not apply. (b) In determining its total solids, instead of following the direction "Grand sample 20 mesh sieve" (Official Methods of Analysis of the Association of Official Agricultural Chemists, Seventh Edition, 1950, page 209, section 13.70 [Ed. Note, 8th Ed., 1955, p. 222, sec. 13.72], under "Total Solids in an Entire Loaf of Bread") comminate the sample by passing it twice through a food chopper.

(5) Raisin bread is baked in units each of which weighs one-half pound or more after cooling. Raisin rolls or raisin buns are baked in units each of which weighs less than one-half pound after cooling.

§ 17.5 Whole wheat bread, graham bread, entire wheat bread, and whole wheat rolls, graham rolls, entire wheat rolls, or whole wheat buns, graham buns, entire wheat buns with skim milk, are baked in units each of which weighs less than one-half pound after cooling.

§ 17.6 Milk is used as the sole moistening ingredient in preparing the dough; or in lieu of milk one or more of the dairy ingredients prescribed for bread and rolls by § 17.1 (a) and (c) are used, with or without water, in a quantity containing not less than 8.2 parts by weight of milk solids for each 100 parts of flour used (including any bromated flour or phosphated flour used)

(2) No ingredient permitted by § 17.1 (a) (3) is used.

(b) Milk rolls or milk buns are baked in units each of which weighs less than one-half pound after cooling.

As used in this section, the term "flour," unqualified, includes flour, enriched flour, bromated flour, enriched bromated flour, and phosphated flour; the term "whole wheat flour" includes whole wheat flour and bromated whole wheat flour. As used in this section, any bromated whole wheat flour used shall be deemed to be an optional ingredient in the whole wheat bread or whole wheat rolls.

(b) Whole wheat bread, graham bread, or entire wheat bread is baked in units each of which weighs one-half pound or more after cooling. Whole wheat rolls, graham rolls, entire wheat rolls, or whole wheat buns, graham buns, entire wheat buns are baked in units each of which weighs less than one-half pound after cooling.

PART 18—MILK AND CREAM; DEFINITIONS AND STANDARDS OF IDENTITIES

§ 18.500 Cream class of food; identity.

§ 18.501 Light cream, coffee cream, table cream; identity.

§ 18.510 Whipping cream class of food; identity.

§ 18.511 Light whipping cream; identity.

§ 18.515 Heavy cream, heavy whipping cream; identity.

§ 18.520 Evaporated milk; identity; label statement of optional ingredients.

(a) Evaporated milk is the liquid food made by evaporating sweet milk to such point that it contains not less than 7.0 percent of milk fat and not less than 25.9 percent of total milk solids. It may contain one or both of the following optional ingredients:

(1) Disodium phosphate or sodium citrate or both, or calcium chloride, added in a total quantity of not more than 0.1 percent of weight of the finished evaporated milk.

(2) Vitamin D in such quantity as to increase the total vitamin D content to not less than 25 U. S. F. units per fluid ounce of the finished evaporated milk. It may be homogenized. It is sealed in a container and so processed by heat as to prevent spoilage.

(b) When the optional ingredient specified in paragraph (a) (2) of this section is present, the label shall bear the statement "with increased vitamin D content" or "vitamin D content increased." Such statement shall immediately and conspicuously precede or follow the name "Evaporated Milk" without intervening written, printed, or graphic matter, wherever such name appears on the label so conspicuously as to be easily seen under customary conditions of purchase.

§ 18.525 Concentrated milk; identity; label statement of optional ingredients.

§ 18.530 Sweetened condensed milk; identity.

§ 18.535 Condensed milk, in which contains corn syrup; identity.

§ 18.540 Dried skim milk, powdered skim milk, skim milk powder; identity.

PART 19—CREAM; DEFINITIONS AND STANDARDS OF IDENTITIES

§ 19.500 Cream class of food; identity.

§ 19.501 Light cream, coffee cream, table cream; identity.

§ 19.510 Whipping cream class of food; identity.

§ 19.511 Light whipping cream; identity.

§ 19.515 Heavy cream, heavy whipping cream; identity.

§ 19.520 Evaporated milk; identity; label statement of optional ingredients.

(a) Evaporated milk is the liquid food made by evaporating sweet milk to such point that it contains not less than 7.0 percent of milk fat and not less than 25.9 percent of total milk solids. It may contain one or both of the following optional ingredients:

(1) Disodium phosphate or sodium citrate or both, or calcium chloride, added in a total quantity of not more than 0.1 percent of weight of the finished evaporated milk.

(2) Vitamin D in such quantity as to increase the total vitamin D content to not less than 25 U. S. F. units per fluid ounce of the finished evaporated milk. It may be homogenized. It is sealed in a container and so processed by heat as to prevent spoilage.

(b) When the optional ingredient specified in paragraph (a) (2) of this section is present, the label shall bear the statement "with increased vitamin D content" or "vitamin D content increased." Such statement shall immediately and conspicuously precede or follow the name "Evaporated Milk" without intervening written, printed, or graphic matter, wherever such name appears on the label so conspicuously as to be easily seen under customary conditions of purchase.

§ 18.510 Whipping cream class of food; identity. Whipping cream is the class of food which conforms to the definition and standard of identity prescribed for the cream class of food by § 18.500, except that it contains not less than 30 percent of milk fat, as determined by the method referred to in such section.

§ 18.511 Light whipping cream, identity. Light whipping cream conforms to the definition and standard of identity prescribed for the whipping cream class of food by § 18.500, except that it contains not less than 30 percent of milk fat, as determined by the method referred to in such section.

§ 18.515 Heavy cream, heavy whipping cream; identity. Heavy cream, heavy whipping cream, conforms to the definition and standard of identity prescribed for the whipping cream class of food by § 18.500, except that it contains not less than 40 percent of milk fat, as determined by the method referred to in such section.

§ 18.525 Concentrated milk; identity; label statement of optional ingredients.

(a) Concentrated milk is the liquid food made by evaporating milk to such point that it contains not less than 85 percent of milk solids and not less than 13.5 percent of milk fat and that it contains not less than 30 percent of milk fat, as determined by the method referred to in such section.

(4) Vitamin D content may be increased by the application of radiant energy or by the addition of a concentrate of vitamin D (with any accompanying vitamin A when such vitamin D in such concentrate is obtained from natural sources) dissolved in a food oil; but if such oil is not milk fat the quantity thereof added is not more than 0.01 percent of the weight of the finished evaporated milk.


§ 18.525 Concentrated milk, plain condensed milk; identity; label statement of optional ingredients. Concentrated milk, or official condensed milk, conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for evaporated milk by § 18.520, except that:

(a) It is not processed by heat;

(b) Its container may be unsealed; and

(c) Optional ingredient § 18.520 (a) (1) is not used.

§ 18.530 Sweetened condensed milk; identity. (a) Sweetened condensed milk is the liquid or semi-liquid food made by evaporating a mixture of sweet milk and refined sugar (sucrose) or any combination of refined sugar (sucrose) and refined corn sugar (dextrose) to such point that the finished sweetened condensed milk contains not less than 28.0 percent of total milk solids and not less than 6.6 percent of milk fat. The quantity of refined sugar (sucrose) or combination of such sugar and refined corn sugar (dextrose) used is sufficient to prevent spoilage.

(b) For the purpose of this section:

(1) The word "milk" means cow's milk;

(2) Such milk may be adjusted, before or after evaporation, by the addition of an abstraction of cream or sweet skim milk, or the addition of concentrated sweet skim milk;


§ 18.535 Condensed milks which contain corn syrup; identity. (a) Condensed milks which contain corn syrup are the foods each of which conforms to the definition and standard of identity prescribed for sweetened condensed milk by § 18.530 except that corn syrup or a mixture of corn syrup and sugar is used instead of sugar or a mixture of sugar and dextrose. For the purpose of this section the term "corn syrup" means a clarified and concentrated aqueous solution of the products obtained by the hydrolysis of cornstarch, and includes dried corn syrup; the solids of such corn syrup contain not less than 40 percent by weight of reducing sugars, calculated as glucose.

(b) The name of each such food is:

(1) "Corn syrup condensed milk;" "condensed milk with corn syrup;" or "condensed milk with sweetened corn syrup," if corn syrup alone is used; or

(2) "—% corn syrup solids —% sugar condensed milk;" "condensed milk with —% corn syrup solids —% sugar;" or "condensed milk with —% corn syrup solids —% sugar," if a mixture of corn syrup and sugar is used, the-blanks being filled in with the whole numbers nearest the actual percentages of corn syrup solids and sugar in such food; alternately "—% sugar" may precede "—% corn syrup solids" in such names.

§ 18.540 Dried skim milk, powdered skim milk, skim milk; identity. Dried skim milk, powdered skim milk, skim milk powder, is the food made by drying sweet skim milk. It contains not more than 5 percent of moisture, as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935, page 265, (Ed. note, 8th edition, 1955, p. 265, sec. 15.801, under the caption "Moisture—Tentative."). The term "skim milk" as used in this section, means cow's milk from which the milk fat has been separated.

Note: 58 Stat. 108, 21 U. S. C. 202c, provides a statutory definition for this food under the name; "Non-fat dry milk solids" and "dried milk solids."
Harmless lactic-acid-producing bacteria, than the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It shall contain not more than 39 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed as follows of this section. If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less time than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk; is added to set the milk to a semisolid mass. The mass of the milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.25 gm. calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass so set, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is massed into a cheese mass. The mass is cut into slabs, which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, which may be rinsed by sprinkling or pouring water over them, with free and continued stirring, as to promote and regulate the drainage; but the duration of such rinsing is so limited that only the whey on the surface of such pieces is removed. The curd is cut into smaller pieces, drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of fat in milk used in the preparation.

(c) Determine moisture by the method prescribed on page 262 (15.124) (Ed. note, 8th edition, 1955, p. 278, sec. 15.125), under “Moisture—Official,” and milk fat by the method prescribed on page 263 (15.131) (Ed. note, 8th edition, 1955, p. 279, sec. 15.136), under “Fat—Official,” of “Official Methods of Analysis of the Association of Official Analytical Chemists,” Seventh Edition, 1950. Subtract the percent of moisture found from 100; divide the remainder into the percent milk fat found. The quotient, multiplied by 100, shall be considered to be the percent of milk fat contained in the solids.

(2) For the purposes of this section:
(a) The word “ancient” means cow’s milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, water, nonfat milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.
(b) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent to 10°C for not more than 0.02 percent, calculated as anhydrous calcium chloride of the weight of the milk.

(c) The method referred to in paragraph (d) of this section is as follows:

1. Reagents—(a) Buffers—(Barium borate-hydroxide buffer) Dissolve 25.0 gm. of barium hydroxide (Ba(OH)2) in 100 ml. of 6.0-0.1 pH buffer (control blank). To the filtrate tightly add 10.0 gm. of sodium metaborate (NaBO2) and 20 ml. of 0.05 percent copper sulfate solution 5.0-10.0 units. To increase the brightness of the blue color and improve the stability of the standards, dilute 5.0-10.0 units of the blank to a liter with water to prepare standard solutions containing 0.5, 1.0, 3.0, and 5.0 units of phenol per milliliter, respectively. Keep standard solutions in the refrigerator.

In a similar manner, prepare for the stock solution such more concentrated standard solutions as may be needed, containing, for example, 20, 30, and 40 units per milliliter.

Prepare appropriate quantities of the phenol standard solution into a series of tubes (preferably graduated at 0.1 ml.) to provide a suitable range of standards as needed, containing 0 (control blank), 0.5, 1.0, 3.0, 5.0, 10.0, and 20.0 units. To increase the brightness of the blue color and improve the stability of the standards, dilute 5.0-10.0 units of the blank to a liter with water to prepare standard solutions containing 0.5, 1.0, 3.0, and 5.0 units of phenol per milliliter, respectively. Keep standard solutions in the refrigerator.

2. Buffers—(b) Color-development buffer—Dissolve 6.0 gm. of sodium metaborate (NaBO2) and 20 ml. of 0.05 percent copper sulfate solution in 100 ml. of water to a liter with water (pH 9.0). Warm each to 25°C, dissolve 25.0 gm. of copper sulfate in water and dilute to 50 ml. Warm each to 25°C, dissolve 0.20 gm. of zinc sulfate in 50 ml. of water and dilute to 100 ml. Add 4 drops (0.08 ml.) of BQO 4, mix, and allow to develop for 30 minutes at room temperature. If the butyl alcohol extraction method is to be used in the test, extract the standards as described under III Conducting the Test. Read the color intensities with a photometer, subtract the value of the blank from the value of each phenol standard, and prepare a standard curve (straight line). When the standards are to be used for visual comparisons they should be stored in a refrigerator.

III. Sampling
1. Hard cheese take a sample from the interior with a clean knife or spatula, to a depth of 4 inch. Clean the instrument and put it in the refrigerator, if not kept at 4°C. If a knife is to be used on the surface, use either of the following methods for sampling:

a. Cut a portion from the end of the loaf or from the side of the cheese, extending in an adequate 5 inches if possible, or to a point somewhat beyond the center in the case of a small cheese. Cut a slice ½ to ⅜ inch deep at half-way around from the edge, midway between the top and bottom. Break the portion into two parts, pulling it apart so that it breaks on a straight line. Be careful not to contaminate the freshly exposed, broken surface. Remove the sample from the freshly exposed surface at or near the center of the cheese.

b. Remove the area of the surface to be sampled—e.g., the end and the adjacentsides—with a clean tractor or other utensil to a depth of ⅜ inch. Clean the instrument and hands with hot water and phenol-free soap and wipe them dry. Transfer the freshly exposed surface to a similar or greater depth and repeat the cleaning. Then take the sample from the center of the freshly ex-
nearly a minute, heating to this point, cut a piece of the test in a similar manner. Proceed in a similar manner.

3. Add to the blank 1.0 ml of the appropriate barium buffer substrate 2-a or 2-b, and macerate again with the rod. Macerate the blank and the test with a glass rod about 8 x 16 mm.

4. Add to the blank 1.0 ml of the appropriate barium buffer substrate 2-a or 2-b (total, 10.0 ml), and mix. The rod may be left in the tube during incubation; or, if removed at this point, cut a piece of filter paper approximately 1 x 1 inch, wrap and hold it tightly at the rod until the rod mixture has withdrawn from within the tube so as to wipe the rod clean, insert the paper with the adhering fat into the tube, and stopper the tube.

5. Incubate in a water bath at 37°-38° C. (99°-100° F.) for 1 hour, mixing or shaking the contents occasionally.

6. Place in a beaker of boiling water for nearly a minute, heating to 65° C. (150° F.), and cool to room temperature.

7. Pipet in 1.0 ml of the zinc precipitant 3-b for ripened cheese or the zinc-copper precipitant 4-b for unripened cheese, and hold it at room temperature.

8. Filter (5-cm. funnel, 9-cm. Whatman No. 2) the contents, collecting 5.0 ml in a tube, preferably graduated at 5.0 and 10.0 ml.

9. Add 5.0 ml of color-development buffer 1-b (total, 10.0 ml), and mix.

10. Add drops of 0.02 M color, and allow the color to develop for 30 minutes at room temperature.

11. Determine the amount of blue color by either of two methods:

a. With a photometer. Read the color intensity of the blank and that of the test, subtract the reading of the blank from that of the test, and convert the result into phenol equivalents, with reference to the standard curve described under "Phenol standards." The butyl alcohol extraction method is ordinarily unnecessary when using a photometer.

b. With visual standards. For quantitative results in borderline instances, color standards, yielding 0.5 to 5 units of color, with butyl alcohol 5-b. Add 5.0 ml of the alcohol and invert the tube slowly several times. Centrifuge if necessary to equilibrate and to increase the clarity of the alcohol layer. Compare the blue color with the colors of standards in the alcohol.

With samples yielding more than 5 units, compute color in aqueous tests with those of aqueous standards.

V. Precautions. The length of time that the crystalline diazoic phanlphosphate and the BQO powder will remain available may be increased greatly by keeping them in a freezing chamber of a refrigerator, and by keeping them dry.

The glassware, stoppers, and sampling tools should be scrupulously clean, and it is decided to check them in hot, running water after cleaning.

The cold barium hydroxyde and the barium buffer must be kept stopped tightly to prevent absorption of carbon dioxide. Phenol contamination from plastic closures on reagent bottles has been encountered, and therefore the use of plastic closures should be avoided. Rubber stoppers should not be used in tests in which butyl alcohol is stored. Glass or cork stoppers should be used.

VI. Modifications for different cheeses. Different blanks of cheese and cheeses of different ages have different buffering capacities, and therefore some of them require modification of conditions of the reagents. The modifications of the barium buffer needed to produce optimal pH conditions for incubation (8.5-10.35), or of the photographic results do not very materially affect the results. For example, pH values as low as 9.6 or as high as 10.35 in the presence of phenol buffered have been found to result in an average decrease of not more than 10 percent below the maximum in the quantity of phenol liberated. The use of the 27-11 buffer substrate with samples for the 27-11 buffer substrate is specified yields pH values not lower than 9.5.

In testing cheeses of unknown history or age, information as to the percentage of cell-free material, especially that which is not readily fermented, is useful as an indication of the correct buffer to use; cheeses with a relatively high percentage of nonfat solids generally require the use of a relatively concentrated buffer to adjust the pH of the mixture correctly. For precise quantitative results on unknown histories, adjust the pH to 10.0-10.55 for the incubation.

Cottage cheese curd is heated in the presence of considerable cold during manufacture, and therefore for phosphate values use a slightly lower temperature. After determining the sensitivity of the test on cottage cheese, apply the following modifications: Use a 1.0-gram sample, 27-11 buffer substrate, 2-hour incubation, and 0.01-sulfuric acid.
The original text starts with: "The milk used is not pasteurized, the cheese so made is cured..." and continues with various entries for different types of cheese, their manufacturing processes, and storage times. Here's a transcription of the key parts:

### Table I: Phosphatase Test Modifications for Different Kinds of Cheese and Cheese of Different Ages—Continued

<table>
<thead>
<tr>
<th>Kind of cheese</th>
<th>Age or extent of curing; other details</th>
<th>Buffer of optimal pH (6.5-10.0)</th>
<th>Precipitant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Edam, gouda</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Blue mold, blue</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Camembert, linburger</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Monterey</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>High-moisture jack</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Provolone, para filata</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Parmesan, reggiano, monter, modena, romano, aslago old</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Asiago fresh</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Asiago medium</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Gorgonzola</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Colby cheese, koch kasee</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Cream cheese</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Semisoft cheese</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Soft ripened cheese</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Noblest, kumstant, sage cheese</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Pasteurized process, pasteurized process pimento, pasteurized process with fruits, meats, etc.</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Pasteurized process cheese foods; pasteurized process cheese foods with fruits, meats, etc.</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Pasteurized process cheese spreads; pasteurized process cheese spreads with fruits, meats, etc.</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
<tr>
<td><strong>Cold-pack, cold-pack cheese foods; cold-pack cheese foods with fruits, meats, etc.</strong></td>
<td>1 week, 2, 4, 8 months</td>
<td>6-0-1</td>
<td>25-11</td>
</tr>
</tbody>
</table>

*8 parts of 25-11 buffer plus 2 parts of water.*

§ 19.502 Cheddar cheese for manufacturing; identity. Cheddar cheese for manufacturing conforms to the definition and standard of identity prescribed for cheddar cheese by § 19.500, except that the milk is not pasteurized, and curing is not required.

§ 19.503 Washed curd cheese, soaked curd cheese; identity. (a) Washed curd cheese, soaked curd cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 40 percent of milk fat, as determined by the methods prescribed in § 19.500 (c) if the milk used is not pasteurized, and cured at a temperature of not less than 35°F for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride) in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to the milk in the quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145°F for a period of not less than 30 minutes or for a time and at a temperature equivalent thereto in phosphatase destruction.

Washed curd cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 minutes to be treated by the method prescribed in § 19.500 (e).

§ 19.504 Washed curd cheese for manufacturing; identity. Washed curd cheese for manufacturing conforms to the definition and standard of identity prescribed for washed curd cheese by § 19.505, except that the milk is not pasteurized, and curing is not required.

§ 19.510 Colby cheese; identity. (a) Colby cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 50 percent of milk fat, as determined by the methods prescribed in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 50 percent of milk fat, as determined by the methods prescribed in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride) in a quantity not more than 0.05 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to the milk in the quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

Washed curd cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 minutes to be treated by the method prescribed in § 19.500 (e).

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145°F for a period of not less than 30 minutes or for a time and at a temperature equivalent thereto in phosphatase destruction.

Washed curd cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 minutes to be treated by the method prescribed in § 19.500 (e).
any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145°F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Colby cheese shall be deemed not to have been made from pasteurized milk if 0.05 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500(e).

§ 19.512 Colby cheese for manufacture; identity. Colby cheese for manufacturing the dairy ingredients and standard of identity prescribed for colby cheese by § 19.510, except that the milk is not pasteurized, and curds are not required.

§ 19.515 Cream cheese; identity; label statement of optional ingredients. (a) Cream cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished cream cheese contains not less than 35 percent of fat and not more than 55 percent of moisture, as determined, respectively, by the methods prescribed under "Fat--Official" on page 302 and under "Moisture--Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940. (These methods appear in the Eighth Edition, 1955, at pages 279 and 278.)

(b) (1) Cream or a mixture of cream with one or more of the dairy ingredients specified in subparagraph (3) of this paragraph, or with or without rennet, are added, and it is held until it becomes coagulated. The coagulated mass may be warmed; it may be stirred; it is then drained. The curd may be pressed, chilled, worked, seasoned with salt; it may be heated with or without rennet, and it may be homogenized or otherwise processed.

(2) In the preparation of cream cheese any one or any mixture of two or more of the optional ingredients gum karaya, gum tragacanth, carob bean gum, gelatin, or alggin may be used; but the quantity of any such ingredient or mixture is such that the total weight of the solids contained therein is not more than 0.5 percent of the weight of the finished cream cheese.

(3) The dairy ingredients referred to in subparagraph (1) of this paragraph are milk, skim milk, concentrated milk, concentrated skim milk, and nonfat dry milk solids. If concentrated milk, concentrated skim milk, or nonfat dry milk solids is used, water may be added in a quantity not in excess of that removed when the milk or skim milk was concentrated or dried.

(4) For the purposes of this section, the term "milk" means sweet milk of cows; "skim milk" means milk from which a portion of the water has been removed by evaporation.

(a) When an optional ingredient listed in paragraph (b) of this section is present in cream cheese, the label shall bear the statement "With Added [[milk]] or "With Added ____________".

(b) When an optional ingredient listed in paragraph (b) of this section is present in neufchatel cheese, the label shall bear the statement "With Added ____________.

§ 19.520 Neufchatel cheese; identity; label statement of optional ingredients. (a) Neufchatel cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished neufchatel cheese contains not less than 20 percent but less than 33 percent of milk fat and not more than 65 percent of moisture, as determined, respectively, by the methods prescribed under "Fat--Official" on page 302 and under "Moisture--Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940. (These methods appear in the Eighth Edition, 1955, at pages 279 and 278.)

(b) (1) Milk or a mixture of milk with one or more of the dairy ingredients specified in subparagraph (3) of this paragraph or a mixture of concentrated milk with or with water not in excess of that removed when the milk was concentrated is pasteurized and may be homogenized. To such milk or mixture harmless lactic-acid-producing bacteria, with or without rennet, are added and it is held until it becomes coagulated. The coagulated mass may be warmed; it may be stirred; it is then drained. The curd may be heated, washed with water and further drained; it may be pressed, chilled, worked, seasoned with salt.

(2) The dairy ingredients referred to in subparagraph (1) of this paragraph are milk, skim milk, concentrated milk, and nonfat dry milk solids. If concentrated milk, skim milk, concentrated skim milk, or nonfat dry milk solids is used, water may be added in a quantity not in excess of that removed when the milk or skim milk was concentrated or dried.

(3) For the purposes of this section the term "skim milk" means milk from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

(c) When an optional ingredient listed in paragraph (b) of this section is present in cream cheese, the label shall bear the statement "With Added ____________.

(d) When an optional ingredient listed in paragraph (b) of this section is present in neufchatel cheese, the label shall bear the statement "With Added ____________.

§ 19.525 Cottage cheese; identity. (a) Cottage cheese is the soft uncurdled cheese prepared by the procedure set forth in paragraph (b) of this section. The finished cottage cheese contains not more than 30 percent of moisture, as determined, respectively, by the methods prescribed under "Moisture--Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940. (This method appears in the Eighth Edition, 1955, at page 276.)

(b) (1) One or more of the dairy ingredients specified in subparagraph (2) of this paragraph may be used in preparing cottage cheese. The term "milk" means milk from which a portion of the water has been removed by evaporation. If concentrated milk, skim milk, or nonfat dry milk solids is used, water may be added in a quantity not in excess of that removed when the milk or skim milk was concentrated or dried.

(2) The dairy ingredients referred to in subparagraph (1) of this paragraph are milk, skim milk, concentrated milk, concentrated skim milk, and nonfat dry milk solids. If concentrated milk, skim milk, concentrated milk, concentrated skim milk, or nonfat dry milk solids is used, water may be added in a quantity not in excess of that removed when the milk or skim milk was concentrated or dried.

(3) For the purposes of this section the term "skim milk" means milk from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

(b) (1) Milk or a mixture of milk with one or more of the dairy ingredients specified in subparagraph (3) of this paragraph or a mixture of concentrated milk with or with water not in excess of that removed when the milk was concentrated is pasteurized and may be homogenized. To such milk or mixture harmless lactic-acid-producing bacteria, with or without rennet, are added and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd may be pressed, chilled, worked, seasoned with salt.

(2) The dairy ingredients referred to in subparagraph (1) of this paragraph are milk, skim milk, concentrated milk, concentrated skim milk, and nonfat dry milk solids. If concentrated milk, skim milk, concentrated milk, concentrated skim milk, or nonfat dry milk solids is used, water may be added in a quantity not in excess of that removed when the milk or skim milk was concentrated or dried.

(3) For the purposes of this section the term "skim milk" means milk from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

§ 19.530 Creamed cottage cheese; identity. (a) Creamed cottage cheese is the soft uncurdled cheese prepared by mixing cottage cheese with pasteurized cream or a pasteurized mixture of cream and milk or skim milk or both. Such cream or mixture is used in such quantity that the milk fat added thereby is not less than 4 percent by weight of the finished creamed cottage cheese. The finished creamed cottage cheese was not less than 0.25 percent of moisture as determined by the method prescribed.

(b) For the purposes of this section "milk" means sweet milk of cows and "skim milk" means milk from which the milk fat has been separated.

§ 19.533 Granular cheeses, stirred curd cheese; identity. Granular cheese, a cheese made from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 39 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto; harmless propionic-acid-producing bacteria may also be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to the milk to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 90 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 85° F. Stirring is continued until the curd becomes firm. The curd is transferred to hoops or forms, and pressed until the desired shape and firmness are obtained. The cheese is salted by immersing it in a saturated salt solution for about 3 days. It is then held at a temperature of about 50° F. to 55° F. for a period of 5 to 10 days, after which it is held at a temperature of about 75° F. until it is approximately 30 days old, or until the acidity of the whey at this point, calculated as lactic acid, does not exceed 0.1 percent. The curd is transferred to a lower temperature for further curing. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of swiss cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

§ 19.540 Swiss cheese, emmentaler cheese; identity. (a) Swiss cheese, emmentaler cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 39 percent of moisture and its solids contain not less than 48 percent of milk fat, as determined by the methods prescribed in § 19.500. It contains small holes, or eyes. It has a mild flavor, due in part to the growth of surfacing agents. It is not less than 60 days old.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto; harmless propionic-acid-producing bacteria may also be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to the milk to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 120° F. Stirring is continued until the curd becomes firm. The curd is transferred to hoops or forms, and pressed until the desired shape and firmness are obtained. The cheese is surface-cooked while held at a temperature of 60° F. to 70° F. for a few days. It is soaked for 1 day in a saturated salt solution. It is then held for 3 weeks in a salting cell and wiped every 2 days with brine cloth to insure growth of biological curing agents on the rind. It is then removed to a heating room and held at progressively higher temperatures, finally reaching 65° F., with a relative humidity of 35 to 50 percent, for several weeks, during which time small holes, or so-called eyes, form. The cheese is then stored at a lower temperature for further curing. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of gruyere cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom by adding thereto one or more of the following: Clark's skimming process, cream, skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

§ 19.537 Granular cheese for manufacturing; identity. Granular cheese for manufacturing conforms to the definition and standard of identity prescribed for granular cheese by § 19.535, except that the milk is not pasteurized, and curing is not required.

§ 19.542 Swiss cheese for manufacturing; identity. Swiss cheese for manufacturing conforms to the definition and standard of identity prescribed for swiss cheese by § 19.540, except that the holes, or eyes, have not developed throughout the entire cheese.

§ 19.543 Gruyere cheese; identity. (a) Gruyere cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 45 percent of moisture and its solids contain not less than 48 percent of milk fat, as determined by the methods prescribed in § 19.500. If the milk used is not pasteurized, the cheese so made is cured...
at a temperature of not less than 35° F. for not less than 60 days.  

(b) Milk, which may be pasteurized or clarified or both, is brought to a temperature of about 150° F. and held for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction.  

§ 19.547 Brick cheese for manufacturing; identity. Brick cheese for manufacturing conforms to the definition and standard prescribed for brick cheese by § 19.545, except that the milk is not pasteurized, and curing is not required.

§ 19.550 Muenster cheese, munster cheese; identity. (a) Muenster cheese shall be deemed to have been manufactured from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is added to the milk or other ingredients specified in this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used, at a temperature not less than 60° F. for not less than 60 days.

§ 19.555 Edam cheese; identity. (a) Edam cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is added to the milk or other ingredients specified in this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used.
(b) Milk, which may be pasteurized or clarified or both, which may be warmed, and which may be homogenized, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmsless artificial green or blue coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage. While being placed in forms, spores of the mold Penicillium roqueforti are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Performations are then made in the shaped curd, and it is held at a temperature of approximately 50°F., at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curdling or development of flavor of blue cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate, but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, used, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(3) Such milk may be adjusted by separating part of the fat therefrom or by adding one or more of the following: Cream, cream which has been treated in the manner provided in subparagraph (2) of this paragraph, concentrated skim milk solids, water sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

§ 19.570 Roquefort cheese, sheep's milk blue-mold cheese, blue-mold cheese from sheep's milk; identity. (a) Roquefort cheese, sheep's milk blue-mold cheese, blue-mold cheese from sheep's milk, is the food prepared from sheep's milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. It is characterized by the presence of blue-green mold throughout the cheese. It is made in loaves weighing between 14 and 17 pounds. It contains not more than 45 percent moisture, and its solids contain not less than 50 percent milk fat, as determined by the method prescribed in § 19.500 (c). It is not less than 90 days old.

(b) Milk, which may be pasteurized or clarified or both, which may be warmed, and which may be homogenized, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmsless artificial green or blue coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage. While being placed in forms, spores of the mold Penicillium roqueforti are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Performations are then made in the shaped curd and it is held at a temperature of approximately 50°F., at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage the surface of the cheese is scraped, if necessary, to remove surface growth of undesirable microorganisms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curdling or development of flavor of roquefort cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means sheep's milk.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate, but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, used, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(3) Such milk may be adjusted by separating part of the fat therefrom or by adding one or more of the following: Cream, cream which has been treated in the manner provided in subparagraph (2) of this paragraph, concentrated skim milk solids, water sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

§ 19.575 Limburger cheese; identity. (a) Limburger cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 45 percent moisture, and its solids contain not less than 50 percent milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, limburger cheese is held at a temperature of less than 35°F for not less than 60 days.
(b) Milk, which may be pasteurized or clarified or both, is brought to a temperature of about 92° F. and subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet with or without calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk is added to set the milk to a semisolid mass. The mass is cut into cubes with sides approximately ½-inch long. After a few minutes the mass is stirred and heated, gradually raising the temperature to 143° F. The curd is then allowed to settle, most of the whey is drained off, and the remaining curd and whey dipped into molds. During drainage the curd may be pressed. It is turned at regular intervals. After drainage the curd is cut into pieces of desired size and drained at intervals for 24 to 48 hours. The cheese is then cured with frequent applications of a weak brine solution to the surface, until the proper growth of surface-curing organisms is obtained. It is then wrapped in burlap or muslin and ripened for as much additional flavor as is desired. When made from pasteurized milk, the milk is brought to a temperature of 99° F. to 80° F. after pasteurization. A culture of lactic-acid-producing bacteria is added. Calcium chloride may be added, as to raw milk. The procedure then is the same as with raw milk, except that heating is to 94° F. After most of the whey has been drained off, salt is added at a temperature of 60° F. to 70° F. is added, so that the pH of the curd is about 4.8. The mixed curd, whey, and brine is dipped into molds and the procedure followed as when raw milk is used. Whether pasteurized or unpasteurized milk is used, a harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of limburger cheese, may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word “milk” means cow’s milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Monterey cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (c).

§ 19.550 Provolone cheese, pasta filata cheese; identity. (a) Provolone cheese, pasta filata cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 45 percent of moisture, and its solids contain not less than 45 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is held at a temperature not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. Part of the whey is drained off, and water or salt brine may be added. The curd is drained and placed in a muslin or cheesecloth, formed into a ball, and pressed; or the curd is placed in a cheese hoop and pressed. Later, the cloth bandage is removed, and the cheese may be covered with paraffin or dipped in vegetable oil, and may have rice flour sprinkled on the surface. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of monterey cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Monterey cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (c).

§ 19.500 High-moisture jack cheese; identity. High-moisture jack cheese conforms to the definition and standard of identity prescribed for monterey cheese by § 19.550, except that its moisture content is not more than 45 percent, but less than 50 percent.

§ 19.500 Provolone cheese, pasta filata cheese; identity. (a) Provolone cheese, pasta filata cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has a stringy texture, and may be made in several shapes. It contains not more than 45 percent of moisture, and its solids contain not less than 45 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is held at a temperature not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto.

(c) For the purposes of this section:

(1) The word “milk” means cow’s milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Monterey cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (c).

(d) The name “Provolone cheese” (“Pasta filata cheese”) may include the common name of the shape of the cheese, or mixtures of two or all of these and other ingredients specified in this section, by the procedure set forth in...
"produced when the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by a granular texture and a hard and brittle rind. It grates readily. It contains not more than 32 percent of moisture, and its solids contain not less than 32 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). It is cured for not less than 14 months.

(d) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring may be added. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless lactic-acid-producing bacteria, or clarified or both, and which may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

§ 19.610 Romano cheese; identity. (a) Romano cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by a granular texture and a hard and brittle rind. It grates readily. It contains not more than 32 percent of moisture, and its solids contain not less than 32 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). It is cured for not less than 14 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring may be added. Sufficient rennet, rennet paste or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless lactic-acid-producing bacteria, or clarified or both, and which may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

§ 19.615 Asiago fresh cheese, asiago soft cheese; identity. (a) Asiago fresh cheese, asiago soft cheese, when made solely from goat's milk, the name is "Romano cheese made from goat's milk," and may be preceded by the word "Pastificato"; when made solely from sheep's milk, the name is "Romano cheese made from sheep's milk," and may be preceded by the word "Casertano;" when made solely from cow's milk, the name is "Romano cheese made from cow's milk," and may be preceded by the word "Siciliano;" and when made from milk of two or all of these, the name may be "Romano cheese.

§ 19.595 Parmesan cheese, reggiano cheese; identity. (a) Parmesan cheese, reggiano cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has a stringy texture, and is made in oblong shapes. It contains not more than 40 percent of moisture, and its solids contain not less than 42 percent milk fat, as determined by the methods prescribed in § 19.500 (c). It is cured for not less than 90 days at a temperature of not less than 35 °F. (b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring may be added. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless lactic-acid-producing bacteria, or clarified or both, and which may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

§ 19.610 Romano cheese; identity. (a) Romano cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has a stringy texture, and is made in oblong shapes. It contains not more than 40 percent of moisture, and its solids contain not less than 42 percent milk fat, as determined by the methods prescribed in § 19.500 (c). It is cured for not less than 14 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring may be added. Sufficient rennet, rennet paste or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless lactic-acid-producing bacteria, or clarified or both, and which may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(d) When Romano cheese is made solely from cow's milk the name of such cheese is "Romano cheese made from cow's milk" and may be preceded by the word "Pastificato"; when made solely from sheep's milk, the name is "Romano cheese made from sheep's milk," and may be preceded by the word "Casertano;" and when made solely from goat's milk, the name is "Romano cheese made from goat's milk," and may be preceded by the word "Ecorninsa;" and when made solely from milk of two or all of these, the name is "Romano cheese.

§ 19.615 Asiago fresh cheese, asiago soft cheese; identity. (a) Asiago fresh cheese, asiago soft cheese, when made solely from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used, the name of the cheese is "Romano cheese made from ________," the blank being filled in with the names of the milks used, in order of predominance by weight.
is used. It contains not more than 45 percent of moisture, and its solids contain not less than 0.02 percent of milk fat, as determined by the methods prescribed in §19.500 (c). It is cured for not less than 60 days.

(2) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in an amount of one or more of the following: Cream, milk, or any mixture of two or more of these. Some of the action is permitted to continue until the milk coagulates to a semisolid mass. The mass is stirred and heated until a temperature of not less than 160°F. is reached, and is held at that temperature for not less than 1/2 hour. The whey is drained off and the curd removed and placed in forms and pressed. The shaped curd is placed in whey and allowed to cool to a temperature of not less than 50°F., and is again pressed. It is then stored under conditions suitable for curdling.

§ 19.650 Hard cheeses; identity. (a) The cheeses for which definitions and standards of identity are prescribed by this section are hard cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 32 percent of moisture, its solids contain not less than 45 percent of milk fat, as determined by the method prescribed in §19.500 (c), and are subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. The development of acidity is continued until the skim milk coagulates to a semisolid mass. The mass is stirred and heated until a temperature of about 160°F. is reached. The development of acidity is continued until the skim milk coagulates to a semisolid mass. The mass is stirred and heated until a temperature of not less than 160°F. is reached, and is held at that temperature for not less than 1/2 hour. The whey is drained off and the curd removed and placed in forms and pressed. The shaped curd is placed in whey and allowed to cool to a temperature of not less than 50°F., and is again pressed. It is then stored under conditions suitable for curdling.

(1) The word "milk" means cow's milk, or goat's milk, or sheep's milk, or mixtures of two or all of these. Such milk may be adjusted to a temperature of not less than 65°F. before addition to the curd. The whey is drained off and the curd removed and placed in forms and pressed. The shaped curd is placed in whey and allowed to cool to a temperature of not less than 50°F., and is again pressed. It is then stored under conditions suitable for curdling.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring may be added. Sufficient rennet (with or without purified calcium chloride) is added to precipitate the casein. The whey is drained off and the curd removed and placed in forms and pressed. The shaped curd is placed in whey and allowed to cool to a temperature of not less than 50°F., and is again pressed. It is then stored under conditions suitable for curdling.

(c) The optional dairy ingredients specified in paragraph (c) of this section, which may be pasteurized, and which may be warmed, are subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring may be added.

(d) The optional dairy ingredients specified in paragraph (b) of this section, which may be pasteurized, and which may be warmed, are subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring may be added.

§ 19.655 Asiago medium cheese; identity. Asiago medium cheese conforms to the definition and standard of identity prescribed by §19.615 for asiago fresh cheese, except that it contains not more than 32 percent of moisture, its solids contain not less than 45 percent of milk fat, and it is cured for not less than 1 year.

§ 19.655 Cook cheese; bock kease; identity. Cook cheese, which is also known as bock kease, is the food prepared from skim milk and other ingredients specified in this section by the procedure set forth in paragraph (b) of this section, or by another procedure which duplicates a brushed cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 60 percent moisture as determined by the methods prescribed in §19.500 (e). When tested for phosphatase by the method prescribed in §19.500 (e) 0.02 gm, of cook cheese shows a phosphatase equivalent of not more than 3 micrograms.

§ 19.657 Sap sago cheese; identity. Sap sago cheese is the food prepared from the skim milk of cows and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. It is of a scale-green color and is made in the shapes of a truncated cone. It contains not more than 38 percent of moisture, as determined by the method prescribed in §19.500 (e).

(b) Slimi milk is allowed to become sour, and is heated to boiling temperature, with stirring. Cold buttermilk may be added. Sufficient sour whey is added to precipitate the casein. The curd is removed, spread out in boxes, and pressed, and while under pressure is allowed to drain and ferment. It is ripened for not less than 5 days. The ripened curd is stirred and drained, salt and dried clover of the species Mellitoco cerasus are added. The mixture is shaped into truncated cones. It is then cured for not less than 1 year.

§ 19.659 Gammelost cheese; identity. Gammelost cheese is the food prepared from the skim milk of cows and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. It contains not more than 52 percent of moisture, as determined by the method prescribed in §19.500 (e).

(b) Slimi milk, which may be pasteurized, is subjected to the action of harmless lactic-acid-producing bacteria, present in such skim milk or added thereto. The development of acidity is continued until the skim milk coagulates to a semisolid mass. The mass is stirred and heated until a temperature of about 160°F. is reached. The development of acidity is continued until the skim milk coagulates to a semisolid mass. The mass is stirred and heated until a temperature of not less than 160°F. is reached, and is held at that temperature for not less than 1/2 hour. The whey is drained off and the curd removed and placed in forms and pressed. The shaped curd is placed in whey and allowed to cool to a temperature of not less than 50°F., and is again pressed. It is then stored under conditions suitable for curdling.

(c) The optional dairy ingredients specified in paragraph (c) of this section, which may be pasteurized, and which may be warmed, are subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring may be added.
a quantity sufficient to reconstitute any concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if, when held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equal to or greater than the equivalent thereto in phosphatase destruction.

A hard cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 5 micrograms, when tested by the method prescribed in §19.500(e).

(d) The name of each hard cheese, for which a definition and standard of identity is prescribed, shall be 'Hard cheese,' preceded or followed by:

(1) The specific common or usual name of each hard cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from..." the blank being filled in with the name or names of the milk used, in order of predominance by weight.

§19.655 Semisoft cheeses; identity; label statement of optional ingredients.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are semisoft cheeses for which specifically applicable definitions and standards are prescribed by other sections of this part. They are made from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain more than 30 percent, but not more than 50 percent, of moisture, and their solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in §19.500(c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which has been pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner to promote the growth of biological curing agents. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft cheese may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or mixtures of two or all of them. Such milk may be adjusted as anhydrous calcium chloride, of a quantity not more than 0.02 percent, calculated as calcium chloride, or other harmless flavor-producing bacteria, present in such milk or added thereto, in phosphatase destruction. A semisoft cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 5 micrograms, when tested by the method prescribed in §19.500(e).

(d) The name of each semisoft cheese for which a definition and standard of identity is prescribed by this section is "Semisoft cheese," preceded or followed by:

(1) The specific common or usual name of such semisoft cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from..." the blank being filled in with the name or names of the milk used, in order of predominance by weight.

§19.660 Semisoft part-skim cheeses; identity; label statement of optional ingredients.

(a) The cheeses for which definitions and standards of identity are prescribed by this section are semisoft part-skim cheeses for which specifically applicable definitions and standards are prescribed by other sections of this part. They are made from partly skimmed milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 50 percent of moisture, and their solids contain not less than 45 percent, but less than 50 percent, of milk fat, as determined by the methods prescribed in this section. If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F., for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and it may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner to promote the growth of biological curing agents. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft part-skim cheeses may be added in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or mixtures of two or all of them. Such milk may be adjusted as anhydrous calcium chloride, of a quantity not more than 0.02 percent, calculated as calcium chloride, or other harmless flavor-producing bacteria, present in such milk or added thereto, in phosphatase destruction. A semisoft part-skim cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 5 micrograms, when tested by the method prescribed in §19.500(e).

(d) The name of each semisoft part-skim cheese for which a definition and standard of identity is prescribed by this section is "Semisoft part-skim cheese," preceded or followed by:

(1) The specific common or usual name of such semisoft part-skim cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from..." the blank being filled in with the name or names of the milk used, in order of predominance by weight.
§ 19.665 Soft ripened cheeses; identity; label statement of optional ingredients. (a) The cheeses for which definitions and standards of identity are prescribed by this section are soft ripened cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, and the milk used in this section, by the procedure set forth in paragraph (b) of this section, is permitted to contain not less than 35 °F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Such treatment may include one or more of theSource:

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The cheeses for which definitions and standards of identity are prescribed by this section are soft ripened cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, and the milk used in this section, by the procedure set forth in paragraph (b) of this section, is permitted to contain not less than 35 °F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Such treatment may include one or more of the following: Cutting, stirring, heating, dilution with water or brine. The whey, or part of the whey, and the solid residue is collected and shaped. It may be placed in forms, and may be pressed. Harmless flavor-producing microorganisms may be added. It is cured under conditions suitable for development of biological curing agents on the surface of the cheese, and the curing is conducted so that the cheese cures from the surface toward the center. Salt may be added during the procedure. A smaller preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of soft ripened cheeses may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk; or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products of goat's milk; (in the case of sheep's milk) the corresponding products of sheep's milk; water, in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from," or "contains," or both, and is filled in with the name or names of the milk used, in order of predominance by weight.

§ 19.670 Spiced cheeses; identity; label statement of optional ingredients. (a) The cheeses for which definitions and standards of identity are prescribed by this section are spiced cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. Their solids contain not less than 35 °F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Such treatment may include one or more of the following: Cutting, stirring, heating, dilution with water or brine. The whey, or part of the whey, and the solid residue is collected and shaped. It may be placed in forms, and may be pressed. Harmless flavor-producing microorganisms may be added. It is cured under conditions suitable for development of biological curing agents on the surface of the cheese, and the curing is conducted so that the cheese cures from the surface toward the center. Salt may be added during the procedure. A smaller preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of soft ripened cheeses may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products of goat's milk; (in the case of sheep's milk) the corresponding products of sheep's milk; water, in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from," or "contains," or both, and is filled in with the name or names of the milk used, in order of predominance by weight.

§ 19.675 Part-skim spiced cheeses; identity; label statement of optional ingredients. (a) The cheeses for which definitions and standards of identity are prescribed by this section are hard grating cheeses for which specifically applicable definitions and standards of identity are prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 34 percent of moisture, and their solids contain not less than 32 percent of milk fat, as determined by the methods prescribed in § 19.500 (c).

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria...
Harmless artificial coloring may be added. Sufficient rennet, rennet paste, or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. The mass is cut into small particles, stirred, and heated. The curd is separated from the whey, drained, shaped into forms, pressed, salted, and cured. The rind may be colored or rubbed with vegetable oil or both. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of hard grating cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of goat's milk) the corresponding products from goat's milk; (in the case of cow's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(d) The name of each hard grating cheese for which a definition and standard of identity is prescribed by this section is "Hard grating cheese," preceded or followed by -

(1) The specific common or usual name of such hard grating cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from ________" the blank being filled in with the name or names of the milk used, in order of dominance by weight.

§ 19.855 Skim-milk cheese for manufacturing; identity. (a) Skim-milk cheese for manufacturing is the food prepared from cow's milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 1.25 percent of ash, as determined by the method therefor prescribed in § 19.600 (c) It is colored with blue-colored paraffin or other similarly adhering coating, colored blue.

(b) Skim-milk cheese for manufacturing is the food prepared from cow's milk and other ingredients specified in paragraph (c) of this section, which may be pasteurized, and which may be warmed, are subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. The mass is cut into small particles, stirred, and heated. The curd is separated from the whey, drained, shaped into forms, pressed, salted, and cured. The rind may be colored or rubbed with vegetable oil or both. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of hard grating cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of goat's milk) the corresponding products from goat's milk; (in the case of cow's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(d) The name of each hard grating cheese for which a definition and standard of identity is prescribed by this section is "Hard grating cheese," preceded or followed by -

(1) The specific common or usual name of such hard grating cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from ________" the blank being filled in with the name or names of the milk used, in order of dominance by weight.

§ 19.850 Pasteurized process cheese; identity; label statement of optional ingredients. (a) (1) Pasteurized process cheese is the food prepared by comminuting and mixing, with the aid of heat, ingredients of two or more varieties of cheese, and the optional ingredients designated in paragraph (d) (1) (2) (3) (4) (5) and (6) of this section, as may be deemed necessary.

(2) During its preparation, pasteurized process cheese is heated for not less than 30 seconds at a temperature of not less than 150° F. When tested for phosphate by the method prescribed in § 18.601, the percentage of 0.25 gm. of pasteurized process cheese is not more than 3 micrograms.

(3) (i) The moisture content of a pasteurized process cheese made from a single variety of cheese is not more than 1 percent greater than the maximum moisture content prescribed by the definition and standard of identity, if any there be, for the variety of cheese used; but in no case is more than 43 percent; except that the moisture content of pasteurized process cheese made from a mixture of two or more varieties of cheese is not more than 45 percent; and the limits prescribed for the moisture content of pasteurized process cheese made from a mixture of two or more varieties of cheese is not more than 47 percent.

(ii) The fat content of the solids of a pasteurized process cheese made from a single variety of cheese is not more than 0.5 percent greater than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity, if any there be, for the variety of cheese used; but in no case is more than 43 percent; except that the fat content of the solids of pasteurized process cheese is not less than 43 percent, and the fat content of the solids of pasteurized process cheese is not less than 45 percent.

(b) The moisture content of a pasteurized process cheese made from two or more varieties of cheese is not more than 1 percent greater than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity, if any there be, for the variety of cheese used; but in no case is more than 43 percent; except that the fat content of the solids of pasteurized process cheese is not more than 44 percent.

(3) (i) The moisture content of a pasteurized process cheese made from a single variety of cheese is not more than 1 percent greater than the maximum moisture content prescribed by the definition and standard of identity, if any there be, for the variety of cheese used; but in no case is more than 43 percent; except that the moisture content of pasteurized process cheese made from a mixture of two or more varieties of cheese is not more than 45 percent; and the limits prescribed for the moisture content of pasteurized process cheese made from a mixture of two or more varieties of cheese is not more than 47 percent.

(4) (i) The moisture content of a pasteurized process cheese made from two or more varieties of cheese is not more than 1 percent greater than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity, if any there be, for the variety of cheese used; but in no case is more than 43 percent; except that the fat content of the solids of pasteurized process cheese is not less than 43 percent, and the moisture content of the solids of pasteurized process cheese is not less than 45 percent.

(5) Moisture and fat are determined by the methods prescribed in § 19.600 (c)

(6) The weight of each variety of cheese in a pasteurized process cheese made from two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, roquefort cheese, or gorgonzola cheese is not less than 25 percent of the total weight of both, and the weight of limburger cheese is not less than 5 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese made from three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, roquefort cheese, or gorgonzola cheese is not less than 5 percent of the total weight of all, and the weight of limburger cheese is not less than 3 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese;
colby cheese and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (e) (2) (ii) of this section. Such mixtures are considered as one variety of cheese for the purposes of this subparagraph.

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, and Swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, and Swiss cheese, respectively.

(b) Pasteurized process cheese may be smoked, or the cheese or cheeses from which it is made may be smoked, before commingling and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(e) The emulsifying agents referred to in paragraph (a) of this section are any one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, tetrasodium pyrophosphate, sodium citrate, calcium citrate, calcium lactate, potassium carbonate, sodium carbonate, or sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agents is not more than 3 percent of the weight of the pasteurized process cheese.

(3) The optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: Lactic acid, acetic acid, and phosphoric acid, in such quantity that the pH of the pasteurized process cheese is not below 5.3.

(4) Cream, in such quantity that the weight of the fat derived therefrom is less than 5 percent of the weight of the pasteurized process cheese.

(5) Water.

(6) Salt.

(7) Harmless artificial coloring.

(8) Spices or flavorings, other than which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety.}

The only fruit, vegetable, or meat ingredient is pimentos in such quantity that the weight of the solids thereof is not more than 0.2 percent of the weight of the finished pasteurized process cheese.

§ 19.765 Pasteurized process cheese with fruits, vegetables, or meats; identity; label statement of optional ingredients. (a) Unless a definition and standard of identity specifically applicable is established by another section of this part, a pasteurized process cheese with fruits, vegetables, or meats or mixture of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese by § 19.750, except that:

(1) The moisture content may be 1 percent more, and the milk fat content of its solids may be 1 percent less, than the limits prescribed by § 19.753 for moisture and fat in the corresponding pasteurized process cheese.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit, vegetable, or meat; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, this is prescribed for the determination of fat by § 19.500 (c) is not applicable.

(b) The name of a pasteurized process cheese with fruits, vegetables, or meats is the name prescribed by § 19.750, followed by the term "flavored with _______", or "flavored with _______", or in lieu of the common or usual name of the fruit, vegetable, or meat as used, in order of predominance by weight.

§ 19.760 Pasteurized process pimento cheese; identity. (a) Pasteurized process pimento cheese is the food which conforms to the definition and standard of identity for pasteurized process cheese with fruits, vegetables, or meats, except that:

(1) Its moisture content is not more than 41 percent, only the fat content of its solids is not less than 49 percent.

(2) The cheese ingredient is cheddar cheese, washed curd cheese, colby cheese, granular cheese or any mixture of two or more of these in any proportion.

(3) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, and granular cheese for manufacturing shall be considered as cheddar cheese, washed curd cheese, colby cheese, and granular cheese, respectively.

(d) The only fruit, vegetable, or meat ingredient is pimentos in such quantity that the weight of the solids thereof is not less than 0.2 percent of the weight of the finished pasteurized process pimento cheese.

§ 19.765 Pasteurized process cheese with fruits, vegetables, or meats; identity; label statement of optional ingredients. (a) Unless a definition and standard of identity specifically applicable is established by another section of this part, a pasteurized process cheese with fruits, vegetables, or meats or mixture of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese by § 19.750, except that:

(1) The moisture content may be 1 percent more, and the milk fat content of its solids may be 1 percent less, than the limits prescribed by § 19.753 for moisture and fat in the corresponding pasteurized process cheese.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit, vegetable, or meat; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, this is prescribed for the determination of fat by § 19.500 (c) is not applicable.

(b) The name of a pasteurized process cheese with fruits, vegetables, or meats is the name prescribed by § 19.750, followed by the term "flavored with _______", or "flavored with _______", or in lieu of the common or usual name of the fruit, vegetable, or meat as used, in order of predominance by weight.

§ 19.760 Pasteurized process pimento cheese; identity. (a) Pasteurized process pimento cheese is the food which conforms to the definition and standard of identity for pasteurized process cheese with fruits, vegetables, or meats, except that:

(1) Its moisture content is not more than 41 percent, only the fat content of its solids is not less than 49 percent.

(2) The cheese ingredient is cheddar cheese, washed curd cheese, colby cheese, granular cheese or any mixture of two or more of these in any proportion.

(3) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, and granular cheese for manufacturing shall be considered as cheddar cheese, washed curd cheese, colby cheese, and granular cheese, respectively.

(d) The only fruit, vegetable, or meat ingredient is pimentos in such quantity that the weight of the solids thereof is not less than 0.2 percent of the weight of the finished pasteurized process pimento cheese.
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19.765 Pasteurized process cheese food; identity; label statement of optional ingredients. A pasteurized process cheese food is the food prepared by comminuting and mixing, with the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section, into a homogeneous plastic mass. One or more of the optional ingredients specified in paragraph (e) of this section may be used.

(2) During its preparation, a pasteurized process cheese food is the food prepared by comminuting and mixing, with the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section, into a homogeneous plastic mass. One or more of the optional ingredients specified in paragraph (e) of this section may be used.

§ 19.766 Pasteurized process cheese food; moisture; fat; milk fat content. The moisture content of a pasteurized process cheese food shall be determined by method prescribed in § 19.500 (a) except that:

(1) Its moisture content may be 1 percent more, and the milk fat content of its solids may be 1 percent less, than the limits prescribed by § 19.763 for moisture and milk fat in the corresponding pasteurized blended cheese.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared water....

§ 19.767 Pasteurized process cheese food; fruits, vegetables, or meats; identity; label statement of optional ingredients. (a) The label of a pasteurized process cheese food with fruits, vegetables, or meats shall bear the statement "flavored with .........." if it contains substances prepared by condensing or precipitating wood smoke, the label shall bear the statement "spiced" or "spice added" or "with added spices," or in lieu of the word "spice" the common or usual name of the spice used.

(b) The label shall bear the statement "flavored with .........." if it contains added flavoring, the label shall bear the statement "flavored with .........." or "contains artificial color."
used, in order of predominance by weight.

(c) If the only vegetable ingredient is pimento, and no meat or fruit ingredient is used, the weight of the solids of such pimento is not less than 8 percent of the weight of the finished food. The name of this food is "Pimento pasteurized process cheese food" or "Pasteurized process pimento cheese food."

§ 19.775 Pasteurized process cheese spread; identity; label statement of optional ingredients.

(1) Pasteurized process cheese spread is the food prepared by combining and mixing, with the aid of heat, one or more of the optional ingredients prescribed in paragraphs (d) and (g) of this section, with or without one or more of the optional ingredients prescribed in paragraph (a) of this section, into a homogeneous plastic mass, which mass, when spreadable at not less than 19.500° F. for 1 minute under the conditions prescribed in §19.500, is not less than 24 percent of the weight of the solids of such emulsifying agent, in such quantity that the weight of the solids of such emulsifying agent is not more than 3 percent of the weight of such substances.

(2) During its preparation, a pasteurized process cheese spread is heated for not less than 30 seconds at a temperature of not less than 190° F. When tested for phenol it conforms to the methods prescribed in §19.500, the phenol equivalent of 0.25 gm. of pasteurized process cheese spread is not more than 3 micrograms.

(3) The moisture content of a pasteurized process cheese spread is more than 44 percent but not more than 60 percent, and the milk fat content is not less than 20 percent.

(4) Moisture and fat are determined by the methods prescribed in §19.500, except that in determining moisture the loss in weight which occurs in drying for 5 hours under the conditions prescribed in such method, is taken as the weight of the moisture.

(5) The weight of the cheese ingredient referred to in subparagraph (1) of this paragraph constitutes not less than 51 percent of the weight of the pasteurized process cheese spread.

(6) The weight of each variety of cheese in a pasteurized process cheese spread made with two varieties of cheese is not less than 55 percent of the total weight of both, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese spread made with three or more varieties of cheese is not less than 5 percent of the total weight of all, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 1 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as "cheddar cheese" as prescribed in paragraph (g) of this section. Such mixtures are considered as one variety of cheese for the purposes of this subparagraph.

(7) For the purposes of this section, "cheddar cheese for manufacturing," "colby cheese for manufacturing," "granular cheese for manufacturing," "brick cheese for manufacturing," and "swiss cheese for manufacturing" are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese spread may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by conditioning or precipitating wood smoke.

(c) (1) 1A The weight of blue cheese, roquefort cheese, gorgonzola cheese, and washed curd cheese for manufacturing, and swiss cheese, respectively. (2) 1A The weight of pimento pasteurized process cheese spread, or "Pimento pasteurized process cheese spread" or "Pasteurized process cheese spread" is more than 15 percent of the total weight of the cheese ingredient.

(d) If an optional acidifying agent is used so that the pH of the finished food is less than 5.0, there shall appear after its name the words "a chemical preservative." In cases vinegar or other acidifying agent added it shall be considered to be acetic acid when the pH of the finished food is less than 5.0. In cases vinegar and other acidifying agents are added and the PH of the finished food is less than 5.0, the name of the acidifying agents other than vinegar shall be followed by the statement "a chemical preservative.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen by customers, the words and statements herein specified, when the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.776 Pasteurized cheese spread; identity; label statement of optional ingredients. Pasteurized cheese spread is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement.
of optional ingredients, prescribed for pasteurized process cheese spread by § 19.775, except that:

(1) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(2) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 19.500 (c) is not applicable.

(b) The name of a pasteurized process cheese spread with fruits, vegetables, or meats is "Pasteurized process cheese spread with ________," the blank being filled with the common names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 19.781 Pasteurized cheese spread with fruits, vegetables, or meats; identity; label statement of optional ingredients. (a) Pasteurized cheese spread with fruits, vegetables, or meats is "Pasteurized process cheese spread with ________," the blank being filled with the name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

(1) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(2) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 19.500 (c) is not applicable.

(c) (1) When the added fruits, vegetables, or meats with the added food ingredients is used, but the moisture content of the mixture in no case is more than 60 percent. The milk fat shall be less than 33 percent of the percent by weight of the cream cheese used, but in no case is less than 27 percent of the finished food. Moisture and fat are determined by the methods prescribed in § 19.500 (c) except that when the added foods contain fat the method prescribed for the determination of fat is not applicable.

(2) The label shall bear the name of the optional water-retaining ingredients used, except that when the added food contains one or a mixture of two or more of the following: A vinegar, acetic acid, lactic acid, citric acid, phosphoric acid.

(3) A sweetening agent consisting of one or a mixture of two or more of the following: A sugar, dextrose, corn syrup, corn syrup solids, glycercine, sucrose, corn syrup solids, maltose, malt syrup, hydrolyzed lactose.

(4) Cream, milk, skim milk, cream whey or any mixture of two or more of these, or any of the foregoing from which part of the water has been removed, and albumin from cream whey.

(5) The name of the food is "Pasteurized process cheese spread with ________" or "Pasteurized process cheese spread with ________" the blank being filled with the common names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 19.782 Cream cheese with other foods; identity; label statement of optional ingredients. (a) Cream cheese with other foods is the class of foods each of which is prepared by mixing, with or without the aid of heat, cream cheese with one or a mixture of two or more properly prepared foods (except other cheeses) such as fresh, cooked, canned, or dried fruits or vegetables; cooked or canned meats; relishes, pickles, or other foods suitable for blending with cream cheese. The amount of the added food or foods must be sufficient to so differentiate the mixture that it does not simulate cream cheese. The mixture may also contain:

(1) One or any mixture of two or more of the following optional ingredients:
- Gum karaya, gum tragacanth, carob bean gum, gelatin, guar gum, carboxymethylcellulose, carrageen, oat gum, algin (sodium alginate), alginate (propylene glycol ester of alginic acid)
- The total quantity of any such substances, including that contained in the cream cheese, is not more than 0.5 percent by weight of the finished food.

(2) Artificial coloring, unless such addition conceals damage or inferiority or makes the finished food appear better or of greater value than it is.

(b) No water or other than that contained in the added food ingredients is used, but the moisture content of the mixture in no case is more than 60 percent.

(2) Artificial coloring, unless such addition conceals damage or inferiority or makes the finished food appear better or of greater value than it is.

(3) An acidifying agent consisting of one or a mixture of two or more of the following: A vinegar, acetic acid, lactic acid, citric acid, phosphoric acid.

(4) A sweetening agent consisting of one or a mixture of two or more of the following: A sugar, dextrose, corn syrup, corn syrup solids, glycercine, sucrose, corn syrup solids, maltose, malt syrup, hydrolyzed lactose.

(5) Cream, milk, skim milk, cream whey or any mixture of two or more of these, or any of the foregoing from which part of the water has been removed, and albumin from cream whey.

(6) The name of the food is "Pasteurized cheese spread with ________" the blank being filled with the common names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 19.783 Pasteurized neufchatel cheese spread with other foods; identity; label statement of optional ingredients. (a) Pasteurized neufchatel cheese spread with other foods is the class of foods each of which is prepared by mixing, with or without the aid of heat, neufchatel cheese with one or a mixture of two or more properly prepared foods (except other cheeses) such as fresh, cooked, canned, or dried fruits or vegetables; cooked or canned meats; relishes, pickles, or other foods suitable for blending with neufchatel cheese. It may contain one or any mixture of two or more of the following optional ingredients named in paragraph (b) of this section. The amount of the added food or foods must be sufficient to so differentiate the mixture that it does not simulate neufchatel cheese. It is spreadable at 70°F.

(2) During its preparation the mixture is heated for not less than 30 minutes at a temperature of not less than 150°F. When tested for phosphatase by the method prescribed in § 19.500 (a) the phosphatase equivalent of such food is not more than 3 micrograms.

(3) (i) No water other than that contained in the ingredients used is added to this food, and the moisture content in no case is more than 65 percent.

(ii) The milk fat is not less than 20 percent by weight of the finished food.

(4) The label shall bear the statement "artificially colored," the blank being filled in with the name or names of the foods added, in order of predominance by weight.

(d) The label shall bear the names of any of the optional ingredients used designated in paragraph (b) (1), (3), (4), and (5) of this section, the blank being filled in with the names or names of the foods so colored.

(2) If an optional acidifying agent is used so that the pH of the finished food is less than 4.2, there shall appear after its name the words "a chemical preservative." In case vinegar is the only acidifying agent used and the pH of the finished food is less than 4.2, only the name or names of the acidifying agents other than vinegar.
§ 19.783 Cold-pack cheese, club cheese, cold-pack swiss cheese; identity; label statement of optional ingredients.

(a) Cold-pack cheese, club cheese, comminuted cheese, is the food prepared by comminuting, without the aid of heat, one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, hard grating cheese, saucisson cheese, skim-spaced cheese, and skim-milk cheese for manufacturing, into a homogeneous plastic mass. One or more of the optional ingredients designated in paragraph (c) of this section may be used.

(b) All cheeses used in a cold-pack cheese are made from pasteurized milk or are held for not less than 60 days at a temperature of not less than 35° F. before being comminuted.

(c) The moisture content of a cold-pack cheese made from a single variety of cheese is not more than the maximum moisture content prescribed by the dairy ingredients herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

19.707 Cold-pack cheese food; identity; label statement of optional ingredients.

(a) Cold-pack cheese food is the food prepared by comminuting and mixing, without the aid of heat, one or more of the optional cheese ingredients herein specified, in any proportion or combination with one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, into a homogeneous plastic mass. One or more of the optional ingredients specified in paragraph (c) of this section may be used.

(b) All cheeses used in a cold-pack cheese food are made from pasteurized milk, or are held for not less than 60 days at a temperature of not less than 35° F. before being comminuted.

(c) The moisture content of a cold-pack cheese food is not more than 42 percent, and the fat content of the solids of cold-pack cheese food is not less than 45 percent.

(d) The moisture and fat are determined by the methods prescribed in § 19.53 (e), except that in determining moisture the loss in weight which occurs in drying for 5 hours, under the conditions prescribed in such method, is taken as the weight of moisture.

(e) The weight of the cheese ingredient prescribed by subparagraph (1) of this paragraph constitutes not less than 51 percent of the weight of the finished cold-pack cheese food.

(f) The weight of each variety of cheese in the cold-pack cheese food made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both, and the weight of limburger cheese is not less than 5 percent of the total weight of all. The weight of each variety of cheese in a cold-pack cheese made from three or more varieties of cheese is not less than 6 percent of the total weight of all, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese is not less than 10 percent of the total weight of all, and the weight of limburger cheese is not less than 3 percent of the total weight of all.

(g) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words "cold-pack cheese food" or "cold-pack cheese food, club cheese" or "comminuted cheese" shall be followed by the word "flavoring" or the word "artificially" shall precede the statement "flavored with ___________."

(h) If it contains added flavorings, the label shall bear the statement "flavoring added." If "flavoring added" is the blank to be filled in with the common or usual name of the flavoring used, the statement "flavoring added" shall be followed by the word "spiced" or "spiced with added flavoring" or "flavored with added flavoring" or "flavored with ___________."

(i) If it contains added fibers, the label shall bear the statement "fibers added." If "fibers added" is the blank to be filled in with the common or usual name of the fibers used, the statement "fibers added" shall be followed by the word "artificial" or "artificially" shall precede the statement "artificially added."
weight of all, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or Limburger cheese is not less than 6 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are otherwise defined as "cheddar cheese" as prescribed in paragraph (f) (6) of this section. Such mixtures are considered as one variety of cheese for the purposes of this subparagraph.

(b) Cold-pack cheese food may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are: One or more cheeses of the same or two or more varieties, except that cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, and skim-milk cheese for manufacturing are not used, and except that semisoft part-skim cheeses, part-skim spiced cheese, and hard grating cheese may not be used, alone or in combination with each other, as the cheese ingredients.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are: cream, milk, skim milk, cheese whey, or any mixture of two or more of these or any fraction of the total whey from which part of the whey has been removed, skim-milk cheese for manufacturing and albumin from cheese whey. All optional dairy ingredients used in cold-pack cheese food are pasteurized or made from products which have been pasteurized.

(e) The other optional ingredients referred to in paragraph (a) of this section are:

1. An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the finished cold-pack cheese food is not below 4.5.

2. Water.

3. Salt.

4. Harmless artificial coloring.

5. Flavors or seasonings, other than any which singly or in combination with other ingredients simulate the flavor of cheese of any age or variety.

6. A sweetening agent consisting of one or any mixture of two or more of the following: Sugar, dextrose, corn sugar, corn syrup, corn syrup solids, glucose syrup, glucose solids, malt syrup, and maltose, or any sugar other than sucrose which is the food which conforms to the definition and standards of identity of "cold-pack cheese food with fruits, vegetables, meats, or spices; identity; label statement of optional ingredients.

(a) Cold-pack cheese food with fruits, vegetables, meats; identity; label statement of optional ingredients.

1. Its milk fat content is not less than 22 percent.

2. It contains any mixture of two or more of the following: Any properly prepared fresh fruit, canned, dried vegetable; any properly prepared cooked or canned meat.

3. When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat shall be used.

(a) The name of a cold-pack cheese food with fruits, vegetables, or meats is "Cold-pack cheese food with ________ " the blank being filled in with the common or usual name of the fruits, vegetables, or meats, used, in order of predominance by weight.

FURTHER DIRECTIONS FOR FOODS

PART 25—DRESSINGS FOR FOODS

25.1 Mayonnaise, mayonnaise dressing; identity; label statement of optional ingredients.

(a) Mayonnaise, mayonnaise dressing, is the emulsified semisolid food prepared from edible vegetable oil, one or both of the acidifying ingredients specified in paragraph (b) of this section, and one or more of the egg-yolk-containing ingredients specified in paragraph (c) of this section. It may be unflavored or flavored with one or more of the following ingredients:

1. Salt.

2. Sugar, dextrose, corn sirup, invert sugar sirup, noninvert maltose sirup, glucose sirup, honey.

3. Any vinegar or any vinegar and water or any vinegar and water to which any vinegar has been added, or any one or more of the following: Any sugar other than sucrose which is the food which conforms to the definition and standards of identity of "cold-pack cheese food with fruits, vegetables, meats, or spices; identity; label statement of optional ingredients.

25.2 French dressing; identity; label statement of optional ingredients.

25.3 Salad dressing; identity; label statement of optional ingredients.


§ 25.1 Mayonnaise, mayonnaise dressing; identity; label statement of optional ingredients.

(a) Mayonnaise, mayonnaise dressing, is the emulsified semisolid food prepared from edible vegetable oil, one or both of the acidifying ingredients specified in paragraph (b) of this section, and one or more of the egg-yolk-containing ingredients specified in paragraph (c) of this section. It may be unflavored or flavored with one or more of the following ingredients:

1. Salt.

2. Sugar, dextrose, corn sirup, invert sugar sirup, noninvert maltose sirup, glucose sirup, honey.

3. Any vinegar or any vinegar and water or any vinegar and water to which any vinegar has been added, or any one or more of the following: Any sugar other than sucrose which is the food which conforms to the definition and standards of identity of "cold-pack cheese food with fruits, vegetables, meats, or spices; identity; label statement of optional ingredients.

4. Monosodium glutamate.

5. Any suitable harmless food seasoning or flavoring (other than citrus oils, etc.) provided it does not impart to the mayonnaise or salad dressing the color imparted by egg yolk.

Mayonnaise may be mixed and packed in an atmosphere of nitrogen or carbon dioxide or nitrogen. Mayonnaise contains not less than 65 percent by weight of vegetable oil.

The acidifying ingredients referred to in paragraph (a) of this section are:

1. Any vinegar or any vinegar diluted with water to an acidity, calculated as acetic acid, of not less than 2½ percent by weight, or any such vinegar or diluted vinegar mixed with the additional optional acidifying ingredients specified in paragraph (b) of this section.

2. Lemon juice or lime juice or both or any such juices in frozen, canned, concentrated, or dried form, or any one or more of these used in water to an acidity, calculated as citric acid, of not less than 2½ percent by weight.

3. The egg-yolk-containing ingredients referred to in paragraph (a) of this section are: Egg yolk, whole, egg yolk, liquid whole eggs, broken eggs, or any one or more of the

4. Any vinegar or any vinegar diluted with water to an acidity, calculated as acetic acid, of not less than 2½ percent by weight.

5. Monosodium glutamate.

6. Any suitable harmless food seasoning or flavoring (other than citrus oils, etc.) provided it does not impart to the mayonnaise or salad dressing the color imparted by egg yolk.

7. Any natural or artificial flavoring.

Mayonnaise may be mixed and packed in an atmosphere of nitrogen or carbon dioxide or nitrogen. Mayonnaise contains not less than 65 percent by weight of vegetable oil.

The acidifying ingredients referred to in paragraph (a) of this section are:

1. Any vinegar or any vinegar diluted with water to an acidity, calculated as acetic acid, of not less than 2½ percent by weight, or any such vinegar or diluted vinegar mixed with the additional optional acidifying ingredients specified in paragraph (b) of this section.

2. Lemon juice or lime juice or both or any such juices in frozen, canned, concentrated, or dried form, or any one or more of these used in water to an acidity, calculated as citric acid, of not less than 2½ percent by weight.

3. The egg-yolk-containing ingredients referred to in paragraph (a) of this section are: Egg yolk, whole, egg yolk, liquid whole eggs, broken eggs, or any one or more of the

4. Any vinegar or any vinegar diluted with water to an acidity, calculated as acetic acid, of not less than 2½ percent by weight.
foregoing with liquid egg white or frozen egg white.

(g) When the additional optional acidifying ingredient as provided in paragraph (b) (1) of this section is used, the label shall bear the statement "Citric acid added" or "With added citric acid."

(2) Wherever the name "Mayonnaise" or "Mayonnaise Dressing" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this paragraph, showing the optional ingredients present, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 25.2 French dressing; identity; label statement of optional ingredients.

(a) French dressing is the separable liquid food or the emulsified viscous fluid food prepared from edible vegetable oil and one or both of the acidifying ingredients specified in paragraph (b) of this section. It may be seasoned or flavored with one or more of the following ingredients:

(1) Salt.

(2) Sugar, dextrose, corn syrup, invert sugar syrup, nonidiatetic molasses syrup, glucose syrup, honey. The foregoing sweetening ingredients may be used in sirup or dried form.

(3) Mustard, paprika, other spice, or spice oil or spice extract.

(4) Monosodium glutamate.

(5) Any suitable, harmless food seasoning or flavoring (other than limitations) provided it does not impart to the dressing the color imparted by egg yolk.

(b) The acidifying ingredients referred to in paragraph (a) of this section are:

(1) Any vinegar or any vinegar diluted with water, or any such vinegar or diluted vinegar mixed with the additional optional acidifying ingredient citric acid, but in any such mixture the weight of the acidifying ingredient is not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice or lime juice or both or any such juices in frozen, canned, concentrated, or dried form, or any one or more of these diluted with water. The optional emulsifying ingredients referred to in paragraph (a) of this section are: Gum acacia (also called gum arabic) carob bean gum (also called locust bean gum) guar gum, gum karaya, gum tragacanth, extract of Irish moss, pectin, propylene glycol ester of alginic acid, sodium carboxymethylcellulose, or any mixture of two or more of these. The quantity used of any such emulsifying ingredient or mixture amounts to not less than 2.5 percent by weight of the finished salad dressing.

(3) Sugar, dextrose, corn syrup, invert sugar syrup, nonidiatetic molasses syrup, glucose syrup, honey. The foregoing sweetening ingredients may be used in sirup or dried form.

(4) Mustard, paprika, other spice, or any spice oil or spice extract, except that no turmeric or saffron is used and no spice oil or spice extract is used which imparts to the salad dressing a color simulating the color imparted by egg yolk.

§ 25.3 Salad dressing; identity; label statement of optional ingredients.

(a) Salad dressing is the emulsified condensed prepared edible vegetable oil, one or both of the acidifying ingredients specified in paragraph (b) of this section, one or more of the egg-yolk-containing ingredients specified in paragraph (c) of this section, and a cooked or partly cooked starch paste prepared with a food starch, tapioca flour, wheat flour, rye flour, or any two or more of these. In the preparation of such starch paste water may be added. Salad dressing may be seasoned or flavored with one or more of the following ingredients:

(1) Salt.

(2) Sugar, dextrose, corn syrup, invert sugar syrup, nonidiatetic molasses syrup, glucose syrup, honey. The foregoing sweetening ingredients may be used in sirup or dried form.

(3) Mustard, paprika, other spice, or any spice oil or spice extract, except that no turmeric or saffron is used and no spice oil or spice extract is used which imparts to the salad dressing a color simulating the color imparted by egg yolk.

(b) The acidifying ingredients referred to in paragraph (a) of this section are:

(1) Any vinegar or any vinegar diluted with water, or any such vinegar or diluted vinegar mixed with the additional optional acidifying ingredient citric acid, but in any such mixture the weight of the acidifying ingredient is not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice or lime juice or both or any such juices in frozen, canned, concentrated, or dried form, or any one or more of these diluted with water. The optional emulsifying ingredients referred to in paragraph (a) of this section are: Gum acacia (also called gum arabic) carob bean gum (also called locust bean gum) guar gum, gum karaya, gum tragacanth, extract of Irish moss, pectin, propylene glycol ester of alginic acid, sodium carboxymethylcellulose, or any mixture of two or more of these. The quantity used of any such emulsifying ingredient or mixture amounts to not less than 2.5 percent by weight of the finished salad dressing.

(c) When the additional optional emulsifying ingredient as provided in paragraph (b) (1) of this section is used, the label shall bear the statement "Citric acid added" or "With added citric acid." When an optional emulsifying ingredient as provided in paragraph (c) of this section is used, the label shall bear the statement "__________ added" or "With added _________."

(d) The optional emulsifying ingredients referred to in paragraph (a) of this section are: Gum acacia (also called gum arabic) carob bean gum (also called locust bean gum) guar gum, gum karaya, gum tragacanth, extract of Irish moss, pectin, propylene glycol ester of alginic acid, sodium carboxymethylcellulose, or any mixture of two or more of these. The quantity used of any such emulsifying ingredient or mixture amounts to not less than 2.5 percent by weight of the finished salad dressing.

(f) Any suitable, harmless food seasoning or flavoring (other than limitations) provided it does not impart to the dressing the color imparted by egg yolk.

§ 25.4 Mayonnaise; identity; label statement of optional ingredients.

(a) Mayonnaise is the emulsified condensed prepared edible vegetable oil, one or both of the acidifying ingredients specified in paragraph (b) of this section, one or more of the egg-yolk-containing ingredients specified in paragraphs (c) and (d) of this section, and a cooked or partly cooked starch paste prepared with a food starch, tapioca flour, wheat flour, rye flour, or any two or more of these. In the preparation of such starch paste water may be added. Mayonnaise may be seasoned or flavored with one or more of the following ingredients:

(1) Salt.

(2) Sugar, dextrose, corn syrup, invert sugar syrup, nonidiatetic molasses syrup, glucose syrup, honey. The foregoing sweetening ingredients may be used in sirup or dried form.

(3) Mustard, paprika, other spice, or any spice oil or spice extract, except that no turmeric or saffron is used and no spice oil or spice extract is used which imparts to the salad dressing a color simulating the color imparted by egg yolk.

(b) The acidifying ingredients referred to in paragraph (a) of this section are:

(1) Any vinegar or any vinegar diluted with water, or any such vinegar or diluted vinegar mixed with the additional optional acidifying ingredient citric acid, but in any such mixture the weight of the acidifying ingredient is not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice or lime juice or both or any such juices in frozen, canned, concentrated, or dried form, or any one or more of these diluted with water. The optional emulsifying ingredients referred to in paragraph (a) of this section are: Gum acacia (also called gum arabic) carob bean gum (also called locust bean gum) guar gum, gum karaya, gum tragacanth, extract of Irish moss, pectin, propylene glycol ester of alginic acid, sodium carboxymethylcellulose, or any mixture of two or more of these. The quantity used of any such emulsifying ingredient or mixture amounts to not less than 2.5 percent by weight of the finished mayonnaise.

(c) When the additional optional emulsifying ingredient as provided in paragraph (b) (1) of this section is used, the label shall bear the statement "Citric acid added" or "With added citric acid." When an optional emulsifying ingredient as provided in paragraph (c) of this section is used, the label shall bear the statement "__________ added" or "With added _________."

(d) The optional emulsifying ingredients referred to in paragraph (a) of this section are: Gum acacia (also called gum arabic) carob bean gum (also called locust bean gum) guar gum, gum karaya, gum tragacanth, extract of Irish moss, pectin, propylene glycol ester of alginic acid, sodium carboxymethylcellulose, or any mixture of two or more of these. The quantity used of any such emulsifying ingredient or mixture amounts to not less than 2.5 percent by weight of the finished mayonnaise.

§ 25.5 Salad dressing; identity; label statement of optional ingredients.

(a) Salad dressing is the emulsified condensed prepared edible vegetable oil, one or both of the acidifying ingredients specified in paragraph (b) of this section, one or more of the egg-yolk-containing ingredients specified in paragraph (c) of this section, and a cooked or partly cooked starch paste prepared with a food starch, tapioca flour, wheat flour, rye flour, or any two or more of these. In the preparation of such starch paste water may be added. Salad dressing may be seasoned or flavored with one or more of the following ingredients:

(1) Salt.

(2) Sugar, dextrose, corn syrup, invert sugar syrup, nonidiatetic molasses syrup, glucose syrup, honey. The foregoing sweetening ingredients may be used in sirup or dried form.

(3) Mustard, paprika, other spice, or any spice oil or spice extract, except that no turmeric or saffron is used and no spice oil or spice extract is used which imparts to the salad dressing a color simulating the color imparted by egg yolk.

(b) The optional emulsifying ingredients referred to in paragraph (a) of this section are: Gum acacia (also called gum arabic) carob bean gum (also called locust bean gum) guar gum, gum karaya, gum tragacanth, extract of Irish moss, pectin, propylene glycol ester of alginic acid, sodium carboxymethylcellulose, or any mixture of two or more of these. The quantity used of any such emulsifying ingredient or mixture amounts to not less than 2.5 percent by weight of the finished salad dressing.

(c) When the additional optional emulsifying ingredient as provided in paragraph (b) (1) of this section is used, the label shall bear the statement "Citric acid added" or "With added citric acid." When an optional emulsifying ingredient as provided in paragraph (c) of this section is used, the label shall bear the statement "__________ added" or "With added _________."
ble gums," if two or more such vegetable gums are used. Label statements specified in this section for declaring the presence of optional ingredients may be combined, as for example, “with added citric acid and sodium carboxymethylcellulose.”

2. Wherever the name “Salad Dressing” appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this paragraph, showing the optional ingredients present, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

PART 27—CANNED FRUITS; DEFINITIONS AND STANDARDS OF IDENTITY; QUALITY, AND FILL OF CONTAINER

Sec.

27.0 Canned peaches; identity; label statement of optional ingredients.

27.1 Canned peaches; quality; label statement of substandard quality.

27.2 Canned apricots; identity; label statement of optional ingredients.

27.3 Canned peaches with rum; identity; label statement of optional ingredient.

27.4 Canned apricots with rum; identity; label statement of optional ingredient.

27.5 Canned pears; identity; label statement of optional ingredients.

27.6 Canned apricots; fill of container; label statement of substandard fill.

27.7 Canned pears; fill of container; label statement of substandard fill.

27.8 Canned apricots with rum; identity; label statement of optional ingredient.

27.9 Canned peaches; quality; label statement of substandard quality.

27.10 Canned apricots; fill of container; label statement of substandard fill.

27.11 Canned apricots with rum; identity; label statement of optional ingredient.

27.12 Canned pears; identity; label statement of optional ingredients.

27.13 Canned apricots with rum; identity; label statement of optional ingredient.

27.14 Canned apples; quality; label statement of substandard quality.

27.15 Canned apricots; fill of container; label statement of substandard fill.

27.16 Canned pears; fill of container; label statement of substandard fill.

27.17 Canned apricots with rum; identity; label statement of optional ingredient.

27.18 Canned apricot; identity; label statement of optional ingredient.

27.19 Canned apricots; fill of container; label statement of substandard fill.

27.20 Canned pears; identity; label statement of optional ingredients.

27.21 Canned pears; quality; label statement of substandard quality.

27.22 Canned pears; fill of container; label statement of substandard fill.

27.23 Canned pears; identity; label statement of optional ingredients.

27.24 Canned cherries; identity; label statement of optional ingredients.

27.25 Canned cherries; quality; label statement of substandard quality.

27.26 Canned cherries; fill of containers; label statement of substandard fill.

27.27 Canned cherries with rum; quality; label statement of optional ingredients.

27.28 Canned fruits cocktail, canned cocktail fruits, canned fruits for cocktail; identity; label statement of optional ingredients.

27.29 Canned fruits cocktail, canned cocktail fruits, canned fruits for cocktail; fill of container; label statement of substandard quality.


§ 27.0 Canned peaches; identity; label statement of optional ingredients. (a) Canned peaches is the food prepared from one of the optional peach ingredients specified in paragraph (b) of this section and one of the optional packing media specified in paragraph (c) of this section. Such food may be seasoned with one or more of the following optional ingredients: (1) Spice; (2) Flavoring, other than artificial flavoring; (3) A degreaser; (4) Peach pits, except in the cases of peeled whole peaches and unpeeled whole peaches, in a quantity not more than 1 peach pit per each 8 ounces of canned peaches, or canned express juice of mature peaches; (5) Peach kernels, except in the cases of peeled whole peaches and unpeeled whole peaches, and except when optional ingredient (4) is used. Such food is sealed in a container and is so processed by heat as to prevent spoilage.

(b) The optional peach ingredients referred to in paragraph (a) of this section are prepared from mature peaches, canned peaches, canned peaches with rum, white clingstone, or white freestone varietal group, and are in the following forms of units: peeled whole, unpeeled whole, peeled halves, unpeeled halves, peeled quarters, peeled slices, peeled dice, peeled mixed pieces of irregular sizes and shapes. Each such form of units prepared from each such varietal group is an optional peach ingredient. Each such ingredient, except in the case of peeled whole peaches and unpeeled whole peaches, is pitted. For the purpose of paragraph (e) of this section, the names of such optional peach ingredients are the words “Yellow Cline” or “Yellow Cline clingstone,” “White Cline” or “White Cline clingstone,” “Yellow Free” or “Yellow Freeestone,” or “White Free” or “White Freestone,” as the case may be, preceded or followed by the word or words “Whole,” “Unpeeled Whole,” “Halves” or “Halved,” “Unpeeled Halves,” or “Unpeeled Halved,” “Quartered,” or “Quarters,” or “Sliced,” or “Slices,” “Dice” or “Diced,” or “Mixed Pieces of Irregular Sizes and Shapes,” as the case may be.

(c) (1) The optional packing media referred to in paragraph (a) of this section are:

   (i) Water.
   (ii) Peach juice.
   (iii) Slightly sweetened water.
   (iv) Light sirup.
   (v) Heavy sirup.
   (vi) Extra heavy sirup.
   (vii) Slightly sweetened peach juice.
   (viii) Light peach juice sirup.
   (ix) Heavy peach juice sirup.
   (x) Extra heavy peach juice sirup.

As used in this subparagraph the term “water” means, in addition to water, any mixture of water and peach juice; and the term “peach juice” means the fresh expressed juice of mature peaches, of any varietal group specified in paragraph (b) of this section, to which no water is added, directly or indirectly.

(2) Each of packing media (1) (ii) to (x) inclusive, is prepared with a liquid ingredient and a saccharine ingredient. Water is the liquid ingredient from which packing media (1) (ii) to (vi) inclusive, are prepared, and peach juice is the liquid ingredient from which packing media (1) (vii) to (x) inclusive, are prepared. The saccharine ingredient from which packing media (1) (iii) to (x) inclusive, are prepared is one of the following: Sugar: any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn syrup or glucose sirup in which the weight of the solids of the dextrose used is not more than one-third the weight of the solids of the sugar used; or any combination of sugar, dextrose, and corn syrup or glucose sirup in which the weight of the solids of the dextrose used added to three times the weight of the solids of the corn syrup or glucose sirup used is not more than the weight of the solids of the sugar used.

(d) The respective densities of packing media (1) (ii) to (x), inclusive, as measured on the U.S. Hydrometer, are more after the peaches are canned, are within the range prescribed for each in the following list:

   Number of packing media: (Briss measurement)
   (1) (ii) and (vii) ... 19'
   (1) (iii) and (viii) ... 24'
   (1) (iv) and (viii) ... 24 to more but less than 21'
   (1) (v) and (ix) ... 21 to more but less than 19'
   (1) (vi) and (x) ... 24 to more but not more than 25'

For the purposes of this section:

(1) The term “invert sugar sirup” means an aqueous solution of invert or partially inverted, refined or partially refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless, except for sweetness.

(2) The term “dextrose” means the hydrated or anhydrous, refined monosaccharides obtained from hydrolyzed starch.

(3) The term “corn sirup” means an aqueous solution obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup; the solids of corn sirup and of dried corn sirup contain not less than 58 percent by weight of reducing sugars.

(4) The term “glucose syrup” means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. “Dried glucose sirup” means the product obtained by drying “glucose sirup.”

(e) The label shall bear the name of the optional peach ingredient used, as specified in paragraph (b) of this section, and the name whereby the optional packing medium used is designated in paragraph (e) of this section, preceded by “In” or “Packed in.” When any of
the optional ingredients permitted by one of the following specified subparagraphs (a) of this section is used, the label shall bear the words set forth below after the number of such subparagraphs:

(1) "Spiced" or "Spice Added" or "With Added Spice," or in lieu of the word "Spice," the common name of the spice;

(2) "Flavoring Added" or "With Added Flavoring," or in lieu of the word "Flavoring," the common name of the flavoring;

(3) "Seasoned with Vinegar" or "Seasoned with _________ Vinegar," the blank being filled in with the word showing the kind of vinegar used;

(4) "Seasoned with Peach Pits";

(5) "Seasoned with Peach Kernels".

When two or more of the optional ingredients specified in paragraph (a) (1) (2) (3) and (4) or (5) of this section are used, such words may be combined, as for example, "Seasoned with Cider Vinegar, Tongue, Cinnamon Oil, and Peach Kernels."

(5) Wherever the name "peaches" appears on the label so conspicuously as to be easily seen under the customary conditions of purchase, the words specified in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter, except that the specific varietal name of the peaches may so intervene.

§ 27.1 Canned peaches; quality; label statement of standard quality.

(a) The standard of quality for canned peaches is as follows:

(1) All units tested in accordance with the method prescribed in paragraph (b) of this section are packed by a weight of not more than 300 grams.

(2) In the cases of halves and quarters, the weight of each unit is not less than ½ ounce, respectively, respective.

(3) In the cases of whole peaches, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein.

(4) Except in the case of unpeeled peaches, there is present in the finished canned peaches not more than 1 square inch of peel per each 1 pound of net contents.

(5) Not more than 20 percent of the units in the container are blemished with scar, blemish, discoloration, or other abnormality.

(6) In the cases of whole peaches, halves, quarters, and slices, all units are untrimmed, or are so trimmed as to preserve normal shape.

(7) Except in the case of mixed pieces of irregular sizes and shapes, not more than 5 percent of the units in a container of 20 or more units, and not more than one unit in a container of less than 20 units, is crushed or broken. (A unit which has lost its normal shape because of ripeness and which bears no mark of crushing shall not be considered to be crushed or broken.)

(b) Canned peaches shall be tested by the following method to determine whether or not they meet the requirements of paragraph (a) (1) of this section:

Tram a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of ½ inch inside diameter, with vertical and side sloping downward and joining; then at the center of the receptacle is ½ inch. Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing units other than whole units. Test no unit from which a test piece with rectangular peel surface at least ½ inch by 1 inch cannot be trimmed. Test the piece by means of a round metal rod ½ inch in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward and downward and which forms the rim of the rod. The rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams. Set the receptacle so that the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 15 grams per second until the test piece is held by the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(e) If the quality of canned peaches falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement: "Below Standard In Quality,..." the blank to be filled in with the words specified after the corresponding number of each clause of paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement: "Partly Crushed or Broken." Such alternative statement shall immediately and conspicuously precede or follow such intervening written, printed, or graphic matter, the name "Peaches" and any words and statements required or authorized to appear with such name by § 27.0 (b).
(vii) Slightly sweetened apricot juice.

(viii) Light apricot juice sirup.

(ix) Heavy apricot juice sirup.

(x) Extra heavy apricot juice sirup.

As used in this subparagraph the term “water” means, in addition to water, any mixture of water and apricot juice; and the term “apricot juice” means the fresh or canned juice of mature apricots to which no water is added, directly or indirectly.

(2) Each of packing media (1) to (x) inclusive, is prepared with a liquid ingredient or mixture of liquid ingredients. Water is the liquid ingredient from which packing media (1) to (x) inclusive, are prepared, and apricot juice is the liquid ingredient from which packing media (1) to (x) inclusive, are prepared. The saccharine ingredient from which packing media (1) to (x) inclusive, are prepared, is one of the following: Sugar; any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar used; any combination of sugar, dextrose, and corn sirup or glucose sirup in which the weight of the solids of the dextrose used added to three times the weight of the solids of the corn sirup or glucose sirup used is not more than the weight of the solids of the sugar used; except that packing media (1) (vii) to (x) inclusive, are not prepared with any invert sugar sirup or with any corn sirup other than dried corn sirup or with any glucose sirup other than dried glucose sirup. A packaging medium prepared with apricot juice and any invert sugar sirup or corn sirup other than dried corn sirup or glucose sirup other than dried glucose sirup is considered to be prepared with water as the liquid ingredient.

(3) The term “corn sirup” means an aqueous solution obtained by the complete hydrolysis of starch, and includes dried corn sirup; the solids of corn sirup and of dried corn sirup contain not less than 58 percent by weight of reducing sugars calculated as anhydrous dextrose. The solids of glucose sirup contain not less than 40 percent by-weight of reducing sugars calculated as anhydrous dextrose. “Dried glucose sirup” means the product obtained by drying “glucose sirup.”

(e) The label shall bear the name of the optional apricot ingredient used, as specified in paragraph (b) of this section, and the name whereby the optional packing medium used is designated in paragraph (c) of this section, preceded by “In” or “Packed in.” When any optional ingredient permitted by one of the following specified subparagraphs of paragraph (a) is used, the labels shall bear the words set forth below after the number of such subparagraph.

(1) “Invert sugar sirup” means an aqueous sirup other than dried glucose sirup.

(2) “Flavoring Added” or “With Added Spice,” or, in lieu of the word “Spice,” the common name of the spice;

(3) “Seasoned with Vinegar” or “Seasoned with _____________ Vinegar,” the blank being filled in with the word showing the kind of vinegar used;

(4) “Seasoned with Apricot Pits”;

(5) “Seasoned with Apricot Kernels.”

When two or more of the optional ingredients specified in paragraph (a) (1) (3) and (4) or (5) of this section are used, such words may be combined, as for example, “Seasoned with Cider Vinegar, Cloves, Cinnamon Oil, and Apricot Kernels.”

(f) Wherever the name “apricots” appears on the label so conspicuously as to be easily seen under the customary conditions of purchase, in the cases of whole apricots, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit thereof trimmed, or are so trimmed as to prevent, hall injury, discoloration, or other abnormalities;

(g) In the cases of whole apricots, halves, and quarters, all units are untrimmed, or are so trimmed as to preserve normal shape;

(h) Except for mixed pieces of irregular sizes and shapes, not more than 5 percent of the units in a container of 20 or more units, and not more than 1 unit in a container of less than 20 units, is crushed or broken. (A unit which has lost its normal shape because of ripeness and which bears no mark of crushing shall not be considered to be crushed or broken.)

(b) canned apricots shall be tested by the following method to determine whether or not they meet the requirements of paragraph (a) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of 1 ⅛ inches inside diameter, with vertical sides; or a rectangular receptacle, 1 inch wide and 1 inch high, with vertical sides sloping downward and joining at the center at a vertical depth of 1 inch. Use the same procedure for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with rectangular peel surface at least ½ inch by 1 inch cannot be trimmed. Test the piece by means of a round metal rod ⅛ inch in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams. Set the receptacle so that the surface of the test piece is in firm contact with the upper end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 10 grams per second until the rod pierces the test piece. When the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(c) If the quality of canned apricots falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of sub-standard quality specified in § 27.10, of this chapter, in the manner and form therein specified, but in lieu of such general statement of sub-standard quality, the label may bear the following statement “Below Standard in Quality———.” the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (a) of this section which such canned apricots fail to meet.
In case the units are whole or halves and are unpeeled, by the word "Unpeeled.

(c) The term "optional packing medium" referred to in paragraph (a) of this section are:

(i) Water.
(ii) Pear Juice.
(iii) Slightly sweetened water.
(iv) Light sirup.
(v) Heavy sirup.
(vi) Extra heavy sirup.
(vii) Slightly sweetened pear juice.
(viii) Light pear juice sirup.
(ix) Heavy pear juice sirup.
(x) Extra heavy pear juice sirup.

As used in this subparagraph the term "water" means, in addition to water, any mixture of water and pear juice; and the term "pear juice" means the fresh or canned expressed juice of mature pears to which no water is added, directly or indirectly.

(2) Each of packing media (1) (iii) to (vii) inclusive, is prepared with a liquid ingredient and a saccharine ingredient. Water is the liquid ingredient from which packing media (1) (ii) to (vii) inclusive, are prepared; and pear juice is the liquid ingredient from which packing media (1) (vii) to (x), inclusive, are prepared. The saccharine ingredient from which packing media (1) (iii) to (vii) inclusive, are prepared is one of the following: Sugar; any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar used; or any combination of sugar, dextrose, and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than the weight of the solids of the sugar used; or any combination of sugar and dextrose with any invert sugar sirup or with any corn sirup other than dextrose corn sirup or with any glucose sirup other than dextrose glucose sirup. A packing medium prepared with pear juice and any invert sugar sirup or corn sirup other than dextrose corn sirup or glucose sirup other than dextrose glucose sirup is considered to be prepared with water as the liquid ingredient.

(3) The respective densities of packing media (1) (iii) to (x), inclusive, as measured on the Brix hydrometer 15 days or more after the pears are canned, are within the range prescribed for each in the following list:

<table>
<thead>
<tr>
<th>Number of Packing Media</th>
<th>Brix Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) (iii) and (vii)</td>
<td>Less than 14°</td>
</tr>
<tr>
<td>(1) (iv) and (viii)</td>
<td>14° or more but less than 16°</td>
</tr>
<tr>
<td>(1) (v) and (ix)</td>
<td>18° or more but less than 20°</td>
</tr>
<tr>
<td>(1) (vi) and (x)</td>
<td>22° or more but not more than 25°</td>
</tr>
</tbody>
</table>

(d) For the purposes of this section:

(1) The term "invert sugar sirup" means an aqueous solution of inverted or partly inverted, refined or partly refined sugars, any combination of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

(2) The term "invert sugar sirup" means the hydrated or anhydrous, refined monosaccharide obtained from hydrolyzed starch.

(3) The term "corn sirup" means an aqueous solution obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup; the solids of corn sirup and of dried corn sirup contain not less than 5 percent by weight of reducing sugars.

(4) The term "dextrose" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of dextrose sirup contain not less than 50 percent by weight of reducing sugars.

(5) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 50 percent by weight of reducing sugars.

(6) The term "invert sugar sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of invert sugar sirup contain not less than 50 percent by weight of reducing sugars.

(7) The term "invert sugar sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of invert sugar sirup contain not less than 50 percent by weight of reducing sugars.

(8) The term "invert sugar sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of invert sugar sirup contain not less than 50 percent by weight of reducing sugars.

(9) The term "invert sugar sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of invert sugar sirup contain not less than 50 percent by weight of reducing sugars.
(1) All units tested in accordance with the method prescribed in paragraph (5) of this section are poured by a weight of not more than 300 grams;
(2) In the cases of halves and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein;
(3) In the cases of whole pears, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein;
(4) Except in the case of unpeeled pears, there is present in the finished canned pears no more than one inch of peel per each 1 pound of net contents;
(5) Not more than 20 percent of the units in the container are blemished with scab, knot injury, discoloration, or other abnormalities;
(6) In the cases of whole pears, halves, and quarters, all units are untrimmed, or are so trimmed as to preserve normal shape; and
(7) Except in the case of mixed pieces of irregular shapes and shapes, not more than 10 percent of the units in a container of 10 and 20 units, and not more than 1 unit in a container of less than 10 units, is crushed or broken. A unit which has lost its normal shape because of pippiness and which bears no mark of crushing shall not be considered to be crushed or broken.

(b) Canned pears shall be tested by the following method to determine whether or not they meet the requirements of paragraph (a) (1) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled remove the peel. The top of the receptacle is circular in shape of 3/4 inches inside diameter, with vertical sides; or rectangular in shape, 3/8 inch by 1 inch inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of 3/8 inch. Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece failed to be trimmed, or are so trimmed as to fit, with peel surface up, into a supporting receptacle.

§ 27.22 Canned pears; fill of container; label statement of substandard fill. (a) The standard of fill of canned pears is the maximum quantity of the optional pear ingredient which can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(b) If canned pears fail below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 27.23 (b) of this chapter, in the manner and form therewith specified.

§ 27.23 Canned pears with rum, identity; label statement of optional ingredients. Canned pears with rum contain the definition of identity, and are subject to the requirements for label statement of optional ingredients prescribed for canned pears by § 27.21, except that it contains added rum in such amount that its alcoholic content is more than 3 percent but less than 5 percent by weight.

§ 27.20 Canned cherries; identity; label statement of optional ingredients. (a) Canned cherries is the food prepared from mature cherries of the red sour, light sweet, or dark sweet variety group. Pitted cherries of each such group and unpitted cherries of each such group are an optional cherry ingredient. For the purposes of paragraph (a) of this section, the names of such optional cherry ingredients are red sour "Red Sour" or "Red Tart," light sweet "Light Sweet" or "Dark Sweet," as the case may be, preceded or followed by the word "ingredient" in case such ingredients are pitted.

(c) (1) Optional packing media referred to in paragraph (a) of this section are:
   (i) Water,
   (ii) Cherry juice,
   (iii) Slightly sweetened water,
   (iv) Light sirup,
   (v) Sirup,
   (vi) Extra heavy sirup,
   (vii) Slightly sweetened cherry juice,
   (viii) Light cherry juice sirup,
   (ix) Heavy cherry juice sirup,
   (x) Extra heavy cherry juice sirup.

As used in this subparagraph the term "water" means, in addition to water, any mixture of water and cherry juice; and the term "cherry juice" means the fresh or canned expressed juice of mature cherries, of any varietal group specified in paragraph (2) of this section, to which no water is added directly, or indirectly.

(b) Each of packing media (1) (i) to (x) inclusive, is prepared with a liquid ingredient and a water ingredient. Water is the liquid ingredient from which packing media (1) (i) to (vi), inclusive, are prepared, and cherry juice is the liquid ingredient from which packing media (1) (vii) to (x) inclusive, are prepared. The saccharine ingredient from which packing media (1) (i) to (x), inclusive, are prepared is one of the following: Sugar; any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn sirup and glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar used; any combination of sugar and glucose sirup other than dried corn sirup or with any glucose sirup other than dried glucose sirup.

(c) The respective densities of packing media (1) (i) to (x), inclusive, as measured on the Brix hydrometer 18 days or more after the cherries are canned, are within the range prescribed for each item in the following list:
Number of packing medium:

In case of sweet cherries:
- (1) and (iii) - Less than 18".
- (1) (iv) and (viii) - 18" or more but less than 20".
- (1) (v) and (ix) - 20" or more but less than 22".
- (1) (vi) and (x) - 22" or more but less than 25".

In case of sour cherries:
- (1) (ii) and (vii) - Less than 18".
- (1) (iv) and (viii) - 18" or more but less than 20".
- (1) (v) and (ix) - 20" or more but less than 22".
- (1) (vi) and (x) - 22" or more but less than 25".

(d) For the purposes of this section:
- The term "sugar" means refined sucrose or invert sugar syrup. The term "invert sugar syrup" means an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

(2) The term "dextrose" means the product obtained by complete hydrolysis of any edible starch.

(3) The term "corn sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch.

(4) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch.

(5) The term "syrup" means a colorless, odorless, and flavorless aqueous solution of sugars calculated by reducing sugars by 100.

(c) The term "syrup" includes dried corn sirup; the solids of corn sirup contain not more than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

For the purposes of this section:
- The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.
- The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of glucose sirup contain not more than 40 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

The solids of corn sirup contain less than 23.5 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.
RULES AND REGULATIONS

media specified in paragraph (c) of this section. It is sealed in a container and is so processed by heat as to prevent spoilage.

(b) The fruit ingredients referred to in paragraph (a) of this section, the forms of each, and the percent by weight of each in the mixture of drained fruit from the first canned fruit cocktail are as follows:

1. Peaches of any yellow variety, which are peeled, cored, and diced, not less than 15 percent and not more than 30 percent;
2. Pears of any variety, which are peeled, cored, and diced, not less than 25 percent and not more than 35 percent;
3. Whole juiced cherry variety, not less than 6 percent and not more than 20 percent;
4. Pineapples of any variety, which are peeled, cored, and cut into sectors or into dice, not less than 6 percent and not more than 16 percent; and
5. One of the following optional corn sirup ingredients, each of which is stemmed, pitted, and cut into approximate halves, not less than 2 percent and not more than 5 percent;
   1) Cherries of any light, sweet variety;
   2) Cherries artificially colored red; or
   3) Cherries artificially colored red and artificially flavored.

Each such fruit ingredient is prepared from mature fruit which is fresh or canned. Notwithstanding the preceding provisions of this paragraph, each 4 1/2 ounces average of the drained canned fruit cocktail and each fraction thereof greater than 4 1/2 ounces average contain not less than 2 sectors or 3 dice of pineapple and not less than 1 approximate half of the optional cherry ingredient.

(c) (1) The optional packing media referred to in paragraph (a) of this section are as follows:

1) Water,
2) Fruit juice,
3) Light syrup,
4) Heavy syrup,
5) Extra heavy syrup,
6) Light fruit juice sirup,
7) Heavy fruit juice sirup.

(2) Each of packing media (1) (iii) (iv) and (v) is prepared with water as its liquid ingredient, and each of packing media (1) (vii) and (viii) is prepared with fruit juice as its liquid ingredient. Except as provided in paragraph (d) of this section, each of packing media (1) (iii) to (vii) inclusive, is prepared with any one of the following saccharine ingredients:

Sugar;
Any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar used; or any combination of sugar, dextrose, and corn sirup or glucose sirup in which the weight of the solids of the dextrose used multiplied by two, added to the weight of the solids of the corn sirup or glucose sirup used multiplied by three, is not more than the weight of the solids of the sugar used.

The respective densities of packing media (1) (iii) to (viii) inclusive, as measured on the Brix hydrometer 15 days or more after the fruit cocktail is canned are as prescribed for each in the following list:

<table>
<thead>
<tr>
<th>Number of packing medium</th>
<th>Brix measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) (iii) and (vii)</td>
<td>15° or more but less than 18°</td>
</tr>
<tr>
<td>(1) (iv) and (vii)</td>
<td>18° or more but less than 23°</td>
</tr>
<tr>
<td>(1) (v) and (viii)</td>
<td>23° or more but not more than 35°</td>
</tr>
</tbody>
</table>

(d) For the purposes of this section:

1) The term “water” means, in addition to water, both the liquid drained from any fruit ingredient previously canned in water as its sole packing medium and any mixture of water and fruit juice, including the liquid drained from any fruit ingredient previously canned in a packing medium consisting wholly of the liquid and saccharine ingredients of a light sirup, heavy sirup, or extra heavy sirup.
2) The term “fruit juice” means the fresh or canned, expressed juice or juices of one or more of the mature fruits named in paragraph (b) of this section previously canned or boiled from any fruit ingredient previously canned in such juice or juices as its sole packing medium, to which no water has been added, directly or indirectly. Fruit juice may be strained or filtered.
3) The term “sugar” means refined sucrose or invert sugar sirup. The term “invert sugar sirup” means an aqueous sirup of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash and which is colorless, odorless and flavorless except for sweetness.
4) The term “dextrose” means the hydrated or anhydrous, refined monosaccharide obtained from hydrolyzed starch.
5) The term “corn sirup” means the liquid ingredient obtained from clarified, concentrated, aqueous solution of the products obtained by the complete hydrolysis of any edible starch. The solids of sugar sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. “Dried glucose sirup” means the product obtained by drying “glucose sirup.”

When the optional packing medium is prepared with fruit juice and invert sugar sirup or corn sirup other than dried corn sirup, or glucose sirup other than that used for glucose sirup, it shall be considered to be light sirup, heavy sirup, or an extra heavy sirup, as the case may be, and not a light fruit juice sirup, heavy fruit juice sirup, or an extra heavy fruit juice sirup.

The term “light sirup,” “heavy sirup,” or “extra heavy sirup” includes a sirup which conforms in all other respects to the provisions of this paragraph, each 4 1/2 ounces of which contains not more than 180 and 220 or more but not liquid and saccharine ingredients of light fruit juice sirup, heavy fruit juice sirup, or extra heavy fruit juice sirup.

(e) The optional ingredients specified in paragraphs (b) (ii) and (iii) and (c) (1) to (8) of this section, inclusive, are hereby designated as optional ingredients which, when used, shall be named on the label by the name whereby each is so specified.

Such names shall immediately and conspicuously, without intervening written, printed, or graphic matter, precede or follow the name “fruit cocktail,” “cocktail fruits,” or “fruits for cocktail” wherever it appears on the label so conspicuously as to be easily seen under customary conditions of purchase.

§ 27.41 Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail; quality; label statement of substandard quality. (a) The standards of quality for canned fruit cocktail is as follows:

1) Not more than 20 percent by weight of the units of peach or pear, or of pineapple if the units thereof are diced, are more than 3/4 inch in greatest edge dimension, or pass through the meshes of a sieve designated as 5/30 inch in Table I of “Standard Specifications for Sieves,” published March 1, 1940, in L. C. 584 of the National Bureau of Standards, United States Department of Commerce. If the units of pineapple are in the form of rings, not more than 20 percent of such units in the container fail to conform to the following dimensions: The length of the outside ring is not more than 0.33 times the 3/16 inch; the thickness is not more than 0.34 inch but is more than 0.3 inch; the length (measured along the radius from the inside arc to the outside arc) is not more than 1 1/4 inches but is more than 3/4 inch.

2) Not more than 10 percent of the grapes in a container containing 10 grapes or more, and not more than 1 grape in a container containing less than 10 grapes, is cracked to the extent that being severed into two parts or is crushed to the extent that their normal shape is destroyed.

3) Not more than 10 percent of the grapes in a container containing 10 grapes or more, and not more than 1 grape in a container containing less than 10 grapes, has the cap stem attached.

4) There is present in the finished canned fruit cocktail not more than 1 square inch of pear peel per each 1 pound of drained weight of units of pear.
plus the weight of a proportion of the packing medium which is the same proportion as the drained weight of the units of peach bears to the drained weight of the entire contents of the can. Such drained weights shall be determined by the method prescribed in § 27.42.

§ 27.42 Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail; fill of container; label statement of standard fill. (a) The standard of fill of container for canned fruit cocktail is a fill such that the total weight of drained fruit plus the weight of a proportion of the packing medium which is the same proportion as the drained weight of units of peach bears to the drained weight of the entire contents of the can. Such drained weights shall be determined by the method prescribed in § 27.42.

(b) If the quality of canned fruit cocktail falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of the standard fill prescribed in § 10.2 (b) of this chapter, in the manner and form therein prescribed.

PART 29—FRUIT BUTTERS, FRUIT JELLIES, FRUIT PRESERVES, AND RELATED PRODUCTS; DEFINITIONS AND STANDARDS OF IDENTITY

Sec. 29.1 Fruit butter; identity; label statement of optional ingredients.

29.2 Fruit jelly; identity; label statement of optional ingredients.

29.3 Preserves, jams; identity; label statement of optional ingredients.


§ 29.1 Fruit butter; identity; label statement of optional ingredients. (a) The fruit butters for which definitions and standards of identity are prescribed by this section are the smooth, cream-colored foods each of which is made from a mixture composed of not less than five parts by weight (as determined by the method prescribed in paragraph (b) (1) of this section) of one or any combination of two, three, four, or five of the optional fruit ingredients specified in paragraph (e) of this section to each two parts by weight (see paragraph (e) (1) of this section) of one of the optional saccharine ingredients specified in paragraph (d) of this section, except that the use of such saccharine ingredient is not required when optional ingredient (5) is used. Such mixture may be seasoned with one or more of the following optional ingredients:

(1) Spice.

(2) Flavoring (other than artificial flavoring).

(3) Salt.

(4) A vinegar, lemon juice, lime juice, citric acid, lactic acid, malic acid, tartaric acid, or any combination of two or more of these. Such mixture may also contain the optional ingredient:

(5) Fruit juice or diluted fruit juice or concentrated fruit juice (optional ingredient) (5) from a fruit prescribed in paragraph (e) of this section.

(b) If the optional fruit ingredients referred to in paragraph (a) of this section is prepared by cooking one of the following items canned, and/or dried (evaporated) mature fruits, with or without added water, and screening out skins, seeds, pits, and cores:

Factor referred to in paragraph (b) (1) of this section

<table>
<thead>
<tr>
<th>Name of fruit</th>
<th>Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple</td>
<td>7.5</td>
</tr>
<tr>
<td>Apricot</td>
<td>7.0</td>
</tr>
<tr>
<td>Grape</td>
<td>9.0</td>
</tr>
<tr>
<td>Peach</td>
<td>6.5</td>
</tr>
<tr>
<td>Plum (other than prunes)</td>
<td>6.5</td>
</tr>
<tr>
<td>Prune</td>
<td>7.0</td>
</tr>
<tr>
<td>Quince</td>
<td>7.5</td>
</tr>
</tbody>
</table>

In any combination of two, three, four, or five fruit ingredients, the weight of each is not less than one-fifth of the weight of the combination.

(d) The optional saccharine ingredients referred to in paragraph (a) of this section are:

(1) Sucrose.

(2) Invert sugar syrup.

(3) Brown sugar.

(4) Invert brown sugar syrup.

(5) Honey.

(6) Any combination of two or more of optional saccharine ingredients (1), (2), (3), and (4).

(7) Any combination of dextrose and optional saccharine ingredient (1), (2), (3), and (4).

(8) Any combination composed of corn syrup, dried corn syrup, glucose syrup, dried glucose syrup, or any two or more of the foregoing, with optional saccharine ingredient (1), (2), (3), and (4) of (7), in which the weight of the solids of corn syrup, dried corn syrup, glucose syrup, dried glucose syrup, or the sum of the weights of the solids of corn syrup, dried corn syrup, glucose syrup, and dried glucose syrup, in case two or more of these are used, does not exceed one-fourth of the total weight of the solids of the combined saccharine ingredients.
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honey is not less than one-tenth of the weight of the solids of such combination, and the weight of honey solids is not less than two-fifths of the weight of the solids of such combination.

(e) For the purposes of this section:

(1) The term “invert sugar syrup” means the weight of the solids of such ingredient.

(2) The term “sugar” means refined sugar (sucrose).

(3) The term “invert sugar syrup” means a sirup made by inverting or partly inverting sugar or partly refined sugar. Its ash content is not more than 0.3 percent of its solids content, but if it is made from partly refined sugar, color and flavor other than sweetness are removed.

(4) The term “invert brown sugar syrup” means a sirup made by inverting or partly inverting brown sugar.

(5) The term “corn sirup” means a clarified, concentrated aqueous solution of the products obtained by the incomplete hydrolysis of cornstarch. The solids of corn sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(6) The term “glucose sirup” means a clarified, aqueous solution of the products obtained by the incomplete hydrolysis of edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. “Dried glucose sirup” means the product obtained by drying “glucose sirup.”

(7) The term “dextrose” means refined anhydrous or hydrated dextrose made from any starch.

(8) The name of each fruit butter for which a definition and standard of identity is prescribed by this section is as follows:

(a) In case the fruit butter is made from a single fruit ingredient, the name is “Butter,” preceded by the name whereby such fruit is designated in paragraph (a) of this section.

(b) In case the fruit butter is made from a combination of two, three, four, or five fruit ingredients, the name is “Butter,” preceded by the common names of the components of the combination whereby such components are designated in paragraph (a) of this section, in the order of predominance. Such mixture is concentrated, dried, and the weight of such ingredients in the combination. Such name shall be preceded by the words “evaporated” or “dried,” followed by the name whereby such fruit is designated in paragraph (a) of this section. When two or more such optional fruit ingredients are used, the name whereby the words “evaporated” or “dried” shall be in the order of predominance, if any, of the weights of such ingredients in the combination.

(9) When a combination of two, three, four, or five optional fruit ingredients is used, and the fruit butter is designated on its label by the name “Mixed Fruit Butter,” the label shall bear the name whereby the fruits from which such ingredients are prepared are designated in paragraph (a) of this section, in the order of predominance, if any, of the weights of such ingredients in the combination.

(10) When optional ingredient (a) (2) of this section appears on its label, the label shall bear the word “spiced” or the statement of optional ingredients used, and the fruit butter is designated by the word whereby the fruits from which such ingredients are prepared are designated in paragraph (a) of this section, in the order of predominance, if any, of the weights of such ingredients in the combination.

(11) The label statements required by subparagraphs (1) and (2) of this paragraph may be combined, as for example, “canned apple and clove added.” The label statements required by two or more of subparagraphs (3) (4) (5) (6) and (7) of this paragraph may be combined, as for example, “prepared with cider, apples, dried prunes, and honey.”

(12) Wherever the name specified in paragraph (a) of this section appears on the label of the fruit butter so conspicuously as to be easily seen under customary conditions of purchase, the words and statements specified in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the varietal name of the fruit used in preparing such fruit butter may be so interposed.

§ 29.2 Fruit jelly; identity; label statement of optional ingredients. (a) The jellies for which definitions and standards of identity are prescribed by this section are the jellied foods each of which is majorly composed of not less than 45 parts by weight as determined by the method prescribed in paragraph (b) of this section of one or any combination of two, three, four, or five of the fruit juices specified in paragraph (a) of this section to each 50 parts by weight (see paragraph (e) (1) of this section) of one of the optional saccharine ingredients specified in paragraph (d) of this section. Such mixture may also contain one or more of the following optional ingredients:

(1) Spice.

(2) A vinegar, lemon juice, lime juice, citric acid, lactic acid, malic acid, tartaric acid, or any combination of two or more of these, in a quantity which reasonably compensates for deficiency, if any, of the natural acidity of the fruit juice ingredient.

(3) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit juice ingredient.

(4) Sodium citrate, sodium potassium tartrate, or any combination of these, in a quantity the proportion of which is not more than 20 percent equivalent to each 100 pounds of the saccharine ingredient used.

(5) Sodium benzoate or benzoic acid, or any combination of these, in a quantity reasonably necessary as a preservative.

(6) Mint flavoring and harmless artificial green coloring, in case the fruit juice ingredient or combination of fruit juice ingredients is extracted from apple, crabapple, pineapple, or two or more of such fruits.

Such mixture is concentrated by heat to such point that the soluble-solids content of the finished jelly is not less than 45 percent as determined by the method prescribed in “Official Methods of Analysis of the Association of Official Agricultural Chemists,” Seventh Edition, page 455, Ed. note, 8th edition, 1965, p. 634, sec. 29.111, under “Solids by Means of Refractometer—Official.”

(b) Any requirement of this section with respect to the weight of any fruit ingredient, whether concentrated, unconcentrated, or diluted, means the weight determined by the following method: Determine the percent of soluble solids in such fruit juice ingredient by the method for soluble solids referred to in paragraph (a) of this section; multiply the percent so found by the weight of such fruit juice ingredient; divide the result by 9.0; subtract from the quotient the weight of any added sugar or other added solids; and multiply the remainder by the factor for such fruit juice ingredient prescribed in paragraph (e) of this section. Each of the fruit juice ingredients referred to in paragraph (a) of this section is the filtered or strained liquid extracted with or without the application of heat and with or without the addition of water, from one of the following mature, properly prepared fruits which are fresh, frozen and/or canned:

<table>
<thead>
<tr>
<th>Name of fruit</th>
<th>Factor referred to in paragraph (b) of this section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple</td>
<td>7.0</td>
</tr>
<tr>
<td>Apricot</td>
<td>7.0</td>
</tr>
<tr>
<td>Blackberry (other than boysenberry)</td>
<td>10.0</td>
</tr>
<tr>
<td>Black raspberry</td>
<td>9.0</td>
</tr>
<tr>
<td>Cherry</td>
<td>7.0</td>
</tr>
<tr>
<td>Cranberry</td>
<td>0.5</td>
</tr>
<tr>
<td>Cranberry</td>
<td>0.5</td>
</tr>
<tr>
<td>Damson</td>
<td>7.0</td>
</tr>
<tr>
<td>Dewberry (other than boysenberry, loganberry, and youngberry)</td>
<td>10.0</td>
</tr>
<tr>
<td>Fig</td>
<td>5.0</td>
</tr>
<tr>
<td>Goose</td>
<td>7.0</td>
</tr>
<tr>
<td>Grape</td>
<td>7.0</td>
</tr>
<tr>
<td>Grapefruit</td>
<td>11.0</td>
</tr>
<tr>
<td>Guava</td>
<td>7.0</td>
</tr>
<tr>
<td>Guava</td>
<td>13.0</td>
</tr>
</tbody>
</table>
In any combination of two, three, four, or five of such fruit juice ingredients the weight of each is not less than one-fifth of the weight of the combination. Each such fruit juice ingredient is any such combination is an optional ingredient.

(d) The optional saccharine ingredients referred to in paragraph (a) of this section are:

- (1) Sugar.
- (2) Invert sugar sirup.
- (3) Any combination composed of optional saccharine ingredients (1) and (2).
- (4) Any combination composed of dextrose and optional saccharine ingredient (1) or (2).
- (5) Any combination composed of corn sirup, dextrose, invert sugar sirup, or any mixture of these, with or without added natural pectin extracting substances such as citrus acid, vinegar, lemon juice, lime juice, or any combination of these, in a quantity which reasonably compensates for the soluble-solids content of the fruit ingredient.
- (6) Honey.
- (7) Any combination composed of honey and optional saccharine ingredients (1), (2), or (3).

The weight of the solids of each component except honey is not less than one-tenth of the weight of the solids of such combination and the weight of honey solids is not less than two-fifths of the weight of the solids of such combination.

(e) For the purposes of this section:

(1) The weight of any optional saccharine ingredient means the weight of the solids of such ingredient.

(2) The term “sugar” means refined sugar (sucrose).

(3) The term “invert sugar sirup” means a sirup made by inverting or partly inverting sugar or partly refined sugar; its ash content is not more than 5.3 percent of its solids content, but if it is made from dextrose, its color and flavor other than sweetness are not impaired.

(4) The term “corn sirup” means a clarified, concentrated aqueous solution of the products obtained by the incomplete hydrolysis of cornstarch. The solids of corn sirup contain not less than 40 percent by weight of reducing sugars calculated as dextrose.

(5) The term “glucose sirup” means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as glucose.

§ 29.3 Preserves, jams; identity; label statement of optional ingredients. (a) The preserves or jams for which definitions and standards of identity are prescribed by this section are the viscous or semisolid foods each of which is made from a mixture composed of not less than 45 parts by weight (see paragraph (c) of this section) of one of the fruit ingredients specified in paragraph (b) of this section to each 100 parts by weight (see paragraph (e) of this section) of one of the optional saccharine ingredients specified in paragraph (d) of this section. Such mixture may also contain one or more of the following optional ingredients:

(1) Spices.
(2) A vinegar, lemon juice, lime juice, citric acid, lactic acid, malic acid, tartaric acid, or any combination of two or more of these, in a quantity which reasonably compensates for the natural acidity of the fruit ingredient.
(3) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit ingredient.

(4) Sodium citrate, sodium potassium tartrate, or any combination of these, in a quantity the proportion of which is not more than 3 ounces avoirdupois to each 100 pounds of the saccharine ingredient used.

(5) Sodium benzoate or benzoic acid or any combination of these, in a quantity reasonably necessary as a preservative.

Such mixture, with or without added water, is concentrated by heat to such point that the soluble-solids content of the finished preserves is not less than 63 percent if the fruit ingredient is specified in Group I of paragraph (b) of this section, and not less than 65 percent if the fruit ingredient is specified in Group II of paragraph (b) of this section. The soluble-solids content is determined by the method prescribed in “Official Methods of Analysis of the Association of Official Agricultural Chemists,” 2nd Edition, page 322 EED, note, 8th edition, 1955, p. 344, sec. 20.151, under “Soluble Solids in Fresh and Canned Fruits, Jams, Marmalades, and Preserves—First Action,” except that no correction is made for water-insoluble solids.

(b) The fruit ingredients referred to in paragraph (a) of this section are the following mature, properly prepared fruits which are fresh, frozen and/or canned:

Group I

- Blackberry (other than dewberry).
- Blueberry.
- Boysenberry.
- Cranberry.
- Crabapple.
- Dewberry (other than boysenberry, loganberry, and yellowberry).
- Elderberry.
- Grapes.
- Grapefruit.
Any combination of two, three, four, or five of such fruits in which the weight of each is not less than one-fifth of the weight of the combination; but the weight of any fruit, combination of two, three, four, or five fruits, each such fruit is an 

(2) When optional ingredient (a) (5) is used, the label shall bear the names of the components of the combination whereby such components are designated in paragraph (d) of this section, in the order of predominance, if any, of the weights of such fruits in the combination. Such names shall be preceded by the words "prepared with.

(3) When optional saccharine ingredient (d) (7) is used, the label shall bear the statement "prepared with honey."

(4) When optional ingredient (a) (5) is used, the label shall bear the words "sodium benzoate and benzoic acid," as the case may be, followed by the words "added as preservative."

(5) When optional saccharine ingredient (d) (6) is used, the label shall bear the statement "prepared with honey."

(6) When the fruit ingredient is a combination of two, three, four, or five fruits and the preserve is designated on its label by the name "Preserve" or "Jam," preceded or followed by the words "Mixed Fruit," the label shall bear the names or synonyms whereby such fruits are designated in paragraph (b) of this section, in the order of predominance, if any, of the weights of such fruits in the combination.

(7) Wherever the name specified in paragraph (d) of this section appears on the label of the preserve so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without interposing written, printed, or graphic matter, except that the varietal name of the fruit used in preparing such preserve may so intervene.

PART 36—SHELLFISH; DEFINITIONS AND STANDARDS OF IDENTITY; FILL OF CONTAINER

CANNED SHRIMP

Sec. 36.3 Canned wet pack shrimp and canned dry pack shrimp in nontransparent containers; all of container; label statement of substandard fill.

CANNED OYSTERS

Sec. 36.5 Canned oysters; identity; label statement of optional ingredients.

Canned oysters; fill of container; label statement of substandard fill.

RAW OYSTERS

Sec. 36.10 Oysters, raw oysters, shucked oysters; identity.

Sec. 36.11 Extra large oysters, oysters counts (or plants), extra large raw oysters, raw oysters counts (or plants), extra large shucked oysters, shucked oysters counts (or plants).

Sec. 36.12 Large oysters, oysters extra selects, large raw oysters, raw oysters extra selects, large shucked oysters, shucked oysters extra selects; identity.
36.16 Small Pacific oysters, small raw Pacific oysters, small raw oysters; identity.  

36.17 Large Pacific oysters, large raw Pacific oysters, large raw oysters; identity.  

36.18 Medium Pacific oysters, medium raw Pacific oysters, medium raw oysters; identity.  

36.19 Small Pacific oysters, small raw Pacific oysters, small raw oysters; identity.  

36.20 Extra small Pacific oysters, extra small raw Pacific oysters, extra small raw oysters; identity.  


CANNED SHELLFISH  

§ 36.3 Canned wet pack shrimp and canned dry pack shrimp in nontransparent cylinders, fill of container; label statement of standard fill.  

(a) The standard of fill of transparent cylinders, canned oysters, and shellfish containers as defined in § 21.31 of this chapter is to facilitate drainage. Two minutes from the time of shucking, before the sieve and the drained shrimp. The weight so found, less the weight of the sieve, shall be considered to be the cut-out weight of the shrimp.  

(b) If canned dry pack shrimp, or canned dry pack shrimp, in nontransparent containers, falls below the applicable standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of standard fill provided in § 10.2 (b) of this chapter, in the manner and form therein specified.  

CANNED OYSTERS  

§ 36.5 Canned oysters; identity; label statement of optional ingredients.  

(a) Canned oysters is the food prepared from one or any mixture of two or all of the forms of oysters specified in paragraph (b) of this section, and a packing medium of water, or the watery liquid drained from them in processing, or a mixture of such liquid and water. The food may be seasoned with salt. It is sealed in containers and so processed by heat as to prevent spoilage.  

(b) When the form of oysters specified in paragraph (a) of this section are prepared from oysters which have been removed from their shells and washed and canned, the shell, or the shell, or the shell, or the shell, or the shell, shall be removed and the drained weight of the oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.  

(c) The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under “2330 Micron (No. 9),” in Table I of “Standard Specifications for Sieves,” published March 1, 1940, by the National Bureau of Standards. Without shifting the material on the sieve, so inclining the sieve as to facilitate drainage. Two minutes from the time drainage begins, wash the sieve and the drained oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.  

(d) If canned oysters fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter in the manner and form therein specified, followed by the statement, “A can of this size should contain ____ oz. of oysters. This can contains only ____ oz.” the blank being filled in with the applicable figures.  

RAW OYSTERS  

§ 36.10 Oysters, raw oysters, shucked oysters; identity.  

(a) Oysters, raw oysters, and shucked oysters, are the class of foods each of which is obtained by shucking shell oysters and preparing them in accordance with the conditions prescribed in paragraph (b) of this section.  

(b) If water, or salt water containing less than 0.75 percent salt, is used in any vessel into which the oysters are shucked, the combined volume of such liquid when such oysters are emptied from such vessel is not less than four times the volume of such water or salt water. Any liquid accumulated with the oysters is removed. The oysters are exposed, by blowing or otherwise, in water or salt water, or both. The total time that the oysters are in contact with water or salt water, the time of washing, rinsing, and any other contact with water or salt water is not more than 30 minutes. In computing the time of contact with water or salt water, the time of washing, rinsing, and any other contact with water or salt water is not more than 30 minutes. 

§ 36.6 Canned oysters; fill of container; label statement of standard fill.  

(a) The standard of fill of container for canned oysters is a fill such that the drained weight of oysters taken from each container is not less than 59 percent of the water capacity of the container.  

(b) Water capacity of containers is determined by the general method provided in § 10.1 (a) of this chapter.  

(c) Drained weight is determined by the following method:  

Keep the unopened canned oyster container at a temperature of not less than 5° or more than 55° Fahrenheit for at least 12 hours immediately preceding the determination. After opening the container so as to distribute its contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if each quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under “2330 Micron (No. 9),” in Table I of “Standard Specifications for Sieves,” published March 1, 1940, by the National Bureau of Standards. Without shifting the material on the sieve, incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, wash the sieve and the drained oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.  

(d) If canned oysters fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter in the manner and form therein specified, followed by the statement, “A can of this size should contain ____ oz. of oysters. This can contains only ____ oz.” the blank being filled in with the applicable figures.  

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that is agitated by blow or otherwise, shall be calculated to the nearest half inch length. Any period of time that oysters are in contact with salt water containing not less than 0.75 percent salt before contact with oysters, shall not be included in the time that the oysters are in contact with water or salt water. Before packing into the container, for shipment or other delivery for consumption, the oysters are thoroughly drained and are packed without any added substance.

(c) For the purposes of this section:

(1) "Shell oysters" means live oysters of any of the species Ostrea gigas, Ostrea lurida, in the shell, which, after removal from their beds, have not been rotated or otherwise held under conditions which result in the addition of water.

(2) "Thoroughly drained" means one of the following:

(i) The oysters are drained on a strainer or skimmer which has an area of not less than 300 square inches per gallon of oysters, drained, and has perforations of at least 3/4 of an inch in diameter and not more than 1/4 of inches apart, or perforations of equivalent areas and distribution. The oysters are distributed evenly over the draining surface of the skimmer and drained for not less than 5 minutes.

(ii) The oysters are drained by any method other than that prescribed by subdivision (i) of this subparagraph whereby liquid from the oysters is removed so that when the oysters are tested within 15 minutes after packing by draining a representative gallon of oysters on a skimmer of the dimensions and in the manner described in subdivision (i) of this subparagraph for 2 minutes, not more than 5 percent of liquid by weight is removed by such draining.

§ 36.12 Extra large oysters, oysters counts (or plants) extra large raw oysters, raw oysters counts (or plants), extra large shucked oysters, shucked oysters counts (or plants) identity. Extra large oysters, oysters counts (or plants), extra large raw oysters, raw oysters counts (or plants), extra large shucked oysters, shucked oysters counts (or plants) are of the species Ostrea virginica and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains not more than 64 oysters, and a quart of the largest oysters selected therefrom contains not more than 36 oysters.

§ 36.13 Medium oysters, oysters select, medium raw oysters, select medium shucked oysters, select shucked oysters identity. Medium oysters, oysters select, medium raw oysters, raw oysters select, medium shucked oysters, shucked oysters select, are of the species Ostrea virginica and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains not more than 310 oysters, but not more than 300 oysters; a quart of the smallest oysters selected therefrom contains not more than 63 oysters, and a quart of the largest oysters selected therefrom contains more than 46 oysters.

§ 36.14 Small oysters, oysters standards, raw small oysters, raw oysters standards, small shucked oysters, shucked oysters standards identity. Small oysters, oysters standards, raw raw oysters, raw oysters standards, small shucked oysters, shucked oysters standards, are of the species Ostrea virginica and conform to the definition and standards of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 300 oysters but not more than 300 oysters; a quart of the smallest oysters selected therefrom contains not more than 63 oysters, and a quart of the largest oysters selected therefrom contains more than 46 oysters.

§ 36.15 Very small oysters, very small raw oysters, very small shucked oysters identity. Very small oysters, very small raw oysters, very small shucked oysters are of the species Ostrea virginica and conform to the definition and standards of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 300 oysters but not more than 500 oysters; a quart of the smallest oysters selected therefrom contains not more than 128 oysters and a quart of the largest oysters selected therefrom contains more than 63 oysters.

§ 36.16 Olympia oysters, raw Olympia oysters, shucked Olympia oysters identity. Olympia oysters, raw Olympia oysters, shucked Olympia oysters are of the species Ostrea lurida and conform to the definition and standard of identity prescribed for oysters by § 36.10.

§ 36.17 Large Pacific oysters, large raw Pacific oysters, large shucked Pacific oysters identity. Large Pacific oysters, large raw Pacific oysters, large shucked Pacific oysters, are of the species Ostrea gigas and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains not more than 64 oysters, and a quart of the largest oysters selected therefrom is not more than twice the weight of the smallest oyster therein.

§ 36.18 Medium Pacific oysters, medium raw Pacific oysters, medium shucked Pacific oysters identity. Medium Pacific oysters, medium raw Pacific oysters, medium shucked Pacific oysters, are of the species Ostrea gigas and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 64 oysters and not more than 96 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 36.19 Small Pacific oysters, small raw Pacific oysters, small shucked Pacific oysters identity. Small Pacific oysters, small raw Pacific oysters, small shucked Pacific oysters, are of the species Ostrea gigas and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 64 oysters and not more than 144 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 36.20 Extra small Pacific oysters, extra small raw Pacific oysters, extra small shucked Pacific oysters identity. Extra small Pacific oysters, extra small raw Pacific oysters, extra small shucked Pacific oysters, are of the species Ostrea gigas and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 144 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 36.21 Virgin oysters, very small raw oysters, very small shucked oysters identity. Very small raw oysters, very small shucked oysters are of the species Ostrea gigas and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 144 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 36.22 Virgin Olympia oysters, very small raw Olympia oysters, very small shucked Olympia oysters identity. Very small raw Olympia oysters, very small shucked Olympia oysters are of the species Ostrea lurida and conform to the definition and standard of identity prescribed for oysters by § 36.10.

§ 36.23 Large raw Salmonia oysters, large shucked Salmonia oysters identity. Large raw Salmonia oysters, large shucked Salmonia oysters are of the species Salmonia gigas and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains not more than 64 oysters, and a quart of the largest oysters selected therefrom contains more than 46 oysters.
liquid egg yolks, yolks, liquid yolks, are yolks of eggs of the domestic hen so separated from the whites thereof as to contain not less than 43 percent total egg solids, as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1955, pages 297 and 298 (Ed. note, 8th edition, 1955, p. 291-292, secs. 16.2, 16.3), under "Total Solids." They may be mixed, or mixed and strained.

§ 42.59 Frozen yolks, frozen egg yolks; identity. Frozen yolks, frozen egg yolks, are the food prepared by freezing egg yolks.

§ 42.60 Dried egg yolks, dried yolks; identity. Dried egg yolks, dried yolks, are the food prepared by drying egg yolks. These are made not less than 95 percent total egg solids, as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1955, pages 297 and 298 (Ed. note, 8th edition, 1955, p. 291-292, secs. 16.2, 16.3), under "Total Solids."

PART 45—OLEOMARGARINE, MARGARINE; DEFINITION AND STANDARD OF IDENTITY

§ 45.1 Oleomargarine, margarine; identity; label statement of optional ingredients. (a) Oleomargarine, margarine is the plastic food prepared with one or more of the optional fat ingredients named in subparagraph (1) (i) (ii) and (iv) of this paragraph, as follows:

(i) The rendered fat or oil, or stearin derived therefrom (any or all of which may be hydrogenated) of cattle, sheep, swine, or goats, or any combination of two or more of such articles.

(ii) Any vegetable food fat or oil, or oil or stearin derived therefrom (any or all of which may be hydrogenated) in an amount not exceeding 50 percent of the weight of the ingredients named in subdivision (i) either equals the weight of the ingredients named in subdivision (ii) or exceeds such weight by a ratio of not greater than 9 to 1.

(iv) Any combination of ingredients named in subdivisions (i) and (ii) of this subparagraph, in such proportion that the weight of the ingredients named in subdivision (i) either equals the weight of the ingredients named in subdivision (ii) or exceeds such weight by a ratio not greater than 9 to 1.

(b) One of the fat ingredients named in subdivision (i) or (ii) of this paragraph, in an amount not exceeding 0.5 percent of the weight of the finished oleomargarine or margarine.

(c) Monoglycerides or diglycerides of fat-forming fatty acids, or a combination of these, in an amount not exceeding 0.5 percent of the weight of the finished oleomargarine or margarine.

(f) Such monoglycerides and diglycerides in combination with the sodium sulfonate derivatives thereof, in a total amount not exceeding 0.5 percent of the weight of the finished oleomargarine.

(g) A combination of (a) and (b) of this subdivision, in which the amount of neither component is stated, or

(h) A combination of (a) and (c) of this subdivision, in a total amount not exceeding 0.5 percent of the weight of the finished oleomargarine.

The weight of the diclycerides in each of ingredients (b) (c) (d) and (e) of this subdivision is calculated at one-half actual weight.

(v) Butter.

(vi) Salt.

(vii) Citric acid incorporated in the fat or oil ingredient used.

(ix) Leupropyl citrate incorporated in the fat or oil ingredient used, in an amount not to exceed 0.02 percent by weight of the finished oleomargarine.

(c) Stearyl citrate incorporated in the fat or oil ingredient used, in an amount not to exceed 0.15 percent by weight of the finished oleomargarine.


(b) When any ingredient named under one of the following specified subparagraphs of paragraph (a) of this section is used, the label shall, except as provided in this paragraph, bear the statement set forth below after the number of such subparagraph:

Subparagraph (1) (i) "Prepared from Animal Fat," or "Made from Animal Fat," or "Vegetable and Animal Fat," or "Made from Vegetable and Animal Fat."

Subparagraph (1) (ii) "Vegetable" or "Made from Vegetable Fat."

Subparagraph (2) (i) "Prepared from Animal and Vegetable Fat." or "Made from Animal and Vegetable Fat."

Subparagraph (2) (ii) "Prepared from Vegetable and Animal Fat," or "Made from Vegetable and Animal Fat."

Subparagraph (3) (i) "Artificial Coloring." or "Artificial Coloring Added." or "With Added Artificial Coloring."

Subparagraph (3) (ii) "Sodium Benzoate or benzoic acid in an amount not exceeding 0.5 percent of the weight of the finished oleomargarine or margarine." or "Sodium Benzoate and Benzoic Acid Added as a Preservative." or "With Added Sodium Benzoate (or, as the case may be, "Benzoic Acid") and Benzoic Acid Added as a Preservative."

Subparagraph (3) (iii) "Citric Acid Added." or "Artificial Flavoring Added." or "With Added Artificial Flavoring."

Subparagraph (3) (iv) "Citric Acid Added to Flavor" or "Citric Acid Added as a Preservative."

Subparagraph (3) (v) "Eucalyptus Citrate Added to Protect Flavor" or "Eucalyptus Citrate Added as a Preservative."

Subparagraph (3) (vi) "Stearyl Citrate Added to Protect Flavor." or "Stearyl Citrate Added as a Preservative."

Where oil is used, the word "oil" may be substituted for "fat" in the label statement. In lieu of the word "animal" or "vegetable" in any such statement, the common or usual name of the fat ingredient may be used. When any ingredient named of the optional ingredients named in paragraph (a) (i) (ii) (iii) and (iv) (vii) (ix), and (c) of this section are used, the "in" shall be replaced with the word "of."
words “added” or “with added” need appear only once, either at the beginning or end of the list of such ingredients declared. The declaration of vitamin A may include the number of United States Pharmacopeia units present in the finished oleomargarine.

(2) Wherever the name “oleomargarine” or “margarine” appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section except those relating to the ingredients used, shall immediately and conspicuously precede or follow, or in part precede and in part follow, such name, without interventing written, printed, or other graphic matter.


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PART 51—CANNED VEGETABLES; DEFINITIONS AND STANDARDS OF IDENTITY; QUALITY; AND FILL OF CONTAINER

CANNED PEAS

Sec. 51.1 Identity; label statement of optional ingredients. (a) Canned peas shall be the food prepared from one of the following optional pea ingredients:

(1) Shelled, succulent peas (Pisum sativum) of Alaska or other smooth skin varieties.

(2) Shelled, succulent peas (Pisum sativum) of sweet, wrinkled varieties.

(3) Shelled, dried peas (Pisum sativum) of Alaska or other smooth skin varieties.

(4) Shelled, dried peas (Pisum sativum) of sweet, wrinkled varieties.

(b) To one such optional pea ingredient water is added.

(c) The following optional ingredients may be used:

(1) Salt.

(2) Monosodium glutamate.

(3) Sugar.

(4) Dextrose.

(5) Spice.

(6) Flavoring.

(7) Artificial coloring:

and in case optional pea ingredient (1) or (3) is used,

(8) Sodium carbonate, sodium bicarbonate, sodium hydroxide, calcium hydroxide, magnesium hydroxide, magnesium oxide, or any mixture or combination of them in such quantity that the pH of the finished canned peas is not more than 8.5, as determined by the glass electrode method for the hydrogen ion concentration.

(d) The food may be seasoned with one or more of the following optional seasonings:

(1) Green peppers.

(2) Mint leaves.

(3) Onions.

(4) Garlic.

(5) Horseradish.

(e) The food is sealed in a container and so processed by heat as to prevent spoilage.

(f) (1) The label shall name the optional pea ingredient present by the use of the word or words “Early” or “June” or “Early June,” “Sweet” or “Sweet Wrinkled” or “Sugar,” “Dried Early” or “Dried June” or “Dried Early June,” “Dried Sweet” or “Dried Sweet Wrinkled” or “Dried Sugar.”

(2) If space is present, the label shall bear the word or words “Spiced” or “With Added Spice” or “Spice Added.”

(3) If flavoring is present, the label shall bear the words “With Added Flavoring” or “Flavoring Added.”

(4) If artificial coloring is present, the label shall state that fact in such manner and form as is provided in § 51.3 (c) and (f).

(5) If an optional seasoning ingredient is used, the label shall bear the words “Seasoned with Green Peppers,” “Seasoned with Mint Leaves,” “Seasoned with Onions,” “Seasoned with Garlic,” or “Seasoned with Horseradish,” as the case may be.

(g) If one or more of the optional ingredients named under paragraph (c) (8) of this section is used, the label shall bear the statement “Traces of ______ Added,” the blank to be filled in with the names of the ingredients used; but in lieu of such statement the label may bear the statement “Traces of Alkalis Added.”

(h) If monosodium glutamate is used, the label shall bear the statement “Monosodium Glutamate Added” or “With Added Monosodium Glutamate.”

(i) Wherever the name “Peas” appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements hereinafter specified, showing the optional ingredients present, shall immediately follow such name without intervening written, printed, or graphic matter, except that the specific varietal name of the peas may so intervene.

§ 51.2 Quality; label statement of substandard quality. (a) The standard of quality for canned peas is as follows:

(1) Not more than 4 percent by count of the peas in the container are spotted or otherwise discolored.

(2) Standard canned peas are normally colored, not artificially colored.

(3) The combined weight of pea pods and other harmless extraneous vegetable material is not more than one-half of 1 percent of the drained weight of peas in the container.

(4) The weight of pieces of peas is not more than 10 percent of the drained weight of peas in the container.

(5) The skins of not more than 15 percent by count of the peas in the container are ruptured to a width of 1/10 inch or more.

(6) Not less than 90 percent by count of the peas in the container are crushed by a weight of not more than 0.75 grams (2 pounds) and

(7) The alcohol-insoluble solids of Alaska or other smooth skin varieties of peas in the container, is not more than 25.5 percent, and of sweet, wrinkled varieties, not more than 21 percent.

(b) Canned peas shall be tested by the following methods to determine whether or not they meet the requirements of paragraph (a) of this section:

(1) After determining the fill of the container as prescribed in § 51.3 (a), distribute the contents of the container over the meshes of a circular sieve made with No. 8 woven-wire cloth which complies with the specifications for such cloth set forth on page 3 of “Standard Specifications for Sieves,” published October 26, 1936, by United States Department of Commerce, National Bureau of Standards. The cloth used is 8 inches if the quantity of the contents of the container is less than 3 pounds, or 12 inches if such quantity is 3 pounds or more. Without shifting the peas, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, remove the peas from the sieve and weigh them. Such weight shall be considered to be the drained weight of the peas.

(2) From the drained peas obtained in subparagraph (1) of this paragraph, take at random a sample of 100 to 150 peas, and count them. Immediately cover these peas with a portion of the liquid obtained in subparagraph (1) of this paragraph, and allow the remaining liquid to the drained peas from which the subdivision was taken. Count those peas in the subdivision which are spotted or...
otherwise discolored, and also those peas
the skins of which are ruptured to a width
of 14 or more of the width of the peas again
the volume of water equal to twice the ca-
be considered to be crushed when its
grams (2 pounds) A pea so tested shall
weight of disc, rod, and device
measured height, or until the combined
is
the combined weight of disc, rod, and
weight of cotyledon is under the approximate cen-
the upper end of the rod. Before low-
-is
a horizontal disc to the highest point of
smooth surface of a rigid plate, lowering
on the approximate center of the level,
the cotyledon is under the approximate cen-
ter of the disc, add weight to the device
at a uniform, continuous rate of 12
grams per second. When the peas are
pressed to one-fourth its previously
measured height, or until the combined
weight of disc, rod, and device is 907.2
A pea so tested shall be considered to be crushed when its
cotyledon is pressed to one-fourth its
original height.

(5) Drain the liquid from the peas
which remained after taking the sub-
division as prescribed in subparagraph
(3) of this paragraph. Transfer the
peas to a pan, and rinse them with a
volume of water equal to twice the ca-

tion from which such peas were drained in subparagraph (1)
of this paragraph. Immediately drain
the peas again by the method prescribed
in subparagraph (1) of this paragraph.
After the 3 minutes' draining, wipe the
moisture from the bottom of the sieve.
Commute the peas thus drained, stir them to a uniform mixture, and weigh
20 grams of peas into a container and
beaker. Add 300 cc of 80 percent alco-
hol (by volume) stir, cover beaker, and
bring to a boil. Simmer slowly for 30
minutes. Fil a Buchner funnel with a
previously prepared filter paper and such
size that its edges extend 1/2 inch or more
up the vertical sides of the funnel.
The previous preparation of the filter paper consists of drying it flat-bottomed
dish for 2 hours at 100° Centigrade, cov-
ering the dish with a tight-fitting cover,
cooling it in a desiccator, and promptly weighing. After the filter paper is fitted
to the funnel, add 80 percent alcohol (by volume) until the washings are clear and colorless. Transfer the
filter paper with the material retained thereon to the dish used in preparing the filter paper, and the material is
filtered through a pre-damped filter paper into a flatten-
ed oven, without covering the dish, for
2 hours at 100° Centigrade. Place the
cover on the dish, cool it in a desiccator,
and promptly weigh. From this weight,
subtract the weight of the dish, cover,
and paper, as previously found. The weight of peas in thus drained, multiplied by 5, shall be considered to be the
percent of alcohol-insoluble solids.

(g) If the quality of canned peas falls
below the standard prescribed in paragraph
(3) of this section, the label must bear the general statement of substandard
quality specified in § 10.3 (a) of this
chapter, in the manner and form therein
specified. The label shall also contain a general statement of substandard
quality when the quality of canned peas falls below the standard in only one respect, the
label must bear the alternative statement
"Below Standard in Quality -------
blank to be filled in with the words
specified after the corresponding
subparagraph number of paragraph (a)
of this section which such canned peas fail to meet, as follows: (1) "Excessive
Discolored Peas" (2) "Artificially Col-
ored" (3) "Excessive Foreign Material";
(4) "Excessive Broken Peas" (5) "Ex-
cessive Cracked Peas" (6) "Not Ten-
der" (7) "Extremely Mealy." Such
alternative statement shall immediately
and conspicuously precede or follow,
when used, the name "Peas" and, or
graphic matter, the name "Peas" and
any words and statements required or
authorized to appear with such name
by § 51.1 (e)

§ 51.3 Fill of container label state-
ment of substandard fill. (a) The stand-
ard of fill of canned peas is a fill such that, when the peas and liquid are
removed from the container and re-
turned thereto, the leveled peas (irre-
spective of the quantity of the liquid), 15
seconds after they are so returned com-
pletely fill the container. A container with lid attached by double seam shall
be considered to be completely filled
when it is filled to the level 1/2 inch
vertical distance below the top of the
double seam; and a glass container shall
be considered to be completely filled
when it is filled to the level 1/2 inch
vertical distance below the top of the
container.

(b) If canned peas fail below the standard of fill of container prescribed in paragraph (a) of this section, the
label shall bear the statement of substandard fill specified in § 10.3 (b) of this
chapter, in the manner and form therein
specified.

CANNED BEANS

§ 51.10 Canned green beans; identity;
label statement of optional ingredients.
(a) Canned green beans is the food pre-
pared from stemmed, succulent pods of
the green-bean plant, and water. It
may be seasoned with salt, monosodium
glutamate, sugar, or dehydrate, or any two
or more of all of these. They are prepared in one or more of the following forms:
(1) Whole pods, including pods which
after removal of either or both ends are
less than 2 3/4 inches in length, or trans-
cut pods not more than 1 inch in
length. There may be present such
broken pieces of pods as normally occur in the commercial packing of such
product.

(b) Pods sliced lengthwise.

(c) Pods cut transversely into pieces
less than 2 3/4 inches in length but not
without shorter end pieces resulting therewith.

(d) Pods of which not less than 15 percent by count are less than 2 3/4 inch in length and not more than 1/2 inch in length.
Any such form is an optional ingredient.
This form or one or more of the other ingredients may be used. The food is
sealed in a container and so processed by heat as to prevent spoilage.

(b) (1) When optional ingredient
specified in paragraph (a) (1) of this
section is used the label shall bear the
word "Whole." If the pods are packed
parallel to the sides of the container the
word "Whole" shall be preceded or fol-
lowed by the words "Vertical Pack," ex-
cept that when the pods are cut at both
ends and are of substantially equal
lengths, the words "Asparagus Style" or
"French Style" may be used in lieu of the words "Vertical Pack." (2) When optional ingredient
specified in paragraph (a) (2) of this
section is used the label shall bear the
words "Sliced Lengthwise" or "French Style.
(3) When optional ingredient
specified in paragraph (a) (3) of this
section is used the label shall bear the word "Cuts."

(4) When optional ingredient
specified in paragraph (a) (4) of this
section is used the label shall bear the words "Short Cut" or "Short Cuts" or
"Inch Cuts," the blank to be filled in with the com-
bination of the names "Whole," or "Inch Cuts," or "Cut," or "Cuts," or "Short Cut," or "Short Cuts," designat-
ing the optional ingredient or the optional ingredients as arranged in the order of predominance,
if any, by weight of such ingredients.

(b) If monosodium glutamate is used,
the label shall bear the statement "Mon-
osodium Glutamate Added," or "With
Added Monosodium Glutamate."

(c) Wherever the name "Green Beans" appears on the label so conspicu-
ously as to be easily seen under the cus-
tomary conditions of purchase, the words and statements prescribed by paragraph
(b) of this section shall immediately
and conspicuously precede or follow such
words. The statements must be printed, or
written, or printed, or graphic matter, except that there may intervene (1) the designation of the length of cut, the (2) the varietal
name, which may include the word
"Stringless," where the beans are in fact
stringless, and (3) the description of the
green beans as "Stringless," which may
also be used between the words "Green" and "Beans," where the beans are in fact
stringless.

§ 51.11 Canned green beans; quality;
label statement of substandard quality.
(a) The standard of quality of canned green beans is as follows:

When tested by the method prescribed in paragraph (b) of this section:

(1) In the case of cut beans (§ 51.10 (a) (3)) and mixtures of two or more of the optional ingredients specified in § 51.10 (a) (1) to (a) (4) inclusive, not more than 60 units per 12 ounces drained weight are less than ½ inch long; Provided, That where the number of units per 12 ounces exceeds 240, not more than 25 percent by count of the total units are less than ½ inch long.

(2) The trimmed pods contain not more than 25 percent by weight of seed and pieces of seed.

(3) In case there are present pods or pieces of pods ≥ 5/8 inch or more in diameter, there are not more than 12 strings per 12 ounces of drained weight which will support ½ pound for 5 seconds or longer.

(4) The deseeded pods contain not more than 0.15 percent by weight of fibrous material.

(5) There are not more than 8 percent by count of blemished units. A unit is considered blemished when the aggregate blemished units constitute 2% of the area of a circle ¾ inch in diameter.

(6) There are not more than 6 unstemmed units per 12 ounces of drained weight.

(7) The combined weight of loose seed and pieces of seed is not more than 5 percent of the drained weight. This provision does not apply in case the greenbean ingredient is pods sliced lengthwise (§ 51.10 (a) (2)).

(8) The combined weight of leaves, detached stems, and other extraneous vegetable matter is not more than 0.6 ounce per 60 ounces drained weight.

(b) Canned green beans shall be tested by the following method to determine whether they meet the requirements of paragraph (a) of this section:

(1) Distribute the contents of the container over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the container (ω) is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth, which complies with the specifications for such cloth set forth under "2262 Micron (No. 8)" in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 664 of the United States Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the container and the drained material. Record, in ounces, the weight so found, less the weight of the sieve, as the drained weight.

(2) Pour the drained material from the sieve into a flat tray and spread it in a layer of fairly uniform thickness. Count the total number of units. For the purpose of this count, loose seed, pieces of seed, loose stems, and extraneous material are not to be included. Divide the number of units by the drained weight recorded in subparagraph (1) of this paragraph and multiply by 12 to obtain the number of units per 12 ounces drained weight.

(3) Examine the drained material in the tray counting and recording the number of blemished units, number of pieces of seed, and, in case the material consists of the optional ingredient specified in paragraph (a) (3) of this section or a mixture of two or more of the optional ingredients specified in § 51.10 (a) (1) to (a) (4) inclusive, count and record the number of units which are less than ½ inch long. If the number of units per 12 ounces exceeds 240, divide the number of units which are less than ½ inch long by the drained weight recorded in subparagraph (1) of this paragraph and multiply by 12 to obtain the number of such units per 12 ounces drained weight. If the number of units per 12 ounces exceeds 240 or less, divide the number of units which are less than ½ inch long by the total number of units and multiply by 100 to obtain the percentage by weight of seed in the trimmed pods.

(4) Except in the case of pods sliced lengthwise, remove the loose seed and pieces of seed, weigh and record weight and return to tray. Divide the weight of loose seed and pieces of seed by the drained weight recorded in subparagraph (1) of this paragraph and multiply by 100 to obtain the percentage by weight of loose seed and pieces of seed in the drained material.

(5) Remove from the tray the extraneous vegetable material, weigh, record weight, and return to tray.

(6) Remove from the tray one or more representative samples of pods ≥ 5/8 inch or more in diameter, weighing ¼ pound or 4 ounces, covering each sample as taken to prevent evaporation. If the tray includes pods or pieces of pods ≥ 5/8 inch or more in diameter, weigh and record weight of each representative sample.

(7) From each representative sample selected in subparagraph (6) of this paragraph discard any loose seed and extraneous vegetable material and detach and discard any attached stems. Except, with optional ingredient specified in § 51.10 (a) (2) (pods sliced lengthwise), trim out, as far as the end of the space formerly occupied by the seed, any portion of pods from which seed have become separated. Remove and discard any portions of seed from the trimmings and record the trimmings and detach and discard the remaining trimmings in subparagraph (9) of this paragraph. Weigh and record the weight of the trimmed pods. Deseed the trimmed pods and reserve the deseeded pods for subparagraph (9) of this paragraph. If the original container contained pods ≥ 5/8 inch or more in diameter, weigh and remove the trimmed string from the pods during the deseeding operation. Reserve these strings for testing as prescribed in subparagraph (6) of this paragraph. Collect the seed on a sieve of mesh fine enough to retain them, and so distribute them that any liquid drains away. Weigh the seed, divide by the weight of the trimmed pod and multiply by 100 to obtain the percentage by weight of seed in the trimmed pods.

In the case of pods sliced lengthwise, remove seed and pieces of seed and reserve the deseeded pods for use as prescribed in subparagraph (6) of this paragraph.

(8) If strings have been removed for testing, as prescribed in subparagraph (7) of this paragraph, test them as follows:

Fasten clamp, weighted to ½ pound, to one end of the string, grasp the other end with the fingers (a cloth may be used to aid in holding the string), and lift gently. Count the string as tough if it supports the ½-pound weight for at least 3 seconds. If the string breaks before 3 seconds, test such parts into which it breaks as are ¾ inch or more in length and if any such part of the string supports the ½-pound weight for at least 3 seconds count the string as tough. Divide the number of tough strings by the weight of the sample recorded in subparagraph (6) of this paragraph and multiply by 12 to obtain the number of tough strings per 12 ounces drained weight.

(9) Combine the deseeded pods with the trimmings reserved in subparagraph (7) of this paragraph, and, if strings were tested as prescribed in subparagraph (8) of this paragraph, add such strings, broken or unbroken. Weigh and record weight of combined material. Transfer to the metal cup of a malted-milk stirrer and mash with a pestle. Wash material adhering to the pestle back into cup with 200 cc. of boiling water. Bring mixture nearly to a boil, add 25 cc. of 50 percent (by weight) sodium hydroxide solution and bring to a boil. (If foaming is excessive, 1 cc. of 50 percent alcohol may be added.) Boil for 5 minutes, then stir for 5 minutes with a malted-milk stirrer capable of a no load speed of at least 7200 r.p.m. Use a rotor with two scoloped buttons shaped as shown in the diagram in Exhibit 1.

Exhibit 1
Transfer the material from the cup to a previously weighed 30-mesh monel metal screen having a diameter of about 3 1/2 to 4 inches and side walls about 1 inch high, and wash fiber on the screen with a stream of water using a pressure not exceeding a head (vertical distance between upper level of water and outlet of glass tube) of 60 inches, delivered through a glass tube 3 inches long and 1/2 inch inside diameter, to a rubber tube of 1/4 inch inside diameter. Wash the pulp portion of the material through the screen and continue washing until the moisture in the fibers may be moistened with phenolphthalein solution, does not show any red color after standing 5 minutes. Again wash to remove phenolphthalein. Dry the screen containing the fibrous material for 2 hours at 100° C., cool, weigh, and deduct weight of screen. Divide the weight of fibrous material by the weight of combined deseeded pods, truncated, and strings and multiply by 100 to obtain the percentage of fibrous material.

(10) If the drained weight recorded in subparagraph (1) of this paragraph was less than 60% of the drained weight, divided this sum by the sum of the weights of extraneous vegetable material in all containers opened, divide this sum by the sum of the drained weights in these containers and multiply by 60.

(c) If the quality of the canned green beans falls below the standard of quality prescribed by paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.3 of this chapter, the manner and form therein specified, but in lieu of the words prescribed for the second line inside the rectangle the following words may be used, when the quality of canned green beans falls below the standard in one only of the following respects:

(1) "Excessive Number Very Short Pieces," if the canned green beans fail to meet the requirements of paragraph (a) (1) of this section.

(2) "Excessive Number Blended Units," if they fail to meet the requirements of paragraph (a) (5) of this section.

(3) "Excessive Number Unstemmed Units," if they fail to meet the requirements of paragraph (a) (6) of this section.

(4) "Excessive Foreign Material," if they fail to meet the requirements of paragraph (a) (8) of this section.

§ 51.15 Canned wax beans; identity; label statement of optional ingredients.

(a) Canned wax beans conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients prescribed for beans by § 51.14 (a) and (b) except that it is prepared from stemmed, succulent pods of the wax-bean plant.

(b) Where the name "Wax Beans" appears on the label so conspicuously as to be easily seen under the customary conditions of purchase, the words and statements prescribed by paragraph (a) of this section shall immediately and conspicuously precede or follow such words and statements intervenient therein, written, printed, or catalyzed, or the words and statements except that there may intervene (1) the designation of the length of cut, (2) the varietal name, which may include the word "sugar," where the beans are in fact stringless, and (3) the description of the wax beans as "Stringless," which may also be used between the words "Wax" and "Beans," where the beans are in fact stringless.

§ 51.16 Canned wax beans; quality; label statement of substandard quality.

(a) The standard of quality for canned wax beans is that prescribed for canned green beans by § 51.11 (a) and (b) if the quality of canned wax beans falls below the standard of quality prescribed by paragraph (a) of this section the label shall bear the statement of substandard quality in the manner and form specified in § 51.11 (a) for canned green beans.

§ 51.20 Canned corn, canned sweet corn, canned sugar corn; identity; label statement of optional ingredients.

(a) Canned corn, canned sweet corn, canned sugar corn is the food consisting of one of the corn ingredients specified in paragraph (b) of this section, with water necessary for proper preparation and processing. It may be seasoned or garnished with one or more of the following optional ingredients:

(1) Salt.

(2) Monosodium glutamate.

(3) Sugar (sucrose)

(4) Pieces of sweet red peppers or sweet green peppers or hot red peppers or hot green peppers or a mixture of any two or more of these.

It is sealed in a container and so processed by heat as to prevent spoilage.

The corn ingredients referred to in paragraph (a) of this section consist of succulent sweet corn of the white or yellow color groups, or mixtures of thece, and are as follows:

(1) Cut kernels from which the hulls have not been separated.

(2) Pieces of the inner portion of the corn kernel substantially free from hull.

(3) Ground kernels from which the hulls have not been separated.

(4) A mixture of the form described in subparagraph (1) of this paragraph with one or both of the forms described in subparagraphs (2) and (3) of this paragraph. When necessary to insure smoothness, starch may be added, in a quantity not more than sufficient for that purpose.

(5) Cut and cooked kernels from which most of the moisture has been evaporated.

In preparing each of the following corn ingredients, the tip caps are removed.

(c) (1) The name of the food is: "Corn" or "Sweet Corn" or "Sugar Corn" with the name of the color group used, "White," "Yellow," or "Golden," or with the names of the color groups used, "White and Yellow" or "White and Golden." when the white color group predominates, and "Yellow and White" or "Golden and White," when the yellow color group predominates, and with: (1) The word "Whole Kernel," when the corn ingredient specified in paragraph (b) (1) of this section is used. When the weight of the label shall bear the statement of substandard quality, as determined by the method prescribed in § 51.21 (b) (1), is not more than 20 percent of the net weight, and the container is closed under conditions creating a high vacuum in the container, the words "Vacuum Packed" or "Vacuum Packed" also are part of the name.

(i) The word "Fritter," when the corn ingredient is specified in paragraph (b) (2) of this section is used.

(ii) The word "Ground," when the corn ingredient specified in paragraph (b) (3) of this section is used.

(v) The word "Evaporated," when the corn ingredient is specified in paragraph (b) (5) of this section is used.

(2) The parts of the name as specified in subparagraph (1) of this paragraph may be arranged in any order of precedence.

The varietal name immediately precedes or follows the name or intervenes between parts of the name of the food. For the purpose of arrangement of the name, the words "Sweet" and "Corn" may be treated as separate parts of the name. When the varietal name immediately precedes or follows the name or intervenes between parts of the name of the food and it accurately designates the color of the corn ingredient, no other designation of the color group need be made.

(d) (1) When the optional seasoning or garnishing ingredient specified in paragraph (a) (4) of this section is used, the label shall bear the words "With ___________ peppers," the blanks being filled in with the words "red" or "green" or both, to show the color of peppers used, and "hot" or "hot and sweet" or "hot and sweet or both," to show the kind of peppers used, as for example, "With green sweet peppers" or "With red hot peppers.

(2) If monosodium glutamate is used, the label shall bear the statement "Monosodium Glutamate Added" or "With Added Monosodium Glutamate.

(3) When the optional starch ingredient specified in paragraph (b) (4) of this section is used, the label shall bear the statement "Starch added to insure smoothness."

(4) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by paragraph (d) of this section shall immediately and conspicuously precede or follow such words and statements intervenient therein, written, printed, or catalyzed, or the words and statements except that it is prepared from stemmed, succulent pods of the wax-bean plant.

§ 51.21 Canned corn, canned sweet corn, canned sugar corn; quality; label statement of substandard quality.

(a) The standard of quality for canned corn is as follows:
(1) When tested by the method prescribed in paragraph (b) of this section, canned corn which the corn ingredient is whole-kernel corn ($51.20 (b) (1)) or evaporated corn ($51.20 (b) (5))

(i) Contains not more than one brown or black discolored kernel or piece of kernel for each 2 ounces of drained weight;

(ii) Contains not more than 1 cubic centimeter of pieces of cob for each 14 ounces of drained weight;

(iii) Contains not more than 1 square inch of husk for each 14 ounces of drained weight;

(iv) Contains not more than 7 inches of silk for each 1 ounce of drained weight.

(2) When tested by the method prescribed in paragraph (c) of this section, canned corn in which the corn ingredient is fritter corn ($51.20 (b) (2)), ground corn ($51.20 (b) (3)) or cream-style corn ($51.20 (b) (4))

(i) Contains not more than one brown or black discolored kernel or piece of kernel for each 2 ounces of net weight;

(ii) Contains not more than 1 cubic centimeter of pieces of cob for each 20 ounces of net weight;

(iii) Contains not more than 1 square inch of husk for each 20 ounces of net weight;

(iv) Contains not more than 6 inches of silk for each 1 ounce of net weight, and

(v) Has a consistence such that the average diameter of the approximately circular area over which the prescribed sample spreads does not exceed 13 inches, except that, in the case of cream-style corn the washed drained material of which contains more than 20 percent of alcoholic-insoluble solids, the average diameter of the approximately circular area over which the prescribed sample spreads does not exceed 10 inches.

(b) The method referred to in paragraph (a) of this section for testing whole-kernel corn ($51.20 (b) (1)) and evaporated corn ($51.20 (b) (5)) is as follows:

(i) Determine the gross weight of the container. Open and distribute the contents of the container over the meshes of an 8-mesh circular sieve which has previously been weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which contains a 5-mesh circular opening for such cloth set forth under "$2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves," published March 18, 1940, in C. 944 of the U. S. Department of Commerce, National Bu
canned corn falls below standard with respect to only one of the factors of quality specified by subdivisions (1) to (4) of paragraph (a) (1) of this section, or by subdivisions (1) to (4) of paragraph (b) (1) of this section, may be substituted for the second line of such general statement of standard quality, "Good Food—Not High Grade," a new line as specified after the corresponding subdivision designation of paragraph (a) of this section which the canned corn fails to meet: (1) or (2) (1) "Excessive discolored kernel." (1) (ii) or (2) (ii) "Excessive cob." (1) (iii) or (2) (iii) "Excessive husk." (1) (iv) or (2) (iv) "Excessive silk." (2) (v) "Excessively liquid."

§ 51.22 Canned corn, canned sweet corn, canned sugar corn where the corn ingredient is one of the forms known as frizzer corn, ground corn, or cream-style corn; fill of container; label statement of standard fill. (a) The standard of fill for canned corn where the corn ingredient is in one of the forms known as frizzer corn (§ 51.20 (b) (2)), ground corn (§ 51.20 (b) (3)), or cream-style corn (§ 51.20 (b) (4)) is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of containers prescribed in § 10.1 (b) of this chapter. (b) If canned frizzer corn, canned ground corn, or canned cream-style corn falls below the standard of fill of container prescribed for canned corn by § 51.20 (b) (a) of this section, the label shall bear the general statement of standard fill specified in § 10.2 (b) of this chapter, in the manner and form therein specified.

§ 51.30 Canned field corn; identity; label statement of optional ingredients. (a) Canned field corn conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for canned corn by § 51.20, except that the corn ingredient consists of succulent field corn or a mixture of succulent field corn and succulent sweet corn. (b) The name of the food conforms to the name specified in § 51.20 (e) except that the words "Corn,""Sweet Corn," and "Sugar Corn" are replaced by the words "Field Corn," and the term "Golden Field Corn" is not used.

§ 51.32 Canned field corn where the corn ingredient is in one of the forms known as frizzer field corn, ground field corn, or cream-style field corn; fill of container; label statement of standard fill. Each of the foods canned frizzer field corn, canned ground field corn, and canned cream-style field corn conforms to the standard of fill of container and label statement of standard fill prescribed for canned frizzer corn, canned ground corn, and canned cream-style corn by § 51.20 (a) and (b).

### Table: Canned Mushrooms

<table>
<thead>
<tr>
<th>Trade designation</th>
<th>Overall Diameter (in)</th>
<th>Overall Height (in)</th>
<th>Weight of drained mushrooms (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. 246</td>
<td>2 1/8</td>
<td>4 1/8</td>
<td>3</td>
</tr>
<tr>
<td>No. 247</td>
<td>2 3/8</td>
<td>5 1/2</td>
<td>4</td>
</tr>
<tr>
<td>No. 248</td>
<td>2 1/2</td>
<td>5 1/2</td>
<td>4</td>
</tr>
<tr>
<td>No. 249</td>
<td>2 1/2</td>
<td>6 1/2</td>
<td>5</td>
</tr>
</tbody>
</table>

§ 51.503 Canned mushrooms; fill of container; label statement of standard fill. The standard of fill of container for canned mushrooms is a fill such that:

(a) The weight of drained mushrooms in a container the dimensions of which are specified in the following table is not less than the weight of drained mushrooms prescribed in such table for such container:

(b) The drained weight of mushrooms in containers of a size not specified in paragraph (a) of this section is not less than 56 percent of the water capacity of the container, if such water capacity is less than 11.0 ounces avoirdupois; not less than 56 percent of the water capacity of the container, if such water capacity is 11.0 ounces or more but less than 25 ounces avoirdupois; and not less than 62 percent of the water capacity of the container, if such water capacity is 25 ounces avoirdupois or more.

§ 51.95 Canned vegetables other than those specifically regulated. (a) The canned vegetables for which definitions and standards of identity are prescribed by this section are those named in column I of the table set forth in paragraph (b) of this section. The vegetable ingredient in each such canned vegetable is obtained by proper preparation from the succulent vegetable prescribed in column II of such table. If two or more forms of such ingredient are designated in column III of such table, the vegetable in each such form is an optional ingredient. (b) The table referred to in paragraph (a) of this section is as follows:

### Table: Canned Vegetables

<table>
<thead>
<tr>
<th>I</th>
<th>Name or synonym of canned vegetable</th>
<th>II</th>
<th>Store</th>
<th>III</th>
<th>Optional forms of vegetable ingredient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artichokes</td>
<td>Flower bud of the artichoke plant.</td>
<td>Shelled lily bulbs, lily bulbs, lily roots.</td>
<td>Shelled lily bulbs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asparagus</td>
<td>Flowering shoot of the asparagus plant.</td>
<td>Whole, half, or sliced, bulbets, small shoots, or frozen.</td>
<td>Whole, half, or sliced.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beans</td>
<td>Speckled beans, lima beans, or butter beans.</td>
<td>Lima beans or butter beans.</td>
<td>Lima beans or butter beans.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beets</td>
<td>Beets in the beet plant.</td>
<td>Shelled lily bulbs, lily roots, or frozen.</td>
<td>Shelled lily bulbs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Broccoli</td>
<td>Broccoli sprouts of the broccoli plant.</td>
<td>Whole or sliced.</td>
<td>Whole or sliced.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cabbage</td>
<td>Cut pieces of the head of the cabbage.</td>
<td>Whole.</td>
<td>Whole.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Celery</td>
<td>Best of the celery plant.</td>
<td>Whole.</td>
<td>Whole.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collards</td>
<td>Collards of the collard plant.</td>
<td>Whole.</td>
<td>Whole.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Escarole</td>
<td>Escarole leaves of the escarole plant.</td>
<td>Whole.</td>
<td>Whole.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kales</td>
<td>Kale leaves of the kale plant.</td>
<td>Whole.</td>
<td>Whole.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mushrooms</td>
<td>Cap and stem of the mushroom.</td>
<td>Whole, half, or sliced, bulbs, or frozen.</td>
<td>Whole, half, or sliced.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name or synonym of canned vegetable</td>
<td>Source</td>
<td>Optional forms of vegetable ingredient</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------------------------------</td>
<td>--------</td>
<td>---------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parsnips</td>
<td>Root of the parsnip plant</td>
<td>Whole; quarters or quartered; slices or slided; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black-eyed peas or black-eyed peas</td>
<td>Seed shelled from pods of the black-eyed pea plant, with or without snap (pieces of immature unshelled pods).</td>
<td>Whole; halved or halved; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field peas</td>
<td>Seed shelled from pods of field pea plant (other than the black-eyed pea plant), with or without snap (pieces of immature unshelled pods).</td>
<td>Whole; pieces; mashed; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Green sweet pepper</td>
<td>Green pods of the sweet pepper plant</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red sweet pepper</td>
<td>Red-pipe pods of the sweet pepper plant</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pimientos or pimentos</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potatoes</td>
<td>Tuber of the potato plant</td>
<td>Whole; slices or slided; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweetpotatoes</td>
<td>Tuber of the sweet potato plant</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salt</td>
<td>Root of the salt plant</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spinach</td>
<td>Leaves of the spinach plant</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swiss chard</td>
<td>Leaves of the Swiss chard</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Truffles</td>
<td>Fruit of the truffle</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turnip greens</td>
<td>Leaves of the turnip plant</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turnips</td>
<td>Root of the turnip plant</td>
<td>Whole; pieces; diced; diced; cut; French style or julienne.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| (c) To the vegetable ingredient water is added; except that pimentos may be canned with or without added water, and sweet potatoes in mashed form are canned without added water, and asparagus may be canned with added water, asparagus juice, or a mixture of both. For the purposes of this section, asparagus juice is the clear, unfermented liquid expressed from the washed and heated sprouts or parts of sprouts of the asparagus plant; mixtures of asparagus juice and water are considered to be water when such mixtures are used as a packing medium for canned asparagus. In the case of artichokes, citric acid or a vinegar may be added in any such quantity as to reduce the pH of the finished canned vegetable to 4.5 or below. The following optional ingredients, in the case of the vegetables specified, may be added:

1. Citric acid or a vinegar, in the cases of all vegetables (except artichokes, in which such ingredient is prescribed, and except canned mushrooms, in which no such ingredient is permitted) in a quantity not more than sufficient to permit effective processing by heat without discoloration or other impairment of the article.

2. An edible vegetable oil, in the cases of artichokes and pimentos.

3. In the case of potatoes, purified calcium chloride, calcium sulfate, calcium nitrate, monocalcium phosphate, or any mixture of two or more such calcium salts, in a quantity reasonably necessary to firm the potatoes, but in no case in a quantity such that the calcium contained in any such calcium salt or mixture is more than 0.051 percent of the weight of the finished food.

4. Snaps, in the cases of shelled beans, black-eyed peas, and field peas.

5. Salt may be added to any of the canned vegetables in this section, in a quantity sufficient to season the food.

6. In the cases of all vegetables (except canned mushrooms) one or more of the following optional seasoning ingredients may be added in a quantity sufficient to season the food:

1. A vinegar.
2. Spices.
3. Refined sugar (sucrose).
4. Refined corn sugar (dextrose).

7. In the case of canned mushrooms, ascorbic acid (vitamin C) may be added in a quantity not to exceed 3.75 grams for each ounce of drained weight of mushrooms.

8. In the case of all vegetables, monosodium glutamate may be added in a quantity sufficient to season the food. The food is sealed in a container, and so processed by heat as to prevent spoilage. If the optional ingredient specified in column (b) of this section, the label shall bear the statement "With Added Trace of Oil." If no such ingredient is permitted) in a quantity not more than sufficient to permit effective processing by heat without discoloration or other impairment of the article.

9. An edible vegetable oil, in the cases of artichokes and pimentos.

10. In the case of tomatoes, purified calcium chloride, calcium sulfate, calcium nitrate, monocalcium phosphate, or any mixture of two or more such calcium salts, in a quantity reasonably necessary to firm the tomatoes, but in no case in a quantity such that the calcium contained in any such calcium salt or mixture is more than 0.051 percent of the weight of the finished food.

11. Salt may be added to any of the canned vegetables in this section, in a quantity sufficient to season the food.

12. In the cases of all vegetables (except canned mushrooms) one or more of the following optional seasoning ingredients may be added in a quantity sufficient to season the food:

1. A vinegar.
2. Spices.
3. Refined sugar (sucrose).

13. Refined corn sugar (dextrose).

14. A fat, other than any form of the vegetable ingredient present.

15. Salt.

16. (f) (1) If the optional ingredient specified in column (b) of this section, the label shall bear the statement "With Added Trace of Oil." If no such ingredient is permitted) in a quantity not more than sufficient to permit effective processing by heat without discoloration or other impairment of the article.

17. In the case of tomatoes, purified calcium chloride, calcium sulfate, calcium nitrate, monocalcium phosphate, or any mixture of two or more such calcium salts, in a quantity reasonably necessary to firm the tomatoes, but in no case in a quantity such that the calcium contained in any such calcium salt or mixture is more than 0.051 percent of the weight of the finished food.

18. Salt may be added to any of the canned vegetables in this section, in a quantity sufficient to season the food.

19. In the cases of all vegetables (except canned mushrooms) one or more of the following optional seasoning ingredients may be added in a quantity sufficient to season the food:

1. A vinegar.
2. Spices.
3. Refined sugar (sucrose).

4. Refined corn sugar (dextrose).

5. A fat, other than any form of the vegetable ingredient present.


7. (f) (2) If the optional ingredient specified in column (b) of this section, the label shall bear the statement "Trace of added Oil." If no such ingredient is permitted) in a quantity not more than sufficient to permit effective processing by heat without discoloration or other impairment of the article.

8. In the case of tomatoes, purified calcium chloride, calcium sulfate, calcium nitrate, monocalcium phosphate, or any mixture of two or more such calcium salts, in a quantity reasonably necessary to firm the tomatoes, but in no case in a quantity such that the calcium contained in any such calcium salt or mixture is more than 0.051 percent of the weight of the finished food.

9. Salt may be added to any of the canned vegetables in this section, in a quantity sufficient to season the food.

10. In the cases of all vegetables (except canned mushrooms) one or more of the following optional seasoning ingredients may be added in a quantity sufficient to season the food:

1. A vinegar.
2. Spices.
3. Refined sugar (sucrose).

4. Refined corn sugar (dextrose).

5. A fat, other than any form of the vegetable ingredient present.


7. (f) (3) If the optional ingredient specified in column (b) of this section, the label shall bear the statement "With Added Trace of Oil." If no such ingredient is permitted) in a quantity not more than sufficient to permit effective processing by heat without discoloration or other impairment of the article.
§ 53.20 Tomato puree, tomato pulp; identity; label statement of optional ingredients: (a) Tomato puree, tomato pulp, is the food prepared from one or any combination of two or all of the following optional ingredients: (1) The liquid obtained from mature tomatoes of red or reddish varieties. (2) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof. (3) The liquid obtained from the residue from partial extraction of juice from such tomatoes. Such liquid is obtained by so straining such tomatoes or residue, with or without heating, as to exclude skins, seeds, and other coarse or hard substances. It is concentrated and seasoned with salt, a vinegar or vinegars, spices or flavorings or both, and omons or garlic or both and is sweetened with sugar or a mixture of sugar and dextrose or a mixture of sugar (or sugar and dextrose) with corn sirup or dried corn sirup or both, in such quantity that the weight of the solids of the corn sirup or dried corn sirup or both, is not more than one-third of the weight of the solids of such mixture. When sealed in a container it is so processed by heat, before or after sealing, as to prevent spoilage. The solids of glucose sirup or after sealing, as to prevent spoilage. The solids of glucose sirup contain not less than 50 percent, by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup." (c) When optional ingredient specified in paragraph (a) (2) of this section is present, in whole or in part, the label shall bear the statement "Made From _____" (or "Made in Part From _____") as the case may be. "Residual Tomato Material from Canning," "Residual Tomato Material from Partial Extraction of Juice," "Extracts," "Residual Tomato Puree" or "Tomato Pulp" appears in the name, without intervening written, printed, or graphic matter.
Flavoring, and Baking Soda Added.” In lieu of the word “Spice” or “Flavoring” in such statement or statements, the common or usual name of such spice or flavoring may be used.

(c) Where a particular calcium salt or salts is more reasonably necessary to firm the tomatoes, but in no case such that the amount of the particular calcium salt or salts is more than 0.026 percent of the weight of the drained weight of the finished canned tomatoes.

§ 53.40 Canned tomatoes; identity; label statement of optional ingredients. (a) Canned tomatoes are mature tomatoes of red or reddish varieties which are peeled and cored and to which may be added one or more of the following optional ingredients:

1. The liquid draining from such tomatoes during or after peeling and coring.
2. The liquid strained from the residue from preparing such tomatoes for canning, consisting of peels and cores with or without such tomatoes or pieces thereof.
3. The liquid strained from mature tomatoes of such varieties.
4. Purified calcium chloride, calcium sulfate, calcium citrate, monocalcium phosphate, or any two or more of these calcium salts, in a quantity reasonably necessary to firm the tomatoes, but in no case such that the amount of the calcium salt contained in such salts, or any two or more of these calcium salts, is more than 0.026 percent of the weight of the drained weight of the finished canned tomatoes. It may be seasoned with one or more of the optional ingredients: Salt. Spices. Flavoring.

(b) When optional ingredient specified in paragraph (a) of this section is present, the label shall bear the statement “With Added Strained Residual Tomato Material From Preparation for Canning.” When one or more of the optional ingredients specified in paragraph (a) of this section is present, the label shall bear the statement “Trace of ______ Added” or “With Added Trace of ______”, the blank being filled in with the words “Calcium Salt” or “Calcium Salts” as the case may be or with the name or names of the particular calcium salt or salts added. When optional ingredient specified in paragraph (a) of this section is present, the label shall bear the statement or statements “Spice Added” or “With Added Spice,” “Flavoring Added” or “With Added Flavoring,” as the case may be. If two or more of optional ingredients specified in paragraph (a) of this section are present, such statements may be combined, as follows: “Flavored and Baked.” When optional ingredients specified in paragraph (a) of this section are present, such statements may be combined as follows: “Flavored with_______, and Baking Soda Added.” In lieu of the word “Spice” or “Flavoring” in such statement or statements, the common or usual name of such spice or flavoring may be used. Wherever the name “Tomatoes” appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement or statements herein specified showing the optional ingredients present shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 53.41 Canned tomatoes; quality; label statement of substandard quality. (a) The standard of quality for canned tomatoes is as follows:

1. The drained weight, as determined by the method prescribed in paragraph (b) (1) of this section, is not less than 50 percent of the weight of water required to fill the container, as determined by the general method for water capacity of containers prescribed in § 10.2 (a) of this chapter.
2. The strength and redness of color as determined by the method prescribed in paragraph (b) (2) of this section, is not less than that of the blended color of any combination of the color discs described in such method in which one-third the area of disc 1, not more than one-third the area of disc 2, is exposed;
3. Feel, per pound of canned tomatoes in the container, covers an area of not more than 1 square inch; and
4. Blemishes, per pound of canned tomatoes in the container, cover an area of not more than one-fourth square inch.

(b) Canned tomatoes shall be tested by the following method to determine whether or not they meet the requirements of paragraph (a) (1) and (2) of this section:

1. Remove lid from container, but in the case of a container with lid attached by double seam, do not remove or alter the height of the double seam. Tilt the opened container so as to distribute the contents over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve used is 8 inches if the quantity is 1 pound or more, or 12 inches if such quantity is 3 pounds or more. The meshes of such sieve are made by so weaving wire of 0.054-inch diameter as to form square openings 100 mesh per linear inch without shifting the tomatoes, so incline the sieve as to facilitate drainage of the liquid. Two minutes from the time drainage begins, weigh the sieve and drained tomatoes. The weight so found, less the weight of the sieve, shall be considered to be the drained weight.
2. Remove from the sieve the drained tomatoes obtained in subparagraph (1) of this paragraph. Cut out and segregate successively those portions of least redness until 50 percent of the drained weight, as determined under subparagraph (1) of this paragraph, has been so segregated. Commute the segregated portions to a uniform mixture without removing or breaking the commuted mixture into the original container to a depth of at least 1 inch. Mix the mixture from air bubbles, and skim off or press below the surface all visible seeds. Compare the color of the mixture, in full diffused daylight or its equivalent, with the blended color of combinations of the following concentric Munsell color discs of equal diameter, or the color equivalents of such discs:
   (i) Red—Munsell 5 R 2.6/13 (glossy finish)
   (ii) Yellow—Munsell 2.5 YR 5/12 (glossy finish)
   (iii) Black—Munsell N 1/ (glossy finish)
   (iv) Grey—Munsell N 4 (mat finish)

(c) If the quality of canned tomatoes falls below the standard prescribed in paragraph (a) of this section which such canned tomatoes fail to meet, as follows: (1) “Excessively Broken Up”; (2) “Poor Color”; (3) “Excessively Blemishes.” If such canned tomatoes fail to meet both (3) and (4), the words “Excessively Blemishes” may be used instead of the words specified after the corresponding number of each subparagraph of paragraph (a) of this section which such canned tomatoes fail to meet, as follows: (1) “Excessively Broken Up”; (2) “Poor Color”; (3) “Excessively Blemishes.” If such canned tomatoes fail to meet both (3) and (4), the words “Excessively Blemishes” may be used instead of the words specified after the corresponding numbers of such clauses. Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name “Tomatoes” and any statements required or authorized to appear with such name by § 53.40 (b).

§ 53.42 Canned tomatoes, fill of container; label statement of substandard fill. (a) The standard of fill of container for canned tomatoes is a fill of not less than 50 percent of the total capacity of the container, as determined by the general method for fill of containers prescribed in § 10.2 (b) of this chapter.
(b) If canned tomatoes fail below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.3 (b) of this chapter, in the manner and form therein specified.
§ 85.1 Application for inspection service. (a) Applications for inspection service on the processing of shrimp under the provisions of section 702a of the Federal Food, Drug, and Cosmetic Act shall be on forms supplied by the Food and Drug Administration, referred to in this subpart as the Administration. The processing of shrimp comprises all operations, including labeling and storage, necessary to prepare for the market shrimp in any of the following forms: raw, peeled, cooked, pickled, iced or frozen devened shrimp, or other preparation of shrimp. No application for a regular inspection period filed with the Administration after May 1, preceding such period in which inspection service shall be continued, unless the applicant shows substantial cause for failure to file such application on or before May 1 of such year. A separate application shall be made for each inspection period in each establishment for which the service is applied. Each application for a regular inspection period shall be accompanied by an advance payment of $300.00 as prescribed by § 85.13 (a) (1) Such payment shall be made in the manner prescribed by § 85.13 (e). (b) For the purposes of §§ 85.1 through 85.14, an establishment is defined as a factory where shrimp may be processed and warehouses and cold storage plants under the control and direction of the packer where such shrimp is stored.

§ 85.2 Granting or refusing inspection service; cancellation of application. (a) The Secretary of Health, Education, and Welfare may grant the inspection service applied for upon determining that the establishment covered by such application complies with the requirements of § 85.6. (b) The Secretary may refuse to grant inspection service at any establishment for cause. In case of refusal, the applicant shall be notified of the reason therefor and shall have returned all advance payments and deposits made, less any expenses incurred for preliminary inspection of the establishment or for other purposes incident to such application. (c) The applicant, by written notice to the Secretary, may withdraw his application for inspection service before July 1 preceding the inspection period covered by the application. In case of such withdrawal, the Secretary shall return to such applicant all advance payments and deposits already made, and other expense incurred incident to such application.

§ 85.3 Inspection periods. (a) The regular inspection period in each establishment in which inspection service under §§ 85.1 through 85.14 is granted, consists of 9 consecutive months. The date of the beginning of such regular inspection period shall be regarded as the date of the beginning of such service during any inspection period. (b) Extension inspection periods shall begin at the close of the preceding inspection period. Extension inspection periods may be granted for periods of 1 month and for fractional parts of 1 month, but in no case less than 1 day. Extension inspection periods for 1 month may be granted in such establishment if application therefore, accompanied by a payment of $600.00 as prescribed by § 85.13 (a) (2) is made at least 2 weeks in advance of the close of such preceding inspection period. Extensions for extension inspection periods for fractional parts of a month may be accepted when accompanied by the payment prescribed by § 85.13 (a) (3) for such extensions. No regular or extension inspection period shall extend beyond June 30 of any year. (c) Upon request of the packer, and with the approval of the Administration, such service during any inspection period may be transferred from one establishment to another to be operated by the same packer; but such transfer shall not serve to lengthen any inspection period or to take in any extension inspection period. In case of such transfer the packer shall furnish all necessary transportation of inspectors. (d) The inspection service shall be continuous throughout the inspection period.

§ 85.4 Assignment of inspectors. (a) An initial assignment of at least one inspector shall be made to each establishment in which inspection service under §§ 85.1 through 85.14 is granted. Thereafter, the Administration shall adjust the number of inspectors assigned to each establishment and tour of duty of each inspector to the requirements for continuous and efficient inspection. (b) Any inspector of the Administration shall have free access at all times to each establishment, to all plants supplying materials to the inspected establishment, and to all fishing and freight boats and other conveyances catching shrimp for, or transporting shrimp to, such establishment.

§ 85.5 Uninspected shrimp excluded from inspected establishments. (a) No establishment to which inspection service has been granted shall at any time thereafter process shrimp which has not been so inspected or handle or store in such establishment any processed shrimp which has not been so inspected; but such establishment after application for inspection service therein or withdrawal therefrom as authorized by § 85.14. (b) All shrimp and other ingredients entering into the finished product may be subject to inspection prior to delivery to the establishment or at any time thereafter, and all shrimp processed in such establishment shall be subject to certification under § 85.12.
RULES AND REGULATIONS

where about the premises as conditions require.
(b) One or more suitable washing devices and one or more suitable inspection belts shall be installed for the washing and subsequent inspection of the shrimp before processing.
(1) Suitable containers, flumes, chutes, or conveyors shall be provided for removing offal from picking room.
(j) Picking or heading tables shall be equipped with flumes supplied with clean, unpolluted water or with mechanical conveyors for removing the picked or headed shrimp.
(k) Equipment shall be provided for code-marking cans and other immediate containers and master cartons used in packaging other than canned shrimp.
(1) An automatic container-counting device shall be installed in each cannery line.
(2) Each sterilizing retort shall be fitted with at least the following equipment:
(a) An automatic control for regulating temperatures.
(b) An indicating mercury thermometer of a range from 170° F. to 270° F. with scale divisions not greater than 2° F. For steam cook, such thermometers shall be installed either within a fitting attached to the side of the retort or within a fitting fixed at the door or wall of the retort. For water cook, such thermometers shall be installed in the door or shell of the retort below the water level. If the thermometer is installed within a fitting such fitting shall communicate with the chamber of the retort through an opening at least 1 inch in diameter. Such fitting shall be equipped with a bleeder at least 7/8-inch in diameter. If the thermometer is installed within the door or shell of the retort, the bulb shall project at least two-thirds of its length into the principal chamber.
(3) A recording thermometer of a range from 170° F. to 270° F. with scale divisions not greater than 2° F. The bulb of such thermometer shall be installed as prescribed for the indicating mercury thermometer. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.
(4) A pressure gauge of a range from 0 to 30 pounds, with scale divisions not greater than 1 pound and diameter of not less than 8 inches. Such gauge shall be connected to the chamber of the retort by a short gooseneck tube. The gauge shall be not more than 4 inches higher than the gooseneck.
(5) For steam cook, a blow-off vent of at least 7/8-inch inside diameter in the top of the retort.
(6) For steam cook, a 7/8-inch bleeder in top of retort.
(n) Each cold storage compartment shall be fitted with at least the following equipment:
(a) An automatic control for regulating temperature.
(b) An indicating thermometer so installed as to indicate accurately the temperature within the storage compartment.
(c) A recording thermometer so installed as to indicate accurately the temperature within the compartment at all times. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.
(o) Provision shall be made for water-glassing, where such glassing is necessary to maintain the quality of frozen shrimp. Glazing shall be done with clean, unpolluted water.
(p) Provision shall be made for immediate icing or cold storage of all packaged shrimp which is destined for sale as uncooked and undercooked shrimp to prevent contamination or spoilage. Shrimp other than that to be canned shall be precooled immediately after the final cleaning or blanching operation to a temperature not exceeding 40° F. if it is to be packaged immediately, or to a temperature not exceeding 40° F. if it is not to be packaged immediately. If such shrimp are to be frozen, they shall be placed in the freezing compartment within 1 hour after final preparation.
(q) If batter is employed, it shall be used within 1 hour after it is prepared. The temperature of the batter shall not exceed 50° F.
(r) The packer shall destroy for food purposes under the immediate supervision of the inspector all shrimp in his possession condemned as not fit, filthy, decomposed, putrid, or otherwise unfit for food. Shrimp condemned on board or unloading platform shall not be taken into the icebox or picking room.
(s) Raw materials other than shrimp that enter into the finished product shall not be used if condemned by the inspector as unfit for food. Such condemned raw materials shall be segregated from usable materials and be held for disposal as directed by the inspector, or they may be destroyed forthwith by the packer if he so desires.
(t) All portions of the establishment shall be adequately lighted to enable the inspector to perform his duties properly.
(u) All floors and other parts of the establishment, including loading platforms, and all fixtures, equipment, and utensils shall be cleaned as often as may be necessary to maintain them in a sanitary condition. Containers for mixing or holding batter shall be adequately cleaned and sanitized before they are used for a new batch of batter. Equipment for applying batter shall be adequately cleaned and sanitized at least once each hour while in operation.
(v) The packer shall require all employees handling shrimp to wash and sanitize their hands after each absence from posts of duty, to observe other proper habits of cleanliness.
(w) The packer shall not knowingly employ in or about the establishment any person afflicted with an infectious or contagious disease, or with any open sores on exposed portions of the body.
§ 85.7 General operating conditions.
(a) Plants supplying raw headless or frozen raw headless shrimp to an inspected establishment, decks and holds of all boats catching shrimp for or transported to the establishment, and the bodies of other conveyances so transporting shrimp shall be kept in a sanitary condition.
(b) Inspected establishments, plants supplies within 1 nautical mile of the establishment, freight boats, and other conveyances serving such establishments shall accept only fresh, clean, sound shrimp. The shrimp shall be refrigerated immediately after they are caught, and shall be kept adequately iced or refrigerated until delivery to the establishment.
(c) After delivery of each load of shrimp to the establishment, deck and holds of each boat and the body of each other conveyance or container making such delivery shall be washed down with clean, unpolluted water, and all debris shall be removed therefrom before such boat or other conveyance or container leaves the establishment premises.
(d) Before being headed, picked, or devened, the shrimp shall be adequately washed with clean, unpolluted water and then passed over the inspection belt and culled to remove all shrimp that are filthy, decomposed, putrid, or otherwise unfit for food. Shrimp condemned on board or unloading platform shall not be taken into the icebox or picking room.
(e) If batter is employed, it shall be used within 1 hour after it is prepared. The temperature of the batter shall not exceed 50° F.
(f) The packer shall destroy for food purposes under the immediate supervision of the inspector all shrimp in his possession condemned as not fit, filthy, decomposed, putrid, or otherwise unfit for food. Shrimp condemned on board or unloading platform shall not be taken into the icebox or picking room.
(g) Raw materials other than shrimp that enter into the finished product shall not be used if condemned by the inspector as unfit for food. Such condemned raw materials shall be segregated from usable materials and be held for disposal as directed by the inspector, or they may be destroyed forthwith by the packer if he so desires.
(h) All portions of the establishment shall be adequately lighted to enable the inspector to perform his duties properly.
(i) All floors and other parts of the establishment, including loading platforms, and all fixtures, equipment, and utensils shall be cleaned as often as may be necessary to maintain them in a sanitary condition. Containers for mixing or holding batter shall be adequately cleaned and sanitized before they are used for a new batch of batter. Equipment for applying batter shall be adequately cleaned and sanitized at least once each hour while in operation.
(j) The packer shall require all employees handling shrimp to wash and sanitize their hands after each absence from posts of duty, to observe other proper habits of cleanliness.
(k) The packer shall not knowingly employ in or about the establishment any person afflicted with an infectious or contagious disease, or with any open sores on exposed portions of the body.
§ 85.8 Code marking.
(a) Permanently legible code marks shall be placed on all immediate containers at the time of packaging. Such marks shall show at least:
(1) The date of packing;
(2) The establishment where packed;
§ 85.9 Processing. (a) The closure of the can or other immediate container and the time and temperature of sterilizing the canned shrimp shall be adequate to prevent bacterial spoilage.

(b) The following times and temperatures shall be the minimums employed for the containers indicated:

**Dry Pack**

<table>
<thead>
<tr>
<th>Kind of container and liner</th>
<th>Size</th>
<th>Initial temperature</th>
<th>Time at 260° F</th>
<th>Time at 250° F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tin</td>
<td>3&quot; x 400 and smaller</td>
<td>Min.</td>
<td>69</td>
<td></td>
</tr>
<tr>
<td>No liner</td>
<td>3&quot; x 505 and smaller</td>
<td>Max.</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3&quot; x 606 (and larger)</td>
<td>Min.</td>
<td>69</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3&quot; x 707 (and larger)</td>
<td>Max.</td>
<td>65</td>
<td></td>
</tr>
</tbody>
</table>

**Wet Pack**

<table>
<thead>
<tr>
<th>Kind of container and size</th>
<th>Initial temperature</th>
<th>Time at 260° F</th>
<th>Time at 250° F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tin</td>
<td>211 x 400 and smaller</td>
<td>Min.</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>240 x 505 and smaller</td>
<td>Max.</td>
<td>65</td>
</tr>
<tr>
<td></td>
<td>300 x 606 (and larger)</td>
<td>Min.</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>314 x 686 (and larger)</td>
<td>Max.</td>
<td>65</td>
</tr>
</tbody>
</table>

For wet-pack shrimp in cans 307 x 400 and smaller, a cook of 12 minutes at 250° F, and for wet-pack shrimp in cans 502 x 510, a cook of 15 minutes at 250° F, may be approved if adequate provisions are made to insure an initial temperature of not less than 120° F in each individual can. For the purposes of this section, initial temperature is defined as the average temperature of the contents of the container at the moment steam is applied to each can in said container.

(c) For steam cook, blow-off vent shall be open during the coming-up period until the mercury thermometer registers at least 215° F. Bleeders shall emit steam during the entire cocking period.

(d) The method of freezing is not specified by the regulations in this part. Whatever method is used must be such as will produce a hard-frozen product in a sufficiently short time to prevent decomposition. Bulk packages containing 5 pounds or more of shrimp per package shall be hard frozen within 24 hours; smaller packages should be hard frozen within 12 hours. After freezing, the shrimp shall be stored in such a manner that its temperature does not exceed 0° F, and shall be handled in such manner as will maintain the hard-frozen condition.

(e) The storage temperatures for shrimp that are not frozen or canned are as follows:

1. Cooked and Peeled shrimp shall be stored at a room temperature not exceeding 35° F.
2. Raw headless shrimp shall be stored at a room temperature not exceeding 35° F. It may be stored at a higher room temperature if sufficiently fed at all times to prevent spoilage.

(f) The inspector shall identify each region on the thermometer chart with the code mark of the lot to which such record relates and the date of such record. The Administration shall keep such charts for at least 5 years, and upon request shall make them available to the packer.

(g) The packer shall keep for at least 1 year all shipping records covering shipments from each lot of shrimp and shall furnish such records to any inspector of the Administration.

§ 85.10 Examination after processing. (a) Adequate samples shall be drawn by the inspector from each lot of processed shrimp processed and condemned to determine whether or not such processed shrimp conforms to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder.

(b) The packer shall destroy for food purposes, under the immediate supervision of the inspector, all processed shrimp condemned by the inspector as not complying with § 85.9 (a) or its filthy, decomposed, putrid, or otherwise unfit for food.

§ 85.11 Labeling. (a) Labels on shrimp packed and canned under §§ 85.1 through 85.14 may bear a mark attesting to such packing and certifying compliance with the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder.

(b) The packer shall keep for at least 5 years, and upon request shall furnish such records to any inspector of the Administration.

§ 85.12 Certificates of inspection, warehousing and export permits. (a) After finding that the processed shrimp comprising any parcel has been handled, prepared, and packed in compliance with all provisions of §§ 85.1 through 85.14, the packer shall not approve or use any such approval for cause. The Administration is also authorized to revoke any such approval for cause. The Administration shall not approve labeling for processed shrimp intended for export under § 85.12 (e).

(d) No commercial brand or brand name appearing on labeling approved as authorized under paragraph (c) of this section and bearing the description in paragraph (a) of this section, and no label simulating such approved labeling, shall be used, after such approval, on processed shrimp other than that which has been processed, packed, and stored in compliance with all provisions of §§ 85.1 through 85.14, but this section shall not apply to any packer's labeling not bearing the mark of an Administration issued after termination of inspection or withdrawal thereof as authorized by § 85.14 or to any distributor's labeling not bearing such mark after written notice by the owner thereof to the Administration that the use of such labeling on inspected processed shrimp has been discontinued and will not be resumed.

(e) Shrimp labeling authorized by paragraph (a) of this section or approved under paragraph (c) of this section shall be used only as authorized by §§ 85.1 through 85.14. Unauthorized use of such labeling shall be subject to the penalties prescribed by the Federal Food, Drug, and Cosmetic Act, as amended.
shrimp if it is broken or if it is substandard in fill and the destination of the lot is known. Such certificate shall become void if such labeling is removed, altered, obliterated, or replaced, or if mishandling, improper storage, or other circumstances change the product so that it no longer complies with the requirements for the issuance of a certificate; but such processed shrimp may be relabeled by the inspector and recertified if the inspector finds that, after being relabeled, it complies with the requirements laid down by this paragraph for the issuance of a certificate.

(b) Unless covered by certificate, processed shrimp shall be moved from an inspected establishment only for storage authorized under paragraph (c) of this section, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 85.10(b).

(c) Applications to move unlabeled processed shrimp for storage in a warehouse or cold storage plant elsewhere than in the establishment where such shrimp was processed shall be on forms supplied by the Administration and shall be accompanied by an agreement signed by the operator of such warehouse or cold storage plant that inspectors shall have free access at all times to all processed shrimp so stored and that conditions which will preserve the identity of each parcel of such processed shrimp shall be continuously maintained pending issuance of a certificate thereon or removal as authorized by paragraph (d) of this section. If such application is approved and it appears to the inspector that the processed shrimp comprising any parcel has been packed in compliance with §§ 85.1 through 85.14 and conforms, except for the absence of labeling, to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and the regulations thereunder, the inspector shall issue to the applicant, on his request, a warehousing permit covering such processed shrimp. Such permit shall specify the code mark by which the pack is to be identified, the places from and to which such parcel is to be moved, the size and kind of containers, the type of pack, whether or not it is fancy grade, the condition of the shrimp if it is broken or if it is substandard in fill, and, if such is the case, that it is intended for export and is authorized under paragraph (c) of this section. When any provision of the agreement is violated, the Administration may revoke any permit issued pursuant to this paragraph, and may also revoke its approval of the application for warehousing or cold storage which accompanied such agreement.

(d) Unless covered by certificate, processed shrimp shall be stored under paragraph (c) of this section shall be moved from the warehouse or cold storage plant where stored only for re-storage under such conditions, or for other use, return upon written permission of the inspector to the establishment where processed, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 85.10(b).

(e) An application to export processed shrimp under the provisions of section 801(d) of the act shall be accompanied by a declaration of the species of the foreign purchaser; if required by the Administration, evidence showing that such processed shrimp is not in conflict with the laws of such country, is wholesome, and accords to such specifications; and, if shipment of labeled processed shrimp is specified or directed, eight specimens of the labeling therefor. Such processed shrimp or packed, according to such specifications is not in conflict with the laws of such country, the Administration shall direct the Inspector to issue to the applicant an export permit covering such processed shrimp comprising any parcel ordered by such purchaser under such specifications, when the inspector finds that such processed shrimp was packed in compliance with the requirements of §§ 85.1 through 85.14 regarding sanitary conditions and processing; is not filthy, decomposed, putrid, or otherwise unfit for human food; and is labeled on the outside of the shipping package to show that it is intended for export. Such permit shall specify the code mark by which it applies and the quantity of the parcel so marked, and shall show that such processed shrimp was packed under sanitary conditions, is wholesome, and accords to such specifications. The applicant shall furnish to the inspector documentary evidence showing the exportation of all such processed shrimp.

§ 85.13 Inspection fees. (a) Except as otherwise provided by the regulations in this part, an initial payment of $500.00 shall accompany each application; thereafter, eight additional advance payments of $500.00 shall be made on or before the first day of each month beginning July 1 and continuing through February of the following year; except that the Administration may require the full amount of advance payments prescribed by this paragraph to accompany an application for inspection of shrimp comprising a parcel of shrimp where an applicant has defaulted in any payment due for any prior packing season.

(2) Whenever it is determined, without hearing, by the Administration that an establishment having the inspection service has been damaged by wind, fire, flood, or other calamity, to such an extent that packing operations cannot be resumed before the end of the fiscal year, no advance payments falling due after such calamity shall be required from the packer for that fiscal year; but whenever it is determined, without hearing, by the Administration that an establishment having the inspection service has been so damaged by any such calamity that operations must be suspended temporarily, but can be resumed within the inspection period of the fiscal year then current, advance payments falling due after such calamity and before the month of resumption of operations shall be postponed until operations are resumed, and thereafter shall be paid in equal monthly installments during the period between the time of resumption of operations and June 1 of the fiscal year then current; Provided, That in the event of a determination described in this subparagraph the total payments and deposits made by the packer involved shall be charged with the cost of the service made available for the establishment without regard to the method provided hereinafter for computing charges against payments and deposits for such service made available for the establishment.

(3) Each application for an extension inspection period of 1 month shall be accompanied by a payment of $600.00, and at subsequent monthly intervals thereafter additional payments of $600.00 shall be made; but if the final payment is to cover a period of less than 30 days, then such payment shall be at the rate of $20.00 for each day of such period.

(b) (1) In addition to the payments prescribed in paragraph (a) of this section, the quantity of shrimp received by the subscribing establishment shall be made to underwrite adequately the cost of the inspection service. Such deposits shall be computed at the rate of 20 cents per pound of raw headless shrimp, received by the plant. For the purposes of this section, the quantity of shrimp received by an establishment shall be determined by weighing on a suitable scale immediately after such shrimp leaves the initial inspection belt; proviso, however, that other arrangements for determining accurately the weight of shrimp received may be employed if approved in advance by the Administration. A record of such weights shall be maintained and made available to the inspector upon request. Any advance deposits in excess of those required for actual shrimp received for the fiscal year (July 1 through June 30) shall be refunded to the packer by the Administration after the completion of the fiscal year.

(2) Deposits for shrimp received as computed under paragraph (b)(1) of this section, together with production deposits prescribed for oysters canned under § 85.28(b)(1), shall be charged with the balance of the total cost of the inspection service that has been provided for by the combined total payments made under paragraph (a) of this section and § 85.28(a) in the case of canned oysters. The balance of the deposits remaining for shrimp received after such charges have been made shall be refunded by the Administration to the packers after the completion of the fiscal year. In the ratio which each packer's deposits for shrimp and production deposits for oysters canned bears to the combined total of such deposits for shrimp received and oysters canned by all packers for the fiscal year.
(3) When inspection service is withdrawn from an establishment as authorized under § 85.14 (a) the Administration shall not return to the packer any advance payments and/or deposits required to be retained in advance of the service. Such payments and/or deposits shall be charged with the cost of the service made available for the establishment, without regard to the description in this section, and the balance which would have accrued to such packer shall remain to the credit of the Food and Drug Administration in the special account "Salaries and Expenses, Certification and Inspection Services."

(c) A separate fee shall be paid to cover all expenses, incurred in accordance with the regulations of the United States Government, for salary, travel, subsistence, and other purposes incident to inspection described under § 85.4 (b) of suppliers of any materials to establishments under the inspection service or for the purpose of issuing a certificate or warehousing or export permit on processed shrimp stored or held at any place other than an establishment to which a seafood inspector is assigned.

(d) When the processing plant and the warehouse or cold storage plant of an establishment are located more than 800 points of such distance apart that transportation between them is required for the inspector to perform his duties in the establishment, the packer shall furnish such transportation at his own expense and pay a separate fee to cover all expenses therefor.

(e) All payments required by the regulations in this part shall be by bank draft or certified check, collectible at par, drawn to the order of the Treasurer, United States, and payable at Washington, D.C. All such drafts and checks, except those for the payment required by § 85.1 (a) shall be delivered to the inspector and promptly scheduled to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C. Whereupon after appropriate records thereof have been made, they shall be transmitted to the Chief Disbursing Officer, Division of Disbursing and Accounting, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

(f) All refunds to the packers shall be by check drawn on the Treasury of the United States pursuant to refund vouchers duly certified and approved by the designated administrative officers.

§ 85.14 Suspension and withdrawal of inspection service. (a) The Administration and the Secretary may withdraw inspection service in any establishment:

(1) Upon failure of the packer to comply with any applicable provision of §§ 85.1 through 85.28 of this part.

(2) Upon the designation by the packer or any person in privity with him of any representation that is false or misleading in any particular relating to the application to any seafood of the inspection service provided by the regulations in this part.

(b) When inspection service is suspended in an establishment, as authorized by paragraph (a) of this section, the Administration shall not then suspend the inspection period in such establishment to compensate for any of the time of suspension.

§ 85.16 Application for inspection service. (a) Applications for inspection service on canned oysters under the provisions of section 701a of the Federal Food, Drug, and Cosmetic Act shall be made to the Food and Drug Administration, referred to in this subpart as the administration. No application for a regular inspection period filed with the administration after September 1 preceding such period in any year shall be considered unless the applicant shows substantial cause for failure to file such application on or before September 1 of the year the inspection period is to begin.

(b) The Secretary may refuse to grant the inspection service at any establishment for cause to be determined by such Secretary, and the application complies with the requirements of § 85.21.

The inspection service shall be continuous and efficient inspection. In case of such transfer the packer shall furnish all necessary transportation of inspecting officers to such establishment.

The inspection service shall be continuous throughout the inspection period.

§ 85.18 Inspection periods. (a) The Administration shall grant an inspection period in any establishment in which inspection service under §§ 85.16 through 85.29 is granted consists of 4 consecutive months. The date of the beginning of such regular inspection period shall be regarded as the date, on or after October 1 but not later than March 1, specified for the beginning of the service in the application therefor, or such other date as may be specified by amendment to such application and approved; but if the Secretary is not prepared to begin the service on the specified date then the period shall start on the date on which service is begun.

(b) Extension inspection periods shall begin on the first day of the preceding inspection period. Extension inspection periods may be granted for periods of 1 month and/or fractional parts of 1 month, but in no case less than 1 day. Any inspection period may be granted in such establishment if application therefor, accompanied by a payment of $500.00, as prescribed by § 85.28 (c) (3), is made at least 2 weeks in advance of the close of such establishment.

Applications for extension inspection periods for fractional parts of a month may be accepted when the Secretary has cause to believe that such inspection period is required for the protection of public health, or because of a disaster, and the Secretary shall return to such packer any advance payments and/or deposits required to be returned therefrom as authorized by § 85.28 (c) (3) for such extensions.

§ 85.19 Assignment of inspectors. (a) An initial assignment of at least one inspector shall be made to each establishment in which inspection service under §§ 85.16 through 85.29 is granted. Thereafter, the administration shall assign the number of inspectors necessary to each establishment and tour of duty of each inspector to the requirements for continuous and efficient inspection.

(b) Any inspector of the administration shall have full control over the performance of his duties at any establishment to which he is assigned, or at any other part of the establishment and to all fishing and freight boats and other conveyances engaged in transporting oysters to such establishments.

§ 85.20 Uninspected oysters excluded from inspected establishments. (a) No establishment to which inspection service on canned oysters has been granted shall at any time thereafter can any oysters that have not been inspected; but this paragraph shall not apply to an establishment after termination of inspection service in such establishment.

(b) All oysters delivered to or held in any inspected establishment may be subject to inspection, but certificates of inspection shall be issued under § 85.27 only on canned oysters.

§ 85.21 General requirements for plant and equipment. (a) All exterior openings of the cannery, including those of the dicing sheds, shall be ade-
quate provisions are made to enable
open drains from shucking shed, shall
thorough cleaning and proper drainage.
Such sheds and rooms shall be ade-
quate lighted, and smooth floors shall be tight and arranged for
thorough cleaning and proper drainage. Open drains from shucking
shall not enter packing room. If shucking
and packing room are in separate
buildings, such buildings shall be not
more than 100 yards apart, unless ade-
quate provisions are made to enable
efficient inspection.
(c) All surfaces of washers, tanks,
belts, tables, flumes, utensils, and other
equipment with which unshucked or
shucked oysters come in contact after
delivery to the establishment shall be of
metal or of other smooth nonporous and
easily cleanable material, provided such
materials are not lead or other toxic sub-
stances. Metal surfaces are to be
soldered or smoothly welded. Shucking
tables shall be so constructed as to pre-
clude contamination of working surfaces
or products. Foot traffic from wheelbarrows
or other containers used in delivering steamed oysters to such
tables.
(d) Adequate supplies of suitable de-
tegent and sanitizing agents approved
by the Administration; clean, unpolluted
running water; and steam shall be pro-
vided for washing, cleaning, and other-
wise maintaining the establishment in a
sanitary condition.
(e) Adequate toilet facilities of sanita-
tary type which comply fully with ap-
licable State laws and local ordinances shall be provided.
(f) An adequate number of sanitary
washbasins, with liquid or powdered
soap, shall be provided in both the shuck-
ing shed and the packing room. Paper
towels shall be provided in the packing
room.
(g) Signs requiring employees hand-
ling oysters to wash their hands after
each absence from post of duty shall be
conspicuously posted in the shucking
and packing room and elsewhere about
the premises as conditions require.
(h) One or more suitable washing de-
vices and one or more suitable inspection
belts shall be installed for the washing
and subsequent inspection of the oysters
before delivery for steaming or other
means of preservation.
(i) If steam boxes are used for open-
ing the oysters, they shall be provided
with adequate steam masts, exhausts,
drains, a safety valve, and a pressure
gauge.
(j) Suitable means shall be provided for
removing shells and debris from
shucked oysters, for washing such
shucked oysters, and for their subsequent dra-
ming.
(k) One or more suitable devices shall
be provided for removing shell and grit
from shucked oysters, for washing such
oysters, and for their subsequent dra-
ming.
(l) One or more suitable inspection
belts shall be installed for the inspection
of shucked oysters.
(m) Equipment shall be provided for
code-marking cans.
(n) An automatic container-counting
device shall be installed in each cannery
line.
(o) Each sterilizing retort shall be
fitted with at least the following equip-
ment:
(1) An automatic control for regulat-
ting temperatures.
(2) An indicating mercury thermom-
er of a range from 170° F. to 270° F.,
with scale divisions not greater than 2°
F., installed either within a fitting at-
tached to source where the retort or
within the door or shell of the retort.
If the thermometer is installed within a
fitting, such fitting shall communicate
with the chamber of the retort through
an opening at least 1 inch in diameter.
Such fitting shall be equipped with a
bleeder at least 3/8-inch in diameter. If
the thermometer is installed within the
doors or shell of the retort, the bulb shall
project at least two-thirds of its length
into the principal chamber.
(3) A recording thermometer of a
range from 170° F. to 270° F., with scale
divisions not greater than 5° F. The
bulb of such thermometer shall be in-
stalled as prescribed for the indicating
mercury thermometer. The case which
surrounds the bulb, the fitting, and any
mechanism shall be provided with an
approved lock, all keys to which shall be in
the sole custody of the inspector.
(4) A pressure gauge of a range from
0 to 500 pounds, with scale divisions
not greater than 1 pound and diameter of
not less than 5 inches. Such gauge
shall be connected to the chamber of
the retort by a short gooseneck tube.
The gauge shall be not more than 4
inches higher than the gooseneck.
(5) A blow-off vent of at least 3/4-inch
inside diameter in the top of the retort.
(f) A ¾-inch bleeder in top of the
retort.
(g) Suitable space and facilities shall
be provided for the inspector to prepare
records and examine samples and for the
safekeeping of records.
§ 85.22 General operating condi-
tions. (a) The decks and holds of all
boats tonging or dredging oysters for or
transporting oysters to an inspected
establishment, and the bodies of other
conveyances so transporting oysters
shall be kept in a sanitary condition.
Such boats shall be equipped with adequate
means for protecting the oysters against
clean, unpolluted water, and all debris
contamination.
(b) Inspected establishments, freight
boats, and other conveyances serving
such establishments shall accept only
live, clean, sound oysters taken from un-
contaminated sources whatever shall not be allowed to
accumulate in the cannery or, except for
shells, about the premises. Shells shall not be allowed to accumulate about the
premises in such a manner as to create a
nuisance.
(h) The delivery of steamed oysters
to shuckers by means of manually roll-
ing, trundling, or wheelbarrowing such
cannery or a moveable shucking tables will
not be permitted.
(i) Shucking knives and shucking
cups shall be thoroughly washed with
soap and water and chlorinated before use and shall be
maintained at a strength of 200 parts per
million.
(j) No shucked oysters shall be re-
turned to the establishment after delivery to the
weigher. Shucking cups shall be cleaned
and sanitized after each delivery to the
weigher.
(k) Shucked oysters being transported
from one building to another shall be properly covered and protected against
clean, unpolluted water, and all debris
contamination.
(l) The shucked oysters shall be
washed, separated from the shell and
grit by suitable devices, and then imme-
diately drained. The time of washing
shall not exceed the minimum time nec-
 essary for cleaning.
(m) From the time of delivery to the
cannery up to the time of final press-
ing, oysters shall be handled expedi-
tiously and under such conditions as
to prevent contamination or spoilage.
(n) The packer shall destroy for food
purposes under the supervision of the
inspector all oysters in his
possession condemned by the inspector as filthy, decomposed, putrid, or unfit for
food. Oysters condemned on the boat or
on the unloading platform shall not be
taken into the cannery, but shall be
destroyed or returned to a bedding
ground.
(o) All portions of the establishment
shall be adequately lighted to enable the
inspector to perform his duties properly.
(p) All floors and other parts of the
establishment including unloading plat-
forms, and all fixtures, equipment, and
utensils shall be clean as often as may
be necessary to maintain them in a sanita-
tary condition.
(q) The packer shall require all em-
ployees handling oysters to wash their
hands after each absence from post of
duty and to observe other proper habits
of cleanliness.
(r) The packer shall not knowingly
employ in or about the establishment
any person afflicted with an infectious or
tuberculosis disease or with any open sores
on exposed portions of the body.
§ 85.23 Code marking. (a) Code marks shall be affixed to all cans and other immediate containers before they are placed in the processing retorts. Such marks shall show at least:

1. The date of packing;
2. The establishment where packed;
3. The conveyance; and
4. Such other symbols as are required by the operator when such oysters are graded for size.

(b) Keys to all code marks shall be given to the inspector.

§ 85.24 Processing. (a) The closure of the can or other immediate container and the time and temperature of sterilizing the canned oysters shall be adequate to prevent bacterial spoilage.

(b) The following times and temperatures shall be the minimum employed for the containers indicated:

<table>
<thead>
<tr>
<th>Size</th>
<th>Initial temperature (°F)</th>
<th>Time at 260° F</th>
<th>Time at 250° F</th>
</tr>
</thead>
<tbody>
<tr>
<td>211 x 212</td>
<td>230</td>
<td>7 Minutes</td>
<td>10 Minutes</td>
</tr>
<tr>
<td>211 x 250</td>
<td>230</td>
<td>7 Minutes</td>
<td>10 Minutes</td>
</tr>
<tr>
<td>211 x 150</td>
<td>230</td>
<td>7 Minutes</td>
<td>10 Minutes</td>
</tr>
<tr>
<td>200 x 133</td>
<td>230</td>
<td>7 Minutes</td>
<td>10 Minutes</td>
</tr>
<tr>
<td>200 x 150</td>
<td>230</td>
<td>7 Minutes</td>
<td>10 Minutes</td>
</tr>
<tr>
<td>200 x 175</td>
<td>230</td>
<td>7 Minutes</td>
<td>10 Minutes</td>
</tr>
</tbody>
</table>

For the purposes of this section, initial temperature is defined as the average temperature of the oysters and the container at the moment steam is admitted to the sterilizing retort.

(c) The blow-off vent shall be open during the coming-up period until the mercury thermometer registers at least 215° F. Bleeders shall emit steam during the entire cooking period.

(d) The inspector shall identify each record on the thermometer chart with the code mark and to which such record relates and the date of such record. The Administration shall keep such charts for at least 5 years, and upon request shall make them available to the packer.

(e) The packer shall keep for at least 1 year all shipping records covering shipments from each lot, and upon request shall furnish such records to any inspector of the Administration.

§ 85.25 Examination after canning. (a) Adequate samples shall be drawn by the inspector from each lot of canned oysters and shall be examined to determine whether or not such canned oysters conform to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder.

(b) The packer shall destroy for food purposes, under the immediate supervision of the inspector, all canned oysters condemned by the inspector as not complying with § 85.24, or as filthy, decomposed, putrid, or otherwise unfit for food.

§ 85.26 Labeling. (a) Labels on canned oysters packed and certified under §§ 85.16 through 85.29 may bear the mark "Production Supervised by the U. S. Food and Drug Administration." Such labels shall be designed and used and prominently displayed, in type of uniform size and style, on a strongly contrasting, uniform background.

(b) Two proofs, or one proof and one photostat thereof, and eight specimens of the labeling shall be sent to the Administration after printing. The Administration is hereby authorized to approve labeling for use on canned oysters inspected under §§ 85.16 through 85.29. Approval shall be subject to the condition that such labeling shall be used as to comply with the provisions of the Federal Food, Drug and Cosmetic Act, amendments thereto, and regulations thereunder.

(c) No commercial or brand name appearing on labels approved as authorized under paragraph (b) of this section and bearing the mark described in paragraph (a) of this section, and no label, if used, shall not be approved by the Administration, shall not be used after such approval or on canned oysters other than those that have been handled, prepared, and packed in compliance with all provisions of §§ 85.16 through 85.29; but this section shall not apply to any packer's labeling not bearing such mark after termination of inspection or withdrawal thereof as authorized by § 85.29 or to any distributor's labeling not bearing such mark after written notice by the owner thereof to the Administration that the use of such labeling on inspected canned oysters has been discontinued and will not be resumed.

(d) Canned-oyster labeling authorized by paragraph (a) of this section or approved under paragraph (b) of this section shall be used after such approval on canned oysters other than those that have been handled, prepared, and packed in compliance with all provisions of §§ 85.16 through 85.29, but this section shall not apply to any packer's labeling not bearing such mark after termination of inspection or withdrawal thereof as authorized by § 85.29 or to any distributor's labeling not bearing such mark after written notice by the owner thereof to the Administration that the use of such labeling on inspected canned oysters has been discontinued and will not be resumed.

§ 85.27 Certificates of inspection; warehousing and export permits. (a) After finding that the canned oysters comprising any parcel have been handled, prepared, and packed in compliance with all provisions of §§ 85.16 through 85.29; bear labeling approved as authorized under § 85.28 (b) and comply with all the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue a certificate showing that such canned oysters so comply. The certificate shall specify the code marks to which it applies, the quantity of the parcel so marked, the place from and to which such parcel is to be moved, the size of the oysters, the size and kind of containers, or the kind of any others used, if they are broken or if they are substandard in fill, and the destination of the parcel. A copy of such certificate shall become part of the records of the Administration. The application for warehousing and export permits shall be subject to the provisions of § 85.27 (b) for the issuance of a certificate.

(b) Unless covered by certificate, canned oysters shall not be warehoused or exported under paragraphs (a) of this section, or for sale or export under paragraph (e) of this section, or for destruction as provided by § 85.23 (b).
dence showing that such canned oysters are not in conflict with the laws of the country to which they are intended for export; and, if shipment of labeled canned oysters is specified or directed, eight specimens of the labeling therefore. If canned oysters prepared or packed according to such specifications are not in conflict with the laws of such country, the Administration shall direct the Inspector to issue to the applicant an export permit covering such canned oysters comprising any parcel ordered by such purchaser under such specifications, when the facts that such canned oysters were packed in compliance with the requirements of §§ 85.16 through 85.29 regarding sanitary conditions and processing; are not filthy, decomposed, putrid, or otherwise unfit for food; accord to such specifications, and are labeled on the outside of the shipping package to show that they are intended for such country. Such permit shall specify the code marks to which it applies and the quantity of the parcel so marked, and shall show that such canned oysters were made under sanitary conditions, are wholesome, and accord to such specifications. The applicant shall furnish to the inspector documentary evidence showing the exportation of all such canned oysters.

§ 85.29 Inspection fees. (a) (1) Except as otherwise provided by the regulations in this part, an initial payment of $600.00 shall accompany each application; thereafter, three additional advance payments of $600.00 each shall be made, as follows: One payment on or before the date of the beginning of the regular inspection period specified in the application for inspection; the remaining two payments on or before the first day of each succeeding month, except that the Administration may require the full amount of all advance payments prescribed by this paragraph to accompany the application of an applicant who has defaulted in any payment due for any prior packing season: Provided, That a packer who is concurrently receiving inspection service of shrimp under the regulations for the inspection of processed shrimp shall not make any additional payments under this subparagraph.

(2) Whenever it is determined, without hearing, by the Administration that an establishment having the inspection service has been damaged by wind, fire, flood, or other calamity to such an extent that packing operations cannot be resumed before the end of the fiscal year then current, no advance payments falling due after such calamity shall be required from the packer for that fiscal year; but whenever it is determined, without hearing, by the Administration that an establishment having the inspection service has been so damaged by any such calamity that the operations must be suspended temporarily, but can be resumed before the end of the fiscal year then current, advance payments falling due after such calamity and before the month of resumption of operations shall be postponed until operations are resumed, and thereupon shall be paid in equal monthly installments during the period between the time of resumption of operations and June 1 of the fiscal year then current: Provided, That in the event of a determination described in this paragraph the total payments and production deposits made by the packer involved shall be charged with the cost of the service made available for the establishment, without regard to the fiscal year in which the payments are made, for continuing charges against payments and production deposits, and the balance of the total payments and deposits remaining shall be refunded by the Administration to the packer after the completion of the fiscal year.

(3) Each application for an extension inspection period of 1 month shall be accompanied by a payment of $600.00, and at subsequent monthly intervals thereafter additional payments of $600.00 shall be made; but if the final payment is to cover a period of less than 30 days, then such payment shall be at the rate of $20.00 for each day of such period.

(b) (1) In addition to the payments prescribed in paragraph (a) of this section, advance deposits based upon the quantity of oysters canned by the subscribing establishment shall be made to underwrite adequately the cost of the inspection service. Such deposits shall be paid in advance in amounts of not less than $300.00, unless the Administration on an estimate of production authorized in accordance with §§ 85.13 (b) and (c), by $15.00 for each 100 cases of canned oysters, and shall be computed at the rate of 15 cents for each case of 48 cans, 211 x 300. Any advance production deposits in excess of those required for actual oysters canned for the fiscal year (July 1 through June 30) shall be refunded to the packers by the Administration after the completion of the fiscal year.

(2) Production deposits as computed under subparagraph (1) of this paragraph, together with deposits for shrimp received as prescribed under § 85.13 (b) (1) in the case of processed shrimp, shall be charged against the total cost of the inspection service which has not been provided for by the combined total payments under paragraphs (a) and (b) of this section or paragraph (a) of § 85.13, in the case of processed shrimp. The balance of the production deposits remaining after such charges have been made shall be refunded by the Administration to the packers after the completion of the fiscal year in the ratio which each packer's production deposits for oysters canned and deposits for shrimp received bears to the combined total of such deposits for oysters canned and shrimp received by all packers for the fiscal year.

(3) When inspection service is withdrawn from the establishment as authorized under § 85.29 (a) the Administration shall not return to the packer any advance payments and/or deposits described in this paragraph, but shall keep the service provided for the establishment, without regard to the method described in this section, and the balance that would have accrued to such packer shall remain to the credit of the Food and Drug Administration in the special account "Salaries and Expenses, Certification and Inspection Services."

(c) A separate fee shall be paid to cover expenses incurred in accordance with the regulations of the United States Government, for travel, subsistence, and for other purposes incident to inspection for the purpose of issuing a certificate or warehousing or export permit on canned oysters stored or held at any place other than an establishment to which a seafood inspector is assigned.

(d) When the cannery and the cannery warehouse of an establishment are located at different points of such distances apart that transportation between them is required for the inspector to perform his duties in the establishment, the packer shall furnish such transportation or shall pay a separate fee to cover all expenses thereafter.

(e) All payments required by the regulations in this part shall be by bank draft or certified check, collectible at par, drawn on the Federal Reserve Bank of the District of Columbia, United States, and payable at Washington, D. C. All such drafts and checks, except those for the payment required by § 85.16 (a), shall be delivered to the Inspector General, Public Health Service, United States Department of Health, Education, and Welfare, Washington, D. C., whereupon after appropriate records thereon have been made they shall be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

(f) All refunds to packers shall be shown drawn on the Treasury of the United States pursuant to refund vouchers duly certified and approved by the designated administrative officials.

§ 85.29 Suspension and withdrawal of inspection service. (a) The Administration may suspend and the Secretary may withdraw the inspection service of shrimp in any establishment upon failure of the packer to comply with any applicable provision of §§ 85.16 through 85.29 or upon the dissemination by the packer or anyone in privity with him of any statement that is false or misleading in any particular regarding the application to any seafood of the inspection service provided by the regulations in this part.

(b) When inspection service is suspended in an establishment, as authorized by paragraph (a) of this section, the Administration shall not lengthen the inspection period in such establishment to compensate for any of the time of suspension.

PART 120—TOXICITIES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

DEFINITIONS, INTERPRETATIONS, AND EXEMPTIONS

Sec. 120.1 Definitions and interpretations.

120.2 Pesticide chemicals considered unsafe.
for residues of Aramite.

Tolerances for residues of heptachlor (1,4,5,6,7,8,8-heptachloro-1,1-dimethyl-3a,4,7,7a-tetrahydro-4,7-methanodendro). These tolerances are established within the Food and Drug Administration charged with administration of the Pesticide Residue Amendment to the Federal Food, Drug, and Cosmetic Act (section 408).

(a) Pesticide Branch means the unit established by the Secretary of Health, Education, and Welfare.

(b) The term "tolerance" means that no amount of the pesticide chemical involved is useful and gives an opinion whether the tolerances proposed by the petitioner reasonably reflect the amounts that may be safely consumed per unit of food by man in the diet of two different species of warm-blooded animals has not been reliably determined.

(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined.

(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined.

(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

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(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

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(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

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(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined.

(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

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(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

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(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

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(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

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(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

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(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined.

(b) The term "tolerance" means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined.
§ 120.6 Exemptions from the requirement of a tolerance. (a) An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health.

(b) When applied to growing crops, in accordance with good agricultural practice, the following pesticide chemicals are exempt from the requirement of a tolerance:

1. The following copper compounds:
   - Bordeaux mixture, copper acetate, base copper carbonate (malachite) 40%, lime mixtures, copper oxichloride, copper silicate, copper sulfate basic, copper-zinc chromate, cuprous oxide.

2. N-Octylbicyclo-(2,2,1) -5-heptene-2,5-dicarboxylic acid.

4. Pyrethon butoxide.
5. Pyrethron cyclonene.
7. Pyrethrum and pyrethrins.
8. Rotenone or derris or cube roots.
9. Ruana.
10. Sabaddia.

These pesticides are not exempted from the requirement of a tolerance when applied to a crop at the time of or after harvest.

PROCEDURE FOR FILING PETITIONS

§ 120.7 Petitions proposing tolerances or exemptions for pesticide residues in or on raw agricultural commodities. (a) Petitions to be filed with the Department under the provisions of section 408(b) shall be submitted in duplicate to the Pesticide Branch. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall be accompanied by an advance deposit for fees described in § 120.33. The petition shall state petitioner’s mail address to which notice of objection under section 408(d)(5) may be sent.

(b) Petitions shall include the following data and be submitted in the following form:

Pesticide Branch,
Food and Drug Administration,
Department of Health, Education, and Welfare,
Washington 25, D. C.

Dear Sirs:
The undersigned, , submits this petition pursuant to section 408(d)(1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide chemical

Attached hereto, in duplicate and constituting a part of this petition, are the following:

A. The name, chemical identity, and composition of the pesticide chemical. (If the pesticide chemical is a chemical ingredient of an economic poison, the complete quantitative formula of the resulting economic poison should be submitted. The submission of this information does not restrict the application of any tolerance or exemption granted to the specific formula(1)s submitted.)

B. The target, frequency, and time of application of the pesticide chemical.

C. Full reports of investigations made with respect to the safety of the pesticide chemical. (These reports should include, where necessary, detailed data derived from appropriate bioassay or field experiments in which the methods used and the results obtained are clearly set forth.)

D. The amount of residue remaining, including a description of the analytical method used. (Sufficient information should be submitted about the analytical method to permit competent investigators to apply it successfully.)

E. Practicable methods for removing residues that exceed tolerances.

F. Proposed tolerances for the pesticide chemical if tolerances are proposed.

G. Reasonable grounds in support of the petition.

Enclosed is (money order, bank draft, or certified check) for $ , payable to the Food and Drug Administration to cover clerical operations, initial administrative review, and the cost incurred in considering the petition after it has been filed.

Very truly yours,

(Petitioner)

Mail address

(Indicate authority)

This petition must be signed by the petitioner or by an authorized official.

The data specified under the several lettered headings should be on separate sheets or sets of sheets suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by reference to the earlier one.

The petitioner will be notified of the date on which his petition is received.

ALL PETITIONS SHOULD BE SUBMITTED IN DUPLICATE. A SINGLE COPY WILL NOT BE ACCEPTED FOR FILING.

(1) Except as noted in paragraph (d) of this section, a petition shall not be accepted for filing if any of the data prescribed by section 408(d) are lacking or are not set forth so as to be readily understood. Data in a petition entitled to protection as a trade secret will be held confidential and not revealed unless it is necessary to do so in administrative or judicial proceedings under section 408.

(2) The Pesticide Branch shall notify the petitioner within 15 days after its receipt of acceptable or non-acceptable conditions in a petition, and if non-acceptable conditions are given a new filing date or the petition will be considered withdrawn without prejudice.

(3) The Pesticide Branch or an advisory committee, the Commissioner shall publish in the Federal Register within 90 days after receipt of the petition a finding of usefulness the date used for computing the 90-day limit for the purposes of section 408(d)(2) shall be moved forward 1 day for each day in excess of 15 from the mailing date of the petition taken by the petitioner to submit the sample. If the sample is not submitted within 180 days after mailing date of the request, the petition will be considered withdrawn without prejudice.

(4) Unless the petition is referred to an advisory committee, the Commissioner shall publish in the Federal Register within 90 days after receipt of the petition a finding of usefulness establishing a tolerance for residues of the pesticide chemical or exempting such residues from the necessity of a tolerance as provided in section 408(d)(2) of the act.

§ 120.8 Withdrawal of petitions without prejudice. In some cases the Pesticide Branch or an advisory committee to which the petition has been referred will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a tolerance or the tolerance requested by petitioner. This may be due to the fact that the data were not sufficiently complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data covering residues by a withdrawal from a future filing. Upon re-filing, the time limitation will begin to run anew from the date of re-filing or the date of receipt of certification from the Secretary of Agriculture, whichever is later. A deposit for fees as specified in § 120.33(f) shall accompany the re-submission of the petition.

§ 120.9 Substantive amendments to petitions. After a petition has been filed with the commissioner, the petitioner may submit additional information or data in support thereof, but in such cases the petition will be given a new filing date or a new initial date of consideration by the advisory committee, and the time limitation will begin to run anew. The additional data shall be accompanied by a deposit of fees as specified in § 120.33(g).

ADVISORY COMMITTEES

§ 120.10 Referral of petition to advisory committee. (a) If within the prescribed period a person filing a petition requests that the petition be re-
ferred to an advisory committee, he shall make such request in writing to the Commissioner and forward with such request an advance deposit for fees prescribed by §120.33 (b) (2). If further advance deposits are not made upon request of the Commissioner, as provided for in §120.33 (b) (3), the request for referral of the petition to an advisory committee shall be considered withdrawn, and a tolerance shall be established within 90 days of the date on which the Commissioner requested the further advance deposit.

(b) If the Chairman believes that a meeting of the committee is necessary before making a recommendation, he shall advise the Commissioner. The Commission will request the National Academy of Sciences to evaluate the proposals or petitions for the purposes of both sections 408 and 409, as provided for in §120.33 (c), and shall notify the petitioner of the results of the evaluation. If the Commission determines that a meeting of the committee is necessary, the Commission shall request the National Academy of Sciences to select qualified experts, including at least one representative from land-grant colleges, willing to serve on the advisory committee. The Commission shall request the National Academy of Sciences to furnish the names of such experts, to supply a biographical sketch showing the background and qualifications of the experts, and to notify the Commission when it furnishes the name of such experts. The experts selected by the Commission shall inform the National Academy of Sciences in writing of their acceptance or refusal to serve. He shall appoint one member of the committee, the commissioner, as chairman, and shall make such request to the National Academy of Sciences to select qualified experts, including at least one representative from land-grant colleges, willing to serve on the advisory committee. The Commission shall request the National Academy of Sciences to furnish the names of such experts, to supply a biographical sketch showing the background and qualifications of the experts, and to notify the Commission when it furnishes the name of such experts. The experts selected by the Commission shall inform the National Academy of Sciences in writing of their acceptance or refusal to serve.

(b) The Commission shall appoint an advisory committee of not less than three experts, to supply a biographical sketch showing the background and qualifications of the experts, and to notify the Commission when it furnishes the name of such experts. The experts selected by the Commission shall inform the National Academy of Sciences in writing of their acceptance or refusal to serve.

§ 120.11 Appointment of advisory committee. (a) Whenever the referral of a petition or proposal to an advisory committee is requested or the Commissioner otherwise deems such referral necessary, the chairman shall request the National Academy of Sciences to select qualified experts, including at least one representative from land-grant colleges, willing to serve on the advisory committee. The Commission shall request the National Academy of Sciences to furnish the names of such experts, to supply a biographical sketch showing the background and qualifications of the experts, and to notify the Commission when it furnishes the name of such experts. The experts selected by the Commission shall inform the National Academy of Sciences in writing of their acceptance or refusal to serve.

(b) Each advisory committee shall consist of not less than three experts, at least one of whom is a representative from a land-grant college. The Commission shall specify a larger number to serve. He shall appoint one member of the committee, the chairman, as chairman, and shall make such request to the National Academy of Sciences to select qualified experts, including at least one representative from land-grant colleges, willing to serve on the advisory committee. The Commission shall request the National Academy of Sciences to furnish the names of such experts, to supply a biographical sketch showing the background and qualifications of the experts, and to notify the Commission when it furnishes the name of such experts. The experts selected by the Commission shall inform the National Academy of Sciences in writing of their acceptance or refusal to serve.

(c) The Commission shall appoint the experts so selected and fix their compensation at not to exceed $50.00 per day for each day or part thereof spent in committee meetings and in traveling to and from committee meetings held outside the city of their residence, plus necessary traveling and subsistence expenses while the experts are serving away from their places of residence. Subsistence expenses shall not exceed $25.00 per day.

§ 120.12 Procedure for advisory committee. (a) The Commissioner shall submit to the chairman of the committee the petition or proposal, together with certification by the Secretary of Agriculture and such other relevant, reliable information as may be available. When the Commissioner submits a proposal to an advisory committee, the chairman shall, upon receiving a copy of the petition or proposal, forward the petition to the National Academy of Sciences, including any materials other than the petition and certification that is furnished by the petitioner. The chairman of the committee shall not disclose data originating with a petitioner prior to publication of a regulation.

(b) The secretariat to advisory committees shall be established by the Commissioner. The secretariat shall furnish copies of the proposal or petition, certification from the Secretary of Agriculture, and any data received by the chairman of the committee.

(c) In case the Commissioner on his own initiative deems it necessary to refer a petition to an advisory committee, he shall, in writing, inform the person filing the petition.

(d) The date of receipt of the committee shall be published in the Federal Register a notice reciting the objections and announcing a public hearing to receive evidence on them. The notice shall designate the place and time at which the hearing shall be conducted, specify the time within which appearances must be filed, and specify the time that the hearing will be held, subject to any appeal. The hearing shall be conducted at the place and time announced in the notice but thereafter it may be moved to a different place and may be continued from day to day if the hearing examiner determines that the petitioner has been adversely affected or prejudiced by the postponement of the hearing. The hearing examiner shall determine whether the hearing should be conducted in an informal or orderly manner as the circumstances require.
cordance with these regulations and the requirements of the Administrative Procedure Act. The presiding officer shall have the power to administer oaths and affirmations; to request the member of an advisory committee designated as provided by § 120.17, to regulate the course of the hearing; to hold conferences for the simplification of the issues, and to dispose of procedural requests; but he shall not have power to render any motion that affects final determination of the merits of the proceeding.

§ 120.16 Parties; burden of proof; appearances. At the hearing, the person whose objections raised the issues to be determined shall be, within the meaning of section 7(c) of the Administrative Procedure Act, the proponent of the order sought, and accordingly shall have the burden of proof. Any interested person shall be permitted to appear at a specified time and place for examination and for use by opposing party or his representative, may direct the appearances of all parties and their representatives to appear at conferences at any time during the hearing with a view to simplification, clarification, or shortening of the hearing.

§ 120.18 Submission of documentary evidence. (a) Any party shall be entitled to submit documentary evidence to be offered at the hearing shall be submitted to the presiding officer and to the parties sufficiently in advance of the offer of such documentary evidence for introduction into the record to permit study and preparation of cross-examination and rebuttal evidence.

(b) The presiding officer, after consultation with the parties at a conference called in accordance with § 120.17, shall make an order specifying the time at which documentary evidence shall be submitted by any person in his order the time within which objection to the authenticity of such documents must be made to comply with paragraph (d) of this section.

(c) Documentary evidence not submitted in advance in accordance with the requirements of paragraphs (a) and (b) of this section shall not be received in evidence in the absence of a clear showing that the offering party had good cause for his failure to produce the evidence sooner.

(d) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the presiding officer upon notice to the other parties within the time specified by the presiding officer in such advance shall be received in evidence, except that a party shall be permitted to challenge such authenticity at a later time upon a clear showing of good cause for failure to have filed such written objection.

§ 120.19 Excerpts from documentary evidence. When portions only of a document are to be relied upon, the offering party shall prepare the pertinent excerpts, adequately identified, and shall supply copies of such excerpts, together with a statement indicating the purpose for which such materials will be offered, to the presiding officer and to the other parties. Only the excerpts, so prepared and submitted, shall be received in the record. However, the whole of the original document should be made available for examination and for use by opposing counsel for purposes of cross-examination.

§ 120.20 Submission and receipt of evidence. (a) Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) When necessary to prevent undue prolongation of the hearing, the presiding officer may limit the number of times any witness may testify, the repetitious examination and cross-examination of witnesses, or the amount of corroborative or cumulative evidence.

(c) The presiding officer shall admit only evidence which is relevant, material, and not unduly repetitious.

(d) Opinion evidence shall be admitted when the presiding officer is satisfied that the witness is properly qualified.

(e) The presiding officer shall file as exhibits any formataria, etc., and any other papers or documents relating to the regulation to which objections were taken and any report, recommendations, underlying data, and reasons that were certified to the Secretary of the Senate by the advisory committee pursuant to section 408(d)(3). The report, recommendations, underlying data, and reasons shall be subject to section 7(c) of the Administrative Procedure Act. All documents constituting the record accumulated up to the start of the hearing shall be open for inspection by interested persons during office hours in the office of the clerk of the Department.

(f) The member of an advisory committee, if any, designated to testify, or any member requested to testify by the petitioner, the Department, the presiding officer, or who upon his own initiative requests to be heard, shall appear and testify with respect to the report, recommendations, underlying data, and reasons of the committee. The designated member shall receive per diem and travel and subsistence expenses when incurred, as though he were attending a meeting of the advisory committee.

(g) If any person objects to the admission or rejection of any evidence or to other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection, and the transcript shall not include extended argument or debate thereon except as ordered by the presiding officer. A ruling of the presiding officer on any such objection shall be a part of the transcript, together with such offer of proof as has been made.

§ 120.21 Transcript of the testimony. Testimony given at a hearing shall be recorded verbatim, and all exhibits, exhibits, charts, tabulations, and similar data offered in evidence at the hearing shall be marked for identification and, upon a showing satisfactory to the presiding officer of their authenticity, relevancy, and materiality, shall be received in evidence subject to the Administrative Procedure Act (see § 7(c), 5 U.S.C. 1006(c)). Exhibits shall, if practicable, be submitted in duplicate.

In case the required number of copies are not made available, the presiding officer shall exercise his discretion as to whether said exhibits shall be read in evidence or whether additional copies shall be required to be submitted within a time to be specified by the presiding officer. Where the testimony of a witness refers to a statute or to a report or document, the presiding officer shall, after inquiry relating to the identification of such statute, report, or document, determine whether the same shall be produced at the hearing and physically be made a part of the evidence by reference.
Where relevant and material matter offered in evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter shall be excluded and the testimony repeated as practicable, subject to the direction of the presiding officer.

§ 120.22 Oral and written arguments. (a) Unless the presiding officer issues an announcement at the hearing authorizing oral argument before him, it shall not be permitted. (b) The presiding officer shall announce at the hearing a reasonable period within which interested persons may present written arguments based upon the evidence received at the hearing, citing the pages of the transcript of the testimony or properly identified exhibits where such evidence occurs.

§ 120.23 Indexing of record. (a) Whenever it appears to the presiding officer that the record of hearing will be of such length that an index to the record will permit a more orderly presentation of the evidence and reduce delay, the presiding officer shall require counsel for the parties to prepare a daily topical index which will be available to the presiding officer and all parties. Preparation of such an index shall be apportioned among all counsel present in such manner as appears just and proper in the circumstances. (b) The index should include each topic of testimony upon which evidence is taken, the name of each witness testifying upon the topic, the page of the record at which each portion of his testimony appeared, and the number of each exhibit upon which the testimony is based. The index should also contain the name of each witness, followed by the topics upon which he testified and the page of the record at which such testimony appears.

§ 120.24 Certification of record. At the close of the hearing, the presiding officer shall afford interested persons a short time (not longer than 1 week, except in unusual cases) in which to point out errors that may have been made in the transcription. The presiding officer shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony and he shall certify the transcript of testimony and the exhibits to the Commissioner.

§ 120.25 Filing the record of the hearing. As soon as practicable after the closing of the hearing, the certified record of the hearing shall be filed in the office of the Hearing Clerk. The record shall include the transcript of the testimony, and exhibits, and any written arguments that may have been filed.

§ 120.26 Copies of the record of the hearing. The Department will make provisions for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purposes. Any person desiring a copy of the record of the hearing or of any part thereof shall be entitled to the same upon payment of the costs thereof.

§ 120.27 Proposed order. As soon as practicable after the time for filing written arguments has ended the Commissioner shall prepare and cause to be published in the Federal Register a proposed order which shall incorporate findings of fact, recommend decisions on the various objections which were the subject of the hearing and tentative regulations. The proposed order shall specify a reasonable time, ordinarily not to exceed 30 days, within which any interested person may file objections to the Commissioner. The objections shall be filed in writing, pointing out with particularity the alleged errors in said proposed order and shall contain a specific reference to the pages of the transcript or to the exhibits on which each exception is based. Such exceptions may be accompanied by a memorandum brief.

§ 120.28 Final order. As soon as practicable after the time for filing exceptions has passed, the record and the exceptions shall be presented to the Secretary and he shall cause to be published in the Federal Register his final order promulgating the regulations.

ADOPTION OF TOLERANCE ON INITIATIVE OF SECRETARY OR ON REQUEST OF INTERESTED PERSON; TEMPORARY TOLERANCES; AMENDMENT AND REPEAL OF TOLERANCES; FEES

§ 120.29 Adoption of tolerance on initiative of Secretary or on request of an interested person. (a) Upon request of a person who has registered or who has submitted an application for the registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135a) establishing reasonable grounds therefor, and upon advance deposit to cover fees as prescribed in § 120.33, the Commissioner may propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Reasonable grounds shall include an explanation showing wherein the person has a substantial interest in such a tolerance or exemption from tolerance; information, if available, as to whether registrant of the pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act has not petitioned for a tolerance or exemption from a tolerance; and adequate data on subjects outlined in clauses (A), (B), (C), (D), (E), and (F) of section 408 (d) (1) of the Federal Food, Drug, and Cosmetic Act. If the Commissioner concludes upon studying the request that it does not warrant a proposal for the issuance of a regulation, he shall so inform the person making the request and state the reasons for his decision. (b) The notice of the proposal shall show whether it is a proposal of the Commissioner or of the person requesting the issuance of a regulation. (c) If within 30 days after publication of the proposal a person who has registered or who has submitted an application for registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act has petitioned for a tolerance or exemption from a tolerance, the Commissioner may propose the issuance of a tolerance or an exemption therefrom.

§ 120.30 Judicial review. (a) The Commissioner of Health, Education, and Welfare hereby designates the Assistant General Counsel for Food and Drugs of the Department of Health, Education, and Welfare as the officer upon whom a copy of petition for judicial review shall be served. Such officer shall be responsible for filing in the court a transcript of proceedings and the record on which the Commissioner requested the further advance deposit.

§ 120.31 Temporary tolerances. (a) A temporary tolerance (or exemption from a tolerance) established under authority of section 408 (d) of the act shall be deemed to be a proposal for a temporary tolerance (or exemption from the requirement of a tolerance) for the purposes of section 408 (d) (1) or (2) of the act. (b) (1) A request for a temporary tolerance or a temporary exemption from a tolerance by a person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act may be issued for a temporary tolerance or an exemption therefrom. (2) Such a proposal shall be accompanied by a copy of such experimental permit, such data as are available on subjects outlined in clauses (A), (B), (C), (D), (E), and (F) of section 408 (d) (1) and (2) of the act, and an advance deposit to cover fees as provided in § 120.33.

§ 120.32 (b) Before an experimental permit has been obtained, the Pesticide Branch upon request of the Department of Agriculture or a person who proposes to apply for an experimental permit will consider available data and discuss its adequacy for the purpose of justifying a tolerance or exemption from a tolerance.

§ 120.33 A notice of the issuance of a temporary tolerance outlines any restrictions as to use of the chemical in the United States under theexperimental permit under the Federal Insecticide, Fungicide, and Rodenticide Act may be published in the Federal Register if the Commissioner decides such publication desirable.
denticide Act when the Commissioner concludes that the public health can be adequately protected during such marketing. A temporary tolerance or exemption from a tolerance may be revoked, or may be revoked if at any time it develops that the application for a temporary tolerance contains a misstatement of a material fact or if new scientific evidence has led the person to conclusion that it is no longer necessary to maintain the tolerance or exemption from tolerance.

§ 120.32 Procedure for amending and repealing tolerances or exemptions from tolerances. (a) The Commissioner on his own initiative or on request from an interested person furnishing reasonable grounds therefor, may propose the issuance of a regulation amending or repealing a tolerance for a pesticide chemical on raw agricultural commodities or granting or repealing an exemption from tolerance for such chemical. Requests for such amendment or repeal shall be made in writing and accompanied by an advance deposit to cover fees as provided in § 120.33 (d).

(b) Reasonable grounds shall include an explanation showing wherein the person has a substantial interest in such amendment or repeal. Evidence that a person has registered or has submitted an application for the registration of an agricultural commodity more than nine months prior to the date of the amendment or repeal shall be accompanied by a deposit of $1,000, unless it meets the requirements of subparagraph (1) or (2) of this paragraph.

(1) Such deposit is not required when, in connection with the change sought under this paragraph, a petition or request is filed for the establishment of new tolerances to take the place of those sought to be amended or repealed and a deposit is made as required by paragraph (a) or (b) of this section.

(2) A request for a temporary tolerance for a pesticide chemical which has not been used at the numerical level shall be accompanied by a deposit of $100 for clerical handling and initial administrative review, plus $100 for each raw agricultural commodity on which the temporary tolerance is sought.

(c) If a petition or a request proposing the establishment of a tolerance is technically incomplete, the deposit, less a $100 fee for clerical handling and initial administrative review, shall be returned unless the petitioner indicates that he wishes to submit a supplement. The deposit shall be returned if the Commissioner, and the supplement shall be accompanied by a nontaxable fee of $100.

(d) When a petition is withdrawn after filing and resubmitted within 6 months, it shall be accompanied by a deposit of $500, or by a deposit equal to the one originally submitted, whichever is smaller. If resubmitted after 6 months, it shall be accompanied by the deposit that would be required if it were being submitted for the first time.

(e) After a petition has been filed, any additional information or data submitted in support of it (i.e., any substantive amendment) shall be accompanied by a deposit equal to the one originally submitted, whichever is smaller.

(f) Objections under section 408 (d) or (5) of the act shall be accompanied by a filing fee of $250.00.

(1) In the event of a referral of a petition or a request under this section to an advisory committee, the costs shall be borne by a person who requests the referral of the data to the advisory committee.

(2) Cost of the advisory committee, including expenses of the secretariat, will not exceed $25,000 per member per day plus cost of duplicating documents referred to the committee, plus necessary traveling and subsistence expenses of the members while they are serving away from their places of residence.

(2) An advance deposit shall be made in the amount of $2,500, plus $100 for each raw agricultural commodity on which the temporary tolerance is sought. Further advance deposits of $2,500 each shall be made upon request of the Commissioner when necessary to prevent excessive cost of the proceedings and the record on which the order is based.

(k) All deposits and fees required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C. Any person making适当 appropriate record thereof they will be transmitted to the Treasurer of the United States, for deposit to the special account in the Food and Drug Administration. The person who files a petition for judicial review of an order under section 408 (d) (5) or (e) of the act shall pay the costs of preparing a transcript of the proceedings and the record on which the order is based or refund the fees.

TOLERANCES FOR RESIDUES

§ 120.101 Specific tolerances for pesticide residues in or on fresh fruits and vegetables. (a) This section designates the poisonous or deleterious substances that, for the purposes of section 406 of the Federal Food, Drug, and Cosmetic Act, are found to be required in the production of the fresh fruits or vegetables named in paragraph (c) of this section. The tolerances established for such substances apply only to residues resulting from their application prior to harvest. A tolerance in terms of parts by weight for the poisonous or deleterious substance, or poisonous or deleterious residue resulting from its addition, to 1 million parts by weight of the fruit or vegetable is set forth after the name of each of the required substances.

(b) The poisonous and deleterious substances, for which tolerances are established by this section, are named by their common names wherever practicable, otherwise by their chemical names as assigned to them by the United States Department of Agriculture. For the purposes of this section, the substances for which common, generic, or Department of Agriculture names are used are as follows:
Tuesday, December 20, 1955

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### FRUITS—Continued

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</tr>
<tr>
<td>Thiram</td>
<td>7 ppm</td>
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<tr>
<td>Ziram</td>
<td>7 ppm</td>
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### Apricots

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<tr>
<td>Chlor dane</td>
<td>0.5 ppm</td>
</tr>
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<td>DDT</td>
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<td>Dicyclohexylamine salt of dinitro O cyclohexyphenol</td>
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</tr>
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<td>0.1 ppm</td>
</tr>
<tr>
<td>EPN</td>
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<tr>
<td>Ferbam</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm of combined fluorine</td>
</tr>
<tr>
<td>Lead arsenate</td>
<td>7 ppm of combined lead</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>1 ppm</td>
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<tr>
<td>Parathion</td>
<td>1 ppm</td>
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<tr>
<td>TDE</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Toxaphene</td>
<td>7 ppm</td>
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<tr>
<td>Zineb</td>
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<tr>
<td>Ziram</td>
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### Citrus fruits (grapefruit, lemons, limes, oranges, tangerines)

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<tr>
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<td>2,4-Dichlorophenoxy acetic acid</td>
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<td>1 ppm</td>
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<tr>
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<tr>
<td>Fluorine compounds</td>
<td>7 ppm of combined fluorine</td>
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<tr>
<td>Lead arsenate</td>
<td>1 ppm of combined lead</td>
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<tr>
<td>Methoxychlor</td>
<td>14 ppm</td>
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<tr>
<td>Parathion</td>
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<tr>
<td>Tetrachlorvinphos</td>
<td>7 ppm of combined antimony trioxide</td>
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<tr>
<td>TDE</td>
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<td>Toxaphene</td>
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### Cranberries

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<td>Methoxychlor</td>
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<td>Parathion</td>
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<td>Zineb</td>
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<tr>
<td>Ziram</td>
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### Blueberries (huckleberries)

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<td>Ferbam</td>
<td>7 ppm</td>
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<tr>
<td>Fluorine compounds</td>
<td>7 ppm of combined fluorine</td>
</tr>
<tr>
<td>Lead arsenate</td>
<td>7 ppm of combined lead</td>
</tr>
<tr>
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<td>14 ppm</td>
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<td>1 ppm</td>
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<tr>
<td>Ziram</td>
<td>7 ppm</td>
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<td>Zineb</td>
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### Cherries—Continued

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<td>Dicyclohexylamine salt of dinitro O cyclohexyphenol</td>
<td>1 ppm</td>
</tr>
<tr>
<td>Dieldrin</td>
<td>0.1 ppm</td>
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<tr>
<td>EPN</td>
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### Cherries—Continued

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<td>Nicotine containing compounds</td>
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<tr>
<td>Zineb</td>
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<td>Ziram</td>
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### Citrus fruits (grapefruit, lemons, limes, oranges, tangerines)

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### Cranberries

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<tbody>
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<td>DDT</td>
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<tr>
<td>Ferbam</td>
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<td>Fluorine compounds</td>
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<tr>
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</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm</td>
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<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm of nicotine</td>
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<tr>
<td>Parathion</td>
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<td>Zineb</td>
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<td>Ziram</td>
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### Currents

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<tr>
<td>Lead arsenate</td>
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<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm of nicotine</td>
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<td>Parathion</td>
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### Dates

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### Figs

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</tr>
<tr>
<td></td>
<td>Lead arsenate</td>
</tr>
<tr>
<td></td>
<td>Methoxychlor</td>
</tr>
<tr>
<td></td>
<td>Nicotine containing compounds</td>
</tr>
<tr>
<td></td>
<td>Parathion</td>
</tr>
<tr>
<td></td>
<td>TDE</td>
</tr>
<tr>
<td></td>
<td>Zineb</td>
</tr>
<tr>
<td></td>
<td>Ziram</td>
</tr>
<tr>
<td>(21) Loganberries</td>
<td>Pesticide</td>
</tr>
<tr>
<td></td>
<td>Benzene hexachloride</td>
</tr>
<tr>
<td></td>
<td>Chlordane</td>
</tr>
<tr>
<td></td>
<td>DDT</td>
</tr>
<tr>
<td></td>
<td>Dicyclohexylamino salt of dinitro O-cyclohexylphenol</td>
</tr>
<tr>
<td></td>
<td>Fluridone</td>
</tr>
<tr>
<td></td>
<td>Fluorine compounds</td>
</tr>
<tr>
<td></td>
<td>Lead arsenate</td>
</tr>
<tr>
<td></td>
<td>Methoxychlor</td>
</tr>
<tr>
<td></td>
<td>Nicotine containing compounds</td>
</tr>
<tr>
<td></td>
<td>Parathion</td>
</tr>
<tr>
<td></td>
<td>TDE</td>
</tr>
<tr>
<td></td>
<td>Zineb</td>
</tr>
<tr>
<td></td>
<td>Ziram</td>
</tr>
</tbody>
</table>
# FRUITS—Continued

(27) *Raspberries* blackberries loganberries, and related berries—Continued

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-Propylcyclopropane</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Lead arsenate</td>
<td>9 ppm m of combined lead</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Toxicophene</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm</td>
</tr>
</tbody>
</table>

(28) *Rhubarb*

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDT</td>
<td>7 ppm</td>
</tr>
</tbody>
</table>

# STRAWBERRIES

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>Chlorazine</td>
<td>0 ppm</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Dicyclohexylamine salt of dinitro O-cyclohexylphenol</td>
<td>1 ppm m</td>
</tr>
<tr>
<td>EPN</td>
<td>3 ppm</td>
</tr>
<tr>
<td>Ferbam</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m of combined fluorine</td>
</tr>
<tr>
<td>Lead arsenate</td>
<td>7 ppm m of combined lead</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>16 ppm m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Toxicophene</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm</td>
</tr>
</tbody>
</table>

(29) *Tangerines* For tolerances established for pesticide residues on tangerines see subparagraph (2) of this paragraph

# VEGETABLES

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDT</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm</td>
</tr>
</tbody>
</table>

(30) *Asparagus* For tolerances established for pesticide residues on asparagus see subparagraph (2) of this paragraph

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m</td>
</tr>
<tr>
<td>Ferbam</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Lead arsenate</td>
<td>7 ppm m of combined lead</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m of nicotine</td>
</tr>
</tbody>
</table>

(31) *Artichokes*

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDT</td>
<td>7 ppm</td>
</tr>
</tbody>
</table>

(32) *Asparagus*

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m</td>
</tr>
<tr>
<td>Ferbam</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Lead arsenate</td>
<td>7 ppm m of combined lead</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m of nicotine</td>
</tr>
</tbody>
</table>

(33) *Beans, green beans, snap beans, lima beans and black eyed peas*

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>Chlorazine</td>
<td>0 ppm</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Dicyclohexylamine salt of dinitro O-cyclohexylphenol</td>
<td>1 ppm m</td>
</tr>
</tbody>
</table>

# VEGETABLES—Continued

(34) *Beans green beans snap beans, lima beans and black eyed peas—Continued*

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>EPN</td>
<td>3 ppm</td>
</tr>
<tr>
<td>Ferbam</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m of combined fluorine</td>
</tr>
<tr>
<td>Magnesium arsenate</td>
<td>8 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>8 ppm m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Toxicophene</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm</td>
</tr>
</tbody>
</table>

(35) *Beets (with or without tops) or beet greens alone*

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlor dane</td>
<td>0 ppm</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm</td>
</tr>
<tr>
<td>EPN</td>
<td>3 ppm</td>
</tr>
<tr>
<td>Ferbam</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>8 ppm m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Toxicophene</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm</td>
</tr>
</tbody>
</table>

(36) *Broccoli*

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m</td>
</tr>
<tr>
<td>Ferbam</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>8 ppm m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Toxicophene</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm</td>
</tr>
</tbody>
</table>

(37) *Brussels sprouts For tolerances established for pesticide residues on brussels sprouts see subparagraph (38) of this paragraph*

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>6 ppm</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>Chlor dane</td>
<td>0 ppm</td>
</tr>
<tr>
<td>Copper arsenate</td>
<td>3 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m</td>
</tr>
<tr>
<td>Ferbam</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>8 ppm m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Toxicophene</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm</td>
</tr>
</tbody>
</table>

(38) *Cabbage, brussels sprouts, kohlrabi, cauliflower*

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>6 ppm</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>Chlor dane</td>
<td>0 ppm</td>
</tr>
<tr>
<td>Copper arsenate</td>
<td>3 ppm m of combined AsO₂</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m</td>
</tr>
<tr>
<td>Ferbam</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>8 ppm m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Toxicophene</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm</td>
</tr>
</tbody>
</table>
### Vegetables—continued

#### (39) Carrots (with or without tops) or carrot tops

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium arsenate</td>
<td>3.6 ppm of combined As₂O₃</td>
</tr>
<tr>
<td>Chlorfenvinphos</td>
<td>0.3 ppm m.</td>
</tr>
<tr>
<td>Copper arsenate</td>
<td>3.6 ppm of combined As₂O₃</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Furadan</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m. of combined fluorine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm m.</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Toxaphene</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm m.</td>
</tr>
</tbody>
</table>

#### (40) Cauliflower

For tolerances established for pesticide residues on cauliflower, see subparagraph (38) of this paragraph.

#### (41) Celery

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoate hexachloride</td>
<td>5 ppm m.</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.6 ppm of combined As₂O₃</td>
</tr>
<tr>
<td>Chlorfenvinphos</td>
<td>0.3 ppm m.</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Disocyclhexylamin-N,N,N,N-tetrachloroaminophenol</td>
<td>1 ppm m.</td>
</tr>
<tr>
<td>Inter.</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Lead arsenate</td>
<td>7 ppm m. of combined lead</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m. nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm m.</td>
</tr>
<tr>
<td>Toxaphene</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm m.</td>
</tr>
</tbody>
</table>

#### (42) Collards

For tolerances established for pesticide residues on collards, see subparagraph (47) of this paragraph.

#### (43) Corn

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoate hexachloride</td>
<td>5 ppm m.</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.6 ppm of combined As₂O₃</td>
</tr>
<tr>
<td>Chlorfenvinphos</td>
<td>0.3 ppm m.</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Furadan</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m. of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m.</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m. nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm m.</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Toxaphene</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm m.</td>
</tr>
</tbody>
</table>

#### (44) Cucumbers—Continued

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDE</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Toxaphene</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm m.</td>
</tr>
</tbody>
</table>

#### (45) Eggplants

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoate hexachloride</td>
<td>5 ppm m.</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.6 ppm of combined As₂O₃</td>
</tr>
<tr>
<td>Chlorfenvinphos</td>
<td>0.3 ppm m.</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Furadan</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m. of combined fluorine</td>
</tr>
<tr>
<td>Lead arsenate</td>
<td>7 ppm m. of combined lead</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m.</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m. nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm m.</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Toxaphene</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm m.</td>
</tr>
</tbody>
</table>

#### (46) Endive and escarole

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDT</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm m.</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm m.</td>
</tr>
</tbody>
</table>

#### (47) Kale and collards

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoate hexachloride</td>
<td>5 ppm m.</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.6 ppm of combined As₂O₃</td>
</tr>
<tr>
<td>Chlorfenvinphos</td>
<td>0.3 ppm m.</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Furadan</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m. of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m.</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m. nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm m.</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm m.</td>
</tr>
</tbody>
</table>

#### (48) Kohlrabi

For tolerances established for pesticide residues on kohlrabi, see subparagraph (38) of this paragraph.

#### (49) Lettuce

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoate hexachloride</td>
<td>5 ppm m.</td>
</tr>
<tr>
<td>Chlorfenvinphos</td>
<td>0.3 ppm m.</td>
</tr>
<tr>
<td>DDT</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Furadan</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 ppm m. of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 ppm m.</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 ppm m. nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 ppm m.</td>
</tr>
<tr>
<td>TDE</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Toxaphene</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 ppm m.</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 ppm m.</td>
</tr>
</tbody>
</table>
### VEGETABLES—continued

(60) **Lima beans**  For tolerances established for pesticide residues on lima beans see subparagraph (83) of this paragraph.

(61) **Melons including cantaloupes, muskmelons, watermelons and other melons**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 p p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.5 p p m of combined As$_2$O$_3$</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.8 p p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Fenamid</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p p m of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p p m</td>
</tr>
<tr>
<td>Nicotine-containing compounds</td>
<td>2 p p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 p p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p p m</td>
</tr>
</tbody>
</table>

(62) **Mushrooms**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p p m</td>
</tr>
<tr>
<td>Nicotine-containing compounds</td>
<td>2 p p m of nicotine</td>
</tr>
</tbody>
</table>

(63) **Mustard greens**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 p p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.5 p p m of combined As$_2$O$_3$</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.8 p p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Fenamid</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p p m of combined fluorine</td>
</tr>
<tr>
<td>Nicotine-containing compounds</td>
<td>2 p p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 p p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p p m</td>
</tr>
</tbody>
</table>

(64) **Okra**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
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</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 p p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.5 p p m of combined As$_2$O$_3$</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.8 p p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p p m of combined fluorine</td>
</tr>
<tr>
<td>Nicotine-containing compounds</td>
<td>2 p p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 p p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p p m</td>
</tr>
</tbody>
</table>

(65) **Onions**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 p p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.5 p p m of combined As$_2$O$_3$</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.8 p p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p p m of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p p m</td>
</tr>
<tr>
<td>Nicotine-containing compounds</td>
<td>2 p p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 p p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p p m</td>
</tr>
</tbody>
</table>

(66) **Peppers**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 p p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.5 p p m of combined As$_2$O$_3$</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.8 p p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p p m of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p p m</td>
</tr>
<tr>
<td>Nicotine-containing compounds</td>
<td>2 p p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 p p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p p m</td>
</tr>
</tbody>
</table>

(67) **Parsnips (with or without tops) or parsnip greens alone**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Nicotine-containing compounds</td>
<td>2 p p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 p p m</td>
</tr>
</tbody>
</table>

(68) **Peas**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 p p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.5 p p m of combined As$_2$O$_3$</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.8 p p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p p m of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p p m</td>
</tr>
<tr>
<td>Nicotine-containing compounds</td>
<td>2 p p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 p p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p p m</td>
</tr>
</tbody>
</table>

(69) **Peppers**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 p p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.5 p p m of combined As$_2$O$_3$</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.8 p p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p p m of combined fluorine</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p p m</td>
</tr>
<tr>
<td>Nicotine-containing compounds</td>
<td>2 p p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>1 p p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p p m</td>
</tr>
</tbody>
</table>

(70) **Potatoes**  Tolerances are not needed for those pesticides applied only to the foliage of potatoes and that are not transllocated to the tubers.

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aldrin</td>
<td>0.1 p p m</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.5 p p m</td>
</tr>
<tr>
<td>Octachlor</td>
<td>0.1 p p m</td>
</tr>
</tbody>
</table>

(71) **Pumpkins**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzen hexachloride</td>
<td>5 p p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>3.5 p p m of combined As$_2$O$_3$</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p p m</td>
</tr>
<tr>
<td>Pesticide</td>
<td>Tolerance</td>
</tr>
<tr>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td><strong>Fenthion</strong></td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>
| **Radishes (with or without tops) or radish tops.**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlor dane</td>
<td>0.3 p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fenthion</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>
| **Spinach**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzene hexachloride</td>
<td>5 p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>36 p m of combined As₂O₃</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.3 p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p m</td>
</tr>
<tr>
<td>EPN</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fenthion</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>
| **Squash; summer squash**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzene hexachloride</td>
<td>5 p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>36 p m of combined As₂O₃</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.3 p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p m</td>
</tr>
<tr>
<td>EPN</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fenthion</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>
| **Sweetpotatoes**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aldrin</td>
<td>0.1 p m</td>
</tr>
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</table>

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(69) **Swiss chard**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzene hexachloride</td>
<td>5 p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>

(70) **Tomatoes**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzene hexachloride</td>
<td>5 p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>36 p m of combined As₂O₃</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.3 p m</td>
</tr>
<tr>
<td>Copper arsenate</td>
<td>36 p m of combined As₂O₃</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ferram</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Lead arsenate</td>
<td>7 p m of combined lead</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>

---

(71) **Turnips or rutabagas (with or without tops) or turnip greens or rutabaga tops**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium arsenate</td>
<td>55 p m of combined As₂O₃</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.3 p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p m</td>
</tr>
<tr>
<td>EPN</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ferram</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>

---

(68) **Pumpkins—Continued**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlor dane</td>
<td>0.3 p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fenthion</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>

---

(67) **Squash; summer squash**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzene hexachloride</td>
<td>5 p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>36 p m of combined As₂O₃</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.3 p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p m</td>
</tr>
<tr>
<td>EPN</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ferram</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>

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(66) **Radishes (with or without tops) or radish tops.**

For tolerances established for pesticides residues on radishes see subparagraph (71) of this paragraph.

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(65) **Saladify**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zineb</td>
<td>7 p m</td>
</tr>
</tbody>
</table>

---

(64) **Spinach**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzene hexachloride</td>
<td>5 p m</td>
</tr>
<tr>
<td>Calcium arsenate</td>
<td>36 p m of combined As₂O₃</td>
</tr>
<tr>
<td>Chlordane</td>
<td>0.3 p m</td>
</tr>
<tr>
<td>DDT</td>
<td>7 p m</td>
</tr>
<tr>
<td>EPN</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ferram</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>

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(63) **Rutabagas (with or without tops) or rutabaga tops.**

For tolerances established for pesticides residues on rutabagas see subparagraph (71) of this paragraph.

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(62) **Pumpkins—Continued**

<table>
<thead>
<tr>
<th>Pesticide</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferram</td>
<td>7 p m</td>
</tr>
<tr>
<td>Fluorine compounds</td>
<td>7 p m of combined fluorne</td>
</tr>
<tr>
<td>Methoxychlor</td>
<td>14 p m</td>
</tr>
<tr>
<td>Nicotine containing compounds</td>
<td>2 p m of nicotine</td>
</tr>
<tr>
<td>Parathion</td>
<td>7 p m</td>
</tr>
<tr>
<td>TDE</td>
<td>7 p m</td>
</tr>
<tr>
<td>Zineb</td>
<td>7 p m</td>
</tr>
<tr>
<td>Ziram</td>
<td>7 p m</td>
</tr>
</tbody>
</table>

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(61) In accordance with section 408(b)(2) of the Federal Food, Drug, and Cosmetic Act these tolerances shall be deemed also tolerances under section 408(b)(2).

§ 129.102 Tolerances for residues of SES (sodium 2,4-dichlorophenoxyethyl sulfate) The following tolerances are established for residues of SES (sodium 2,4-dichlorophenoxyethyl sulfate) in or on the raw agricultural commodities indicated:

(a) 6 parts per million in or on potatoes, peanuts, peanut hulls, peanut hay (b) 2 parts per million in or on asparagus, strawberries

§ 129.103 Tolerances for residues of capitan A tolerance of 20 parts per million is established for residues of capitan (N-t-chloroethylmethyl mercapto-4-cyclohexene-1,2-dicarboximide) in or on the raw agricultural commodities apples, apricots, cantaloupes, cherries, cucumbers, celery, grapefruits, lemons, limes, mangos, nectarines, oranges, peaches, pears, peppermint, plums, plums, pumpkins, quinces, summer squash, strawberries, tangerines, tomatoes, watermelon, winter squash

§ 129.104 Extended tolerance for residues of heptachlor (1, 2, 3, 5, 5, 7, 7, 8-heptachloro-3a,4,7,7-tetrahydro-4,7-methanoindene) The tolerance of 0.1 part per million for residues of heptachlor (§ 129.101(e)(6)) in 20 F.R. 1607) is extended to also include the following raw agricultural commodities: Alfalfa, clover,
sweet clover; beets (including sugar beets); cabbage, brussels sprouts, kohlrabi, cauliflower; corn; pasture grass and other grasse; onions; peas; peanuts; sugar cane; sweet potatoes; turnips with tops and rutabagas (yellow turnips) without tops.

§ 120.105 Tolerance for residues of Systox (O,O-diethyl (2-ethylmercaptoethyl) thioephosphate, a mixture of the thiono and thiol isomers). A tolerance of 0.75 parts per million is established for residues of Systox (O,O-diethyl (2-ethylmercaptoethyl) thioephosphate — a mixture of the thiono and thiol isomers) and derived anticholinesterase products as determined by in vitro cholinesterase inhibition of pooled human plasma, using technical Systox as a standard (this standard effects 50-percent inhibition of pooled human plasma cholinesterase at a concentration of 0.3-0.625 parts per million in water as a medium) is established in or on the following raw agricultural commodities: Apples, broccoli, brussels sprouts, carrots, cauliflower, cabbages, cayenne pepper, muskmelons, oranges, peas, potatoes, strawberries, and rambutan.

§ 120.106 Tolerance for residues of Aramite (2-(p-tert-butylphenoxy)-iso-phenyl phenyl sulfone) is established in or on the following raw agricultural commodities: Cucumbers, brussels sprouts, cabbage, cauliflower, cayenne pepper, muskmelons, oranges, peas, potatoes, strawberries, and rambutan.

§ 120.107 Tolerance for residues of Aramite. (a) A tolerance of 1 part per million is established for residues of Aramite (2-(p-tert-butylyphenoxy)-isopropyl-2-chloroethyl sulfite) on the raw agricultural commodities apples, blueberries, cantaloupes, celery, cucumbers, grapefruit, grapes, green beans, lemons, muskmelons, oranges, peaches, pears, plums, raspberries, strawberries, sweet corn (kernels) but not foliage thereof, tomatoes, watermelons.

(b) A tolerance of zero is established for residues of Aramite in or on the raw agricultural commodities alfalfa and soybeans (whole plant).

§ 120.108 Tolerance for residues of 2-(2-tert-butylyphenoxy)-1,1-dimethylethylene. A tolerance of 1 part per million is established for residues of 2-(2-tert-butylyphenoxy)-1,1-dimethylethylene is established in or on the following raw agricultural commodities: Asparagus, cottonseed, onions (dry bulbs only), pineapple, spinach, sugar cane.

§ 120.109 Tolerance for residues of Chlorobenzilate (ethyl 4,4'-dichlorobenzilate) A tolerance of 5 parts per million is established for residues of Chlorobenzilate (ethyl 4,4'-dichlorobenzilate) in or on each of the following raw agricultural commodities: Apples, cantaloupe, lemons, oranges, and pears.

§ 120.110 Tolerances for residues of maneb (manganese ethylenebisdithiocarbamate) Tolerances for residues of maneb (manganese ethylenebisdithiocarbamate) calculated as zinc ethylenebisdithiocarbamate, are established as follows:

(a) 7 parts per million in or on apples, beans, carrots (with or without tops) or cabbage, celery, cranberries, cucumbers, eggplant, fava, grapes, melons, onions, peaches, peppers, spinach, summer squash, tomatoes, and potatoes.

(b) 0.1 part per million in or on almonds and potatoes.

§ 120.111 Tolerances for residues of maneb (manganese ethylenebisdithiocarbamate) in or on the following raw agricultural commodities: Alfalfa, apples, apricots, avocados, beans, beets, blueberries, broccoli, brussels sprouts, cabbage, cauliflower, celery, cherries, cranberries, cucumbers, dates, eggplants, grapes, kales, lettuce, mangoes, melons, mustard greens, onions (including green onions) passion fruit, peaches, pears, peppers, pineapples, plums, potatoes, prunes, ruitabagas, squash (both summer and winter squash), strawberries, tomatoes, turnips (including tops).

§ 120.112 Tolerances for residues of Sulphonaphenone (p-chlorophenyl phenyl sulfone). A tolerance of 0.1 parts per million is established for residues of Sulphonaphenone (p-chlorophenyl phenyl sulfone) in or on each of the following raw agricultural commodities: Apples, peaches, pears.

§ 120.113 Exemption from the requirement of a tolerance for residues of allethrin. (a) Allethrin (allyl homolog of cinem 1) is exempted from the requirement of a tolerance for residues when used before harvest in the production of beans, broccoli, brussels sprouts, cabbage, cauliflower, collards, corn, radish, kale, kohlrabi, lettuce, mushrooms, mustard greens, radish, rutabaga, turnips.

(b) Allethrin is not exempted from the requirement of a tolerance when used at time of or after harvest.

§ 120.114 Tolerance for residues of ferbam. A tolerance of 0.1 part per million is established for residues of ferbam (ferric dimethyldithiocarbamate) calculated as zinc ethylenebisdithiocarbamate, in or on almonds.

§ 120.115 Tolerance for residues of zineb. A tolerance of 0.1 part per million is established for residues of zineb (zinc ethylenebisdithiocarbamate) in or on mushrooms.

§ 120.116 Tolerances for residues of ziram. (a) A tolerance of 7 parts per million is established for residues of ziram (zinc dimethyldithiocarbamate) calculated as zinc ethylenebisdithiocarbamate, in or on almonds.

(b) A tolerance of 0.1 part per million is established for residues of ziram (zinc dimethyldithiocarbamate) calculated as zinc ethylenebisdithiocarbamate, in or on almonds and pecans.

§ 120.117 Tolerance for residues of chloretetracycline. A tolerance of 7 parts per million is established for residues of chloretetracycline in or on cooked poultry. This tolerance level shall not be exceeded in any part of the poultry.

§ 120.118 Tolerances for residues of Phygon (dichloro or 2,3-dichloro-1,4-naphthoquinone) A tolerance of 3 parts per million is established for residues of Phygon (dichloro or 2,3-dichloro-1,4-naphthoquinone) in or on each of the following raw agricultural commodities: Celery, tomatoes.

§ 120.119 Tolerances for residues of EPN (O-ethyl-p-nitrophenyl benzene thio phosphonate). Tolerances for residues of EPN (O-ethyl-p-nitrophenyl benzene thio phosphonate) are established as follows:

(1) 3 parts per million in or on grapes, olives, sugar beets (but not sugar beet tops) tomatoes.

(2) 0.5 part per million in or on almonds, cottonseed, pecans, walnuts.

PART 125—LABEL STATEMENTS CONCERNING DIETARY PROPERTIES OF FOOD FAVORABLE OR APPEALING TO BE OR REPRESENTED FOR SPECIAL DIETARY USES

Sec. 125.1 Definitions and interpretations of terms. 125.2 General label statements. 125.3 Label statements relating to vitamins. 125.4 Label statements relating to minerals. 125.5 Label statements relating to infant food. 125.6 Label statements relating to certain foods used in control of body weight or in dietary management with respect to disease. 125.7 Label statements relating to non-nutritive constituents. 125.8 Label statements relating to hypoallergenic food. 125.9 Label statements relating to certain foods used as a means of regulating the intake of sodium in dietary management.

AUTHORITY: §125.1 to 125.6 Issued under sec. 701 (a), 63 Stat. 1030; 21 U. S. C. 371 (a), Interpret or apply see sec. 403 (j), 52 Stat. 1047; 21 U.S. C. 433 (j).

§ 125.1 Definitions and interpretations of terms. (a) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in the regulations in this part.

(b) Any requirement of the regulations in this part with respect to the quantity of vitamin A means the biologically measured activity of vitamin A and its precursors; but if any such precursor is sold as such or is added to a food the label shall designate such precursor by its common or usual name and not as vitamin A.

(c) Specification in the regulations in this part of a quantity of any vitamin, mineral, or other dietary property as a minimum daily requirement shall not be construed as a determination that such quantity is sufficient for the treatment of any disease resulting from a deficiency in such vitamin, mineral, or other property.

(d) For the purposes of the regulations in this part, the terms "infant," "child," and "adult" mean persons not more than 12 months old, more than 12 months but less than 12 years old, and 12 years or more old, respectively.

§ 125.2 General label statements. (a) If a food (including food to which any one or more of §§125.3 to 125.8, inclusive, is applicable) purports to be or is repre-
sented for any special dietary use by man, its label shall bear a statement of the dietary properties upon which such use is based in whole or in part. Such statement shall show the presence or absence of any substance, any alteration of the character or chemical constitution, and any other dietary property of such food upon which such use is based.

(6) If a food (including food to which any one or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented for special dietary use by reason of its use for treating any disease resulting from a dietary deficiency of any vitamin, mineral, or other dietary constituent, and any other dietary property of such food upon which such use is based.

(7) If a food (including food to which any one or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented for special dietary use by reason of its use for treating any disease resulting from a dietary deficiency of any vitamin, mineral, or other dietary constituent, and any other dietary property of such food upon which such use is based.

The foregoing requirements of this paragraph shall not apply to cow's milk and evaporated milk, and unless the exemption under subparagraph (3) of this paragraph applies, the label shall bear a statement of the proportion of the quantity of vitamin in a specified quantity of food. The quantity of food specified as required by this section, shall be the quantity customarily or usually consumed during a period of one day, or, if the proportion is not practicable of consumption within such period, if the need in human nutrition for such vitamin has not been established, the label shall bear a statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such vitamin. This paragraph shall not apply to cow's milk and evaporated milk with increased vitamin D, or represented for special dietary use by reason of its vitamin property from the label (except as provided in this section with respect to fortified salt, and unless the exemption under subparagraph (3) of this paragraph applies) shall bear a statement of the proportion of the quantity of vitamin D required by the labeled food as above required.

§ 125.3 Label statements relating to vitamins.

(a) A food shall bear a statement of the vitamin content of such food. The quantity of vitamin represented for special dietary use shall be limited to the proportion of the quantity of vitamin in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or, if the proportion is not practicable of consumption within such period, if the need in human nutrition for such vitamin has not been established, the label shall bear a statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such vitamin.

(b) If a food purports to be or is represented for special dietary use by man or woman by reason of its vitamin property, and any such use is for treating any disease resulting from a dietary deficiency of any vitamin, the label shall bear a statement of the quantity of such vitamin in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or, if the proportion is not practicable of consumption within such period, if the need in human nutrition for such vitamin has not been established, the label shall bear the statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such vitamin.

(c) If a food purports to be or is represented for special dietary use by man or woman by reason of its vitamin property, and any such use is for treating any disease resulting from a dietary deficiency of any vitamin, the label shall bear a statement of the quantity of such vitamin in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or, if the proportion is not practicable of consumption within such period, if the need in human nutrition for such vitamin has not been established, the label shall bear the statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such vitamin.

§ 125.4 Label statements relating to minerals.

(a) (1) A food shall bear a statement of the nutrient content of such food. The quantity of nutrient represented for special dietary use shall be limited to the proportion of the quantity of nutrient in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or, if the proportion is not practicable of consumption within such period, if the need in human nutrition for such nutrient has not been established, the label shall bear the statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such nutrient.

(b) (1) A food shall bear a statement of the nutrient content of such food. The quantity of nutrient represented for special dietary use shall be limited to the proportion of the quantity of nutrient in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or, if the proportion is not practicable of consumption within such period, if the need in human nutrition for such nutrient has not been established, the label shall bear the statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such nutrient.

§ 125.5 Label statements relating to special dietary use.

(a) If a food purports to be or is represented for special dietary use by reason of its mineral property from the label (except as provided in this section) shall bear a statement of the proportion of the quantity of mineral represented for special dietary use of such food as above required. The label shall also bear a statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such mineral.

(b) Compliance with the provisions of subparagraphs (3) and (5) of this paragraph shall not be construed as relieving the burden of proof upon the food manufacturer or processor to prove the practicability of consumption within such period, or a quantity reasonably suitable for and practicable of consumption within such period.

(c) Compliance with the provisions of subparagraphs (3) and (5) of this paragraph shall not be construed as relieving the burden of proof upon the food manufacturer or processor to prove the practicability of consumption within such period, or a quantity reasonably suitable for and practicable of consumption within such period.

(d) Compliance with the provisions of subparagraphs (3) and (5) of this paragraph shall not be construed as relieving the burden of proof upon the food manufacturer or processor to prove the practicability of consumption within such period, or a quantity reasonably suitable for and practicable of consumption within such period.

(e) Compliance with the provisions of subparagraphs (3) and (5) of this paragraph shall not be construed as relieving the burden of proof upon the food manufacturer or processor to prove the practicability of consumption within such period, or a quantity reasonably suitable for and practicable of consumption within such period.

(f) Compliance with the provisions of subparagraphs (3) and (5) of this paragraph shall not be construed as relieving the burden of proof upon the food manufacturer or processor to prove the practicability of consumption within such period, or a quantity reasonably suitable for and practicable of consumption within such period.

§ 125.6 Label statements relating to special dietary use by man or woman by reason of its mineral property in respect of any element not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the proportion of the quantity of such element in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such element has not been established, the label shall bear the statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such element.

§ 125.7 Label statements relating to special dietary use by man or woman by reason of its mineral property in respect of any element not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the proportion of the quantity of such element in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such element has not been established, the label shall bear the statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such element.

§ 125.8 Label statements relating to special dietary use by man or woman by reason of its mineral property in respect of any element not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the proportion of the quantity of such element in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such element has not been established, the label shall bear the statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such element.

§ 125.9 Label statements relating to special dietary use by man or woman by reason of its mineral property in respect of any element not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the proportion of the quantity of such element in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such element has not been established, the label shall bear the statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such element.

§ 125.10 Label statements relating to special dietary use by man or woman by reason of its mineral property in respect of any element not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the proportion of the quantity of such element in a specified quantity of such food. The quantity of food specified as required by this section shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such element has not been established, the label shall bear the statement: "The need for _______ in human nutrition has not been established:" the blank to be filled in with the name of such element.
reason of its mineral property from the application of sections 402 (a) and 201 (n) of the act, as in the case where the need for such element in human nutrition is not substantially supported by the opinion of experts qualified by scientific training and experience to determine such needs.

(b) For the purposes of the regulations in the following are minimum daily requirements:

(1) For calcium (Ca) 750 milligrams for a child or an adult, except a pregnant or lactating woman in which case the minimum daily requirement is 1.5 grams.

(2) For phosphorus (P) 750 milligrams for a child or an adult, except a pregnant or lactating woman in which case the minimum daily requirement is 1.5 grams.

(3) For iron (Fe) 7.5 milligrams for a child less than six years old, 10 milligrams for a child six or more years old or for an adult, except a pregnant or lactating woman in which case the minimum daily requirement is 1.5 grams.

(4) For iodine (I) 0.1 milligram for a child or an adult, except a pregnant or lactating woman in which case the minimum daily requirement is 15 milligrams.

§ 125.5 Label statements relating to infant food. If a food which purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of sodium in dietary management, if a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of sodium in dietary management, if a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of sodium or salt (sodium chloride), the label shall bear a statement of the number of milligrams of sodium. In 100 grams, and a statement of the number of milligrams of sodium in an average serving of the food. The average serving shall be expressed in terms of a convenient unit or units of such food or a convenient unit of measure that can be readily understood and utilized by purchasers of such food. For example, an average serving might be expressed in terms of slices, cookies, wafers, etc., or in terms of cups, tablespoonsfuls, teaspoonfuls, etc.

Subchapter C—Drugs

PART 130—DRUGS EXEMPTED FROM PRESCRIPTION DISPENSING

Subsection (b) of section 503 (b) (1) (C) of the Act is effective for it.

§ 130.9 Label statements relating to certain foods used as a means of regulating the intake of sodium in dietary management. If a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of sodium or salt (sodium chloride), the label shall bear a statement of the number of milligrams of sodium. In 100 grams, and a statement of the number of milligrams of sodium in an average serving of the food. The average serving shall be expressed in terms of a convenient unit or units of such food or a convenient unit of measure that can be readily understood and utilized by purchasers of such food. For example, an average serving might be expressed in terms of slices, cookies, wafers, etc., or in terms of cups, tablespoonsfuls, teaspoonfuls, etc.

Cross Reference: See § 1.108 of this chapter for general regulations covering exemptions from prescription requirements.

§ 130.1 Exemption for certain drugs limited by new-drug applications to prescription sale. (a) The prescription-dispensing requirements of section 503 (b) (1) (C) of the Federal Food, Drug, and Cosmetic Act are not necessary for new-drug applications to prohibit the sale under the provisions of section 503 (b) (1) of the act.

(b) The N-acetyl-p-aminophenol (p-hydroxyacetanilid) preparations meeting all the following conditions:

(i) The N-acetyl-p-aminophenol is prepared with or without other drugs in tablets of 0.325 gram or more suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The N-acetyl-p-aminophenol and all other components of the preparation meet their approved standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 0.325 gram (5 grains) of N-acetyl-p-aminophenol per dosage unit.

(v) The preparation is labeled with adequate directions for use in minor conditions as a simple analgesic.

(vi) The dosages of N-acetyl-p-aminophenol recommended or suggested in the labeling do not exceed: For adults, 0.325 gram (5 grains) per dose or 1 gram (15 grains) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

§ 130.2 The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against administration of the drug to children...
under 6 years of age and against use of the drug for more than 10 days, except as such uses may be directed by a physician.

(2) Sodium gentisate (sodium-2, 5-dihydroxycarboxylate), and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(i) The sodium gentisate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The sodium gentisate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 0.5 gram (7.7 grams) of anhydrous sodium gentisate per dosage unit.

(v) The preparation is labeled with adequate directions for use in minor conditions as a simple analgesic.

(vi) The dosages of sodium gentisate recommended for use in children under 6 years of age and for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against administration of the drug to children under 6 years of age, except as directed by a physician, and against driving a car or operating machinery while using the drug, since it may cause drowsiness.

(3) Isoamylhydrocupreme and zolamime hydrochloride (N, N-dimethyl-N-7-2-thiazolyl-4'-p-methoxybenzyl-ethylenediamine hydrochloride) preparations meeting all the following conditions:

(i) The isoamylhydrocupreme and zolamime hydrochloride are prepared in dosage form suitable for self-medication as rectal suppositories or as an ointment and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The isoamylhydrocupreme and zolamime hydrochloride, and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 0.25 percent of isoamylhydrocupreme and 1.0 percent of zolamime hydrochloride.

(v) If the preparation is in suppository form, it contains not more than 5.0 milligrams of isoamylhydrocupreme and not more than 20.0 milligrams of zolamime hydrochloride per suppository.

(vi) The preparation is labeled with adequate directions for use in temporary relief of local pain and itching associated with minor conditions.

(vii) The directions provide for the use of not more than two suppositories or two applications of ointment in a 24-hour period.

(viii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against use of the preparation in case of rectal bleeding, as this may indicate serious disease.

(4) Phenytoxolamine dihydrogen citrate (N,N-(a-phenyl-1-oxo)-ethylamine dihydrogen citrate) preparations meeting all the following conditions:

(i) The phenytoxolamine dihydrogen citrate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The phenytoxolamine dihydrogen citrate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 88 milligrams of phenytoxolamine dihydrogen citrate (equivalent to 50 milligrams of phenytoxolamine) per dosage unit.

(v) The preparation is labeled with adequate directions for use in temporary relief of the symptoms of hay fever and/or the symptoms of other minor conditions in which it may be used.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 65 milligrams of phenytoxolamine dihydrogen citrate (equivalent to 50 milligrams of phenytoxolamine) per dose or 246 milligrams of phenytoxolamine dihydrogen citrate (equivalent to 150 milligrams of phenytoxolamine) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against: Exceeding the recommended dosage.

(b) Administration of the drug to children under 6 years of age, except as directed by a physician.

(c) Driving a car or operating machinery while using the drug, since it may cause drowsiness.

(d) Exposing the drug within reach of children, if it is in candy form.

(5) Oxetencyclazine and polymyxin B sulfate preparations meeting all the following requirements:

(i) The oxetencyclazine and polymyxin B sulfate are prepared in ointment or other dosage form suitable for self-medication by external application to the skin and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The oxetencyclazine, polymyxin B sulfate, and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 5 milligrams of oxetencyclazine hydrochloride and not more than 30 milligrams of oxetencyclazine and an amount of polymyxin B sulfate equivalent to not more than 10,000 units of polymyxin B.

(v) The preparation is labeled with adequate directions for use by external application to prevent infection in minor burns, surgical incisions, and abrasions.

(vi) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(a) Use of the preparation in the eye.

(b) Exposing the drug within reach of children, if it is in candy form.
(vi) The labeling bears, in juxtaposition with the directions for use, clear warnings statements against:

(a) Application to infants or young children.
(b) Use on open cracks or weeping stages of athlete’s foot.
(c) Contact with mucous membranes.
(d) Use in the event of irritation.

### TABLE 141A—PENICILLIN AND PENICILLIN-CONTAINING DRUGS: TESTS AND METHODS OF ASSAY

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### RULES AND REGULATIONS

- **Culture media.** Use ingredients that conform to the standards prescribed by the U. S. P. or N. F.
  - (1) Make nutrient agar for the seed layer and for carrying the test organism as follows:
    - Peptone
    - Yeast extract
    - Beef extract
    - Glucose
    - Agar
    - Distilled water
    - pH
    - After sterilization.
  - (2) Make nutrient agar for the base layer as follows:
    - Peptone
    - Yeast extract
    - Beef extract
    - Glucose
    - Agar
    - Distilled water, pH
    - After sterilization.
  - (3) Make nutrient broth for preparing an inoculum of the test organism, as follows:
    - Peptone
    - Yeast extract
    - Beef extract
    - Glucose
    - Dipotassium phosphate
    - Potassium dihydrogen phosphate
    - Distilled water
    - pH
    - After sterilization.

In lieu of preparing the media from the individual ingredients specified in paragraph (b) (1), (2), and (3) of this section, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modification of the individual ingredients specified in paragraph (b) (1), (2), and (3) of this section are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

**Working standard.** Keep the working standard (obtained from the Food and Drug Administration) at room temperature in tightly stoppered vials,
which in turn are kept in larger stoppered tubes containing a suitable desterile. Weigh out carefully in an atmosphere of 50 percent relative humidity or less between 4 and 5 milligrams of the working standard in 10 percent to 25 percent 1 percent phosphate buffer (pH 6.0) to make a stock solution of any convenient concentration. Keep this solution at a temperature of about 10° C., and use for 2 days only. From this stock solution make appropriate working dilutions.

(d) Preparation of sample. Dissolve aerobically, in sterile distilled water, the sample to be tested to make an appropriate stock solution.

(e) Preparation of plates. Add 21 ml. of agar to each Petri dish (20 x 10 millimeters) and distribute the agar even in the plates and allow it to harden. Use the plates the same day they are prepared. The test organism is M. pyogenes var. aureus (P. C. I. 199-P or American Type Culture Collection C-350). Maintain the test organism on agar slants and transfer to a fresh agar slant about once a week. Prepare an inoculum for the plates by transferring the culture from the agar slant into broth and incubate 24 hours at 32° C.-35° C. From 16 to 24 hours thereafter add 2.0 milliliters of this broth culture to each 100 milliliters of agar which has been melted and cooled to 48° C. to 50° C. Mark with a straightedge the points corresponding to the corresponding dilutions of the sample under test. The value of Q is the sum of the values for all plates and W is the sum of the W values for all plates. To estimate the potency one plate is the point on the chart corresponding to the values of V and W and the potency can be read from the radial lines on the chart.

The error of the assay is estimated by using the nomograph which requires five values, namely, the potency, V W, R, and R. As (the range of the v's) is the highest value of W minus the lowest value of V obtained from the individual plates. Similarly, R is the difference between the highest and lowest W values. After obtaining these five values, construct a straightedge the points corresponding to v and w on the respective scales on the right side of the nomograph. Mark with a pin or sharp-pointed pencil the intersection of the straightedge and the diagonal line of the nomograph. Move the straightedge so that it connects the value of R at its scale and the diagonal line of the nomograph. The value of Q is thus determined by the scale value where the straightedge crosses the line labeled “Q” T is obtained by adding the squares of Q and v. and one with a 0.55 unit per milliliter. Use the following equation to calculate the value of Q: 

\[
Q = \sqrt{\left(\frac{Q}{W}\right)^2 + \left(\frac{V}{W}\right)^2}
\]

where V and W are the diameters of the zones of inhibition in millimeters of the 1.0 unit and 0.25 unit dilutions of the standard, respectively, and v and w refer similarly to the corresponding dilutions of the sample under test. The value of Q is the sum of the values for all plates and W is the sum of the W values for all plates. The potency equals the percentage error of the assay. The error of the assay calculated from this estimate only as closely one assayist can check himself on any given set of dilutions of unknown and standard solutions. It does not give any measure of weighing or errors due to variations in materials or subdivisions of a lot of penicillin.

The chart for determining potency should not be used for determinations of potency lower than 50 percent or higher than 150 percent of the standard. If the potency lies outside these limits, the assay should be repeated using a higher or lower dilution. The radial lines on the chart beyond these limits are to be used with the same proper number to bring them into the range of the chart. The error of the assay using the ratio of doses 2 to 1 is estimated by using the nomograph (Chart 2) in the same manner as described for the 4 to 1 ratio of doses. However, the resultant error of the assay derived in this manner must be divided by 2 to give the correct error of the assay for the 2 to 1 ratio of doses.

(b) Assay by alternative methods. The potency of the sample may also be determined by the iodometric method as described in § 181.5 (d) or by the standard-curve technique, using a single dose of standard and unknown. In the case of the standard-curve technique, dilute the sample to be tested to 8.0 by 1.0 unit per milliliter (estimated) in 1-percent phosphate buffer pH 6.0. Place six cylinders on the inoculated agar surface so that they are at approximately 90° intervals on a 6 cm. radius from the center of the plate for each sample. Fill 3 cylinders on each plate with the 1.0 unit/ml standard and 3 cylinders with the 1.0 unit/ml (estimated) sample, alternating the plates. Incubate the plates for 16 to 18 hours at 32° C.-35° C. and measure the diameter of each circle of inhibition. At the same time prepare a standard curve using concentrations of the standard of 0.6, 0.9, 1.0, 1.2, 1.5, and 1.5 units/ml in sterile 1 percent phos-
PENICILLIN ASSAY – Chart for Determining Potency as Percent of Standard from Two-Dose Plate Method, Ratio of Doses 4:1

CHART 1.

PENICILLIN ASSAY
Nomographs for estimating Error of Assay
(2 dose, 4 plate method. Ratio of doses 4:1)

CHART 2.
The standard curve through these points.

After the plates have incubated read the diameters of the zones of inhibition. Average the readings of 1.0 unit/ml. concentration and the readings of the point tested for each set of 3 plates and average also all 81 readings of the 1.0 unit/ml. concentration. The average of the 81 readings of the 1.0 unit/ml. concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 unit/ml. reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.3 unit concentration, the average of the 81 readings of the 1.0 unit concentration is 30.0 mm., and the average of the 1.0 unit concentration of this set of 3 plates is 19.3 mm., the correction is 0.2 mm. If the average reading of the 0.3 unit concentration of these same 3 plates is 19.0 mm., the corrected value is then 19.2 mm. Plot these corrected values including the average of the 1.0 unit/ml. concentration on 2-cycle semilog paper using the concentration in units per ml. as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points. The 10 points selected to determine the curve are arbitrary and should be so chosen that the limits of the curve will fill the needs of the laboratory. However, the potency of the sample under test should fall in the interval of from 60 percent to 150 percent of the correction point of the standard curve.

To estimate the potency of the sample average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger average zone size than the average of the standard, add the difference between them to the 1.0 unit zone on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 unit value on the curve. From the curve read the potency corresponding to these corrected values of zone size.

To estimate the potency of sodium penicillin, calcium penicillin, and potassium penicillin, and sodium penicillin is satisfactory when assayed by the methods described in this section if the immediate containers are represented to contain:

(1) 200,000 units or less and contain 85 percent or more of the number of units so represented.

(2) More than 300,000 units and contain 90 percent or more of the units so represented.

§ 141a.2 Sodium penicillin, calcium penicillin, potassium penicillin; sterility—(a) Culture medium. In the test for bacteria, use U. S. P. fluid thioglycolate medium I or a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such medium and has growth-promoting, buffering, and oxygen-tension-controlling properties equal to or better than those of such medium. In the preparation of the medium from either the individual ingredients or any dehydrated mixture avoid contamination with calcium. In the test for molds and yeasts use U. S. P. Sabouraud Liquid Medium (G-failed).

(b) Conduct of test for bacteria. Add not more than 10 milliliters of sterile distilled water, or sterile physiological salt solution, to each immediate container in the sample to be tested. From each of not less than seven immediate containers transfer separately the equivalent of approximately 300 milligrams, or the entire contents if the container is packaged to contain less than 300 milligrams, to individual tubes (38 x 200 millimeter size) each containing 75-100 milliliters of thioglycolate medium and sufficient penicillinase to completely inactivate the penicillin used in the test. (Prior to use, the tubes containing the medium with added penicillinase are incubated at 30° C.-35° C. for not less than 24 hours and examined for sterility.) After adding the penicillin to the tubes let them stand at room temperature for 3 hours, with frequent shaking. To one of such tubes add 1.0 milliliter of a 1:1,000 dilution of an 18-24 hour broth culture of M. pyogenes var. aureus (P. C. X-209P and American Type Culture Collection 6530P). Incubate all tubes at 35° C.—36° C. for 5 days. The batch meets the requirements of the test for bacteria if on the first or second test the control tube and no other tube shows
growth, or if the number of tubes (excluding the control tubes) that show growth in three or more consecutive tests is not more than 10 percent (compensate for contamination that may have been induced during the test) of the total number of samples tested.

(c) Conduct of test for molds and yeasts. Add 0.60 C. to individual tubes each containing 75–100 milliliters of U. S. P. Saborouard Liquid Medium. Incubate all tubes at approximately 25° C. for 5 days. The batch meets the requirements if when so tested no animal shows a rise in any of the temperature readings of 0.6° C. or more above the control temperature of such animal. If one or more of the animals shows such a rise in temperature, or if the sum of the temperature rises of the three animals exceeds 1.4° C., repeat the test on five additional animals. The sample is non-pyro-genic if not more than one of these five animals shows a rise in temperature of 0.6° C. or more above the control temperature of such animal.

§ 141a.4 Sodium penicillin, calcium penicillin, potassium penicillin; toxicity. Inject intravenously each of five mice, within the weight range of 18 to 25 grams, with 0.5 milliliter of the sample prepared by diluting with sterile distilled water to approximately 4,000 units per milliliter. The injection should be made over a period of not more than 5 seconds. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with five unused mice weighing (±0.5 gram) each; if all animals survive the repeat test, the sample is nontoxic.

§ 141a.5 Sodium penicillin, calcium penicillin, potassium penicillin—(a) Moisture. In an atmosphere of about 10 percent relative humidity transfer about 100 milligrams of the finely powdered sample to a tared weighing bottle or weighing tube equipped with a capillary-tube stopper, the capillary having an inside diameter of 0.30 millimeter. Weigh the bottle or weighing tube and place it in a vacuum oven without removing the stopper and dry at a temperature of 65° C. and a pressure of 5 millimeters of mercury or less for 2 hours or weigh with 0.01 milligram accuracy. Fill the vacuum oven with air or dried by passing it through a drying agent such as sulfuric acid or silica gel. Place weighing bottle or tube in a desiccator over a desiccating agent such as phos- phorous pentoxide or silica gel, allow to cool to room temperature, and reweigh.

(b) pH. Dilute the sample to be tested with carbon-dioxide-free distilled water so that the resulting solution contains 5,000 to 10,000 units per milliliter. Determine the pH of this solution at 25° C. using a pH meter equipped with a glass and a calomel electrode.

(g) Microscopic test—crystallinity of sodium penicillin and potassium penicillin. Mount in mineral oil and examine by means of a polarizing microscope.

Crystalline penicillin shows resolvable particles which reveal the phenomena of birefringence (interference colors) and extinction positions on revolving the microscope stage. Crystalline penicillin reveals diagnostic refractive indices when examined by the immersion method.

(d) Heat stability—(1) Crystalline penicillin, crystalline penicillin G. Store a weighed sample (approximately 30 milligrams) of crystalline penicillin in an unstoppered 50–milliliter Erlenmeyer flask for 4 days in an electric oven at a temperature of 100–120° C. If the sample is nontoxic it shows no loss of potency.

§ 141a.6 Crystalline penicillin, sodium penicillin, potassium penicillin; heat stability. Weigh 0.5 milligram of the sodium penicillin G standard against a working standard, to obtain the milligrams of sodium penicillin G working standard, to obtain the milligrams of sodium penicillin G working standard, using the above method.

<table>
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<tr>
<th>Units of penicillin G per milliliter</th>
<th>Difference in titers X1.607</th>
<th>X N of Na₂SO₃</th>
<th>Milligrams in 2.0 milliliters X X001</th>
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<tr>
<td>Percent loss of potency</td>
<td>(Original assay—assay after 4 days at 100° C.) X100</td>
<td>X X001</td>
<td>X X001</td>
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</table>

(2) Crystalline penicillin O. Proceed as directed in subparagraph (1) of this paragraph except that the sample is weighed before the heating period, and dilute the sample to be tested with carbon-dioxide-free distilled water.

Units of penicillin O per milliliter | Difference in titers X1.612 | X N of Na₂SO₃ | Milligrams in 2.0 milliliters X X001 |

(Original assay—assay after 4 days at 100° C.) X100 | X X001 | X X001 |
Penicillin G does not show a loss of more than 10 percent of its original potency. (c) Crystalline penicillin G—(1) Reagents. The reagents described in the first division (i) and (ii) of this sub-
paragraph are freshly prepared every three days and are of such quality that when used in the procedure known as the penicillin G test not less than 97 per-
cent of penicillin G is recovered.

(i) Amly acetate (iso-amyl acetate) solution. Saturate the amyl acetate (boiling range 134.5°-141° C.) with the
N-ethyl piperidine salt of penicillin G by adding 2 milligrams of the salt for each 1.0 milliliter of the solvent. Cool this solution to 0°-5° C. and filter it through a tared-glass filter immediately
before use.

(ii) Acetone solution. Saturate a re-
agent grade acetone with the N-ethyl piperidine salt of penicillin G, using about 3 milligrams of the salt for each 1.0 milliliter of solution. Cool this solution to 0°-3° C. and filter it through a tared-glass filter immediately before use.

(iii) N-Ethyl piperidine solution. N-
ethyl piperidine (boiling range 129.5°-131° C.) should be stored in brown
bottles in a refrigerator. Dilute 1.0 milli-
liter of this reagent with 4.0 milliliters of amyl acetate to make this solution with the N-ethyl piperidine salt of penicillin G, using about 3 milligrams of the salt for each 1.0 milliliter of solution. Cool this solution to 0°-3° C. and filter it through a tared-glass filter immediately before use.

(iv) Phosphoric acid solution. Pre-
pare by dissolving 1.0 milliliter of reagent
grade phosphoric acid (65 percent) in 2-
milliliters of water. Cool to 0°-5° C. and
shake before using.

(v) Silica gel. Use dry silica gel (mesh size 6-16, Tyler standard) Place about 0.5 gram of the silica gel in a
micro filter funnel (approximately 10-
millimeter diameter) having a fluted-
glass disc of medium porosity.

(2) Procedure. Accurately weigh from 60 to 100 milligrams of the sample to be tested in a 100-milliliter weighing bottle, stopper the bottle and allow to stand for not less than 2 hours in a
refrigerator at 0°-8° C. Remove the liquid from the precipitate by means of a
tared micro filter stick and wash with a
total of 1 milliliter of the acetone solution adding the latter by means of a hypoderm-
ic syringe equipped with a fine needle. Place the filter stick inside the glass tube dry under vacuum at room temperature for not less than 1 hour, and wash.

Saturate each N-ethyl piperidine penicillin G residue for saturating reagents.

(j) Penicillin K content. Determine the content of penicillin K by the fol-
lowing method:

Dissolve a weighed sample or the con-
tents of a vial with 0.5 N phosphate (Na2HPO4 and K2HPO4) buffer pH 6.0 to give a solution containing approximately 1,000 units/ml. In the case of calcium penicillin where a precipitate of calcium phosphate occurs, remove the precipitate by filtration and use the clear
filtrate. Place a 15.0-milliliter aliquot of this solution in a 25.0-milliliter sep-
atorial funnel equipped with calcium
chloride and a glass filter. (Carry out all operations at room temperature.) Allow the mixture to stand with occasional swirling to separate the droplets of chloroform until the top
layer is clear (usually about 10 minutes)

Draw off all but about 1.5 milliliters of the lower chloroform layer through a small
suction flask and collect the filtrate in

Calculate the quantity of penicillin K and G between chloroform and aque-
ous phosphate buffer at pH 6.0.)

(c) Penicillin G content of crystalline
penicillin G. Accurately weigh approxi-
matel 300 milligrams of the sample to be tested in a 250-millitler Erlenmeyer
flask, dissolve in 1.0 milliliter of 25 per-
cent KOH solution, add with stirring
50.0 milliliters of 0.5 percent H2SO4 solu-
tion and heat on the steam bath for 2
hours, allowing the wash with a

Cool to room temperature and add 25.0 milliliters of 10 percent acetic acid solution. When the reaction has
ceased, add 15.0 milliliters of 13 N
H2SO4, stepwise with agitation and cool-
ing. Add 30.0 grams of NaCl and agitate
until a clear colorless solution is ob-
tained. Transfer to a separatory funnel and extract with three portions of
chloroform, 30 milliliters, 20 milliliters,
and 10 milliliters in that order. Filter
the extract through a pledget of cotton
previously moistened with chloro-
form and collect in a second separatory
funnel. Add 20.0 milliliters of 0.1
NH4OH to the combined extracts, shake
for 5 minutes and allow the phases to
separate for 10 minutes. Discard all but
a few milliliters of the chloroform layer.

Draw off the last few milliliters of chlo-
roform and about 15.0 milliliters of the
NH4OH layer into a glass-stoppered test
tube and centrifuge 2 minutes to obtain
a clear aqueous layer. Prepare a blank
by dissolving 50.0 milliliters of 0.1
NH4OH with 6.0 milliliters of chloro-
form as described above. Determine the optical density of the blank compared with 0.1 NH4OH at 220 and 224 mc.

Determine the optical density of the sample at 220 and 224 mc compared with the blank. Calculate the quantity of benzyl alcohol in the solution from the equation:

Calculate the quantity of penicillin G in the sample from the equation:

(b) Penicillin O content. Determine by means of a suitable infrared spec-
trophotometer, using the following pro-
cedure: Grind the sample to a uniform
powder using a mortar and pestle. Weigh by difference, 100-150 milligrams of liq-

\[ \frac{\text{mg N-ethyl piperidine penicillin precipitate}}{100} \times 100 = \% \text{ penicillin G} \]

\[ \frac{\text{mg N-ethyl piperidine penicillin precipitate}}{100} \times 100 = \% \text{ penicillin G} \]

\[ \frac{\text{mg N-ethyl piperidine penicillin precipitate}}{100} \times 100 = \% \text{ penicillin G} \]
ud petrolatum into aagate mortar. Divide the actual weight of the liquid petrolatum by three, and add exactly this amount of the powdered penicillin O to the liquid petrolatum in the mortar. Mix with a small spatula and then mull thoroughly with the pestle until a uniform consistency is obtained. Use two circular rock-salt plates, each of 2 inches diameter as the absorption cell. Plate a small drop of the mull in the center of one of the rock-salt plates. Place a brass spacer, 0.0056 inch thick, on the plate. (This may be in the shape of a circular gasket with a 1-inch center hole and a slit to permit the escape of air when the two plates are pressed together.) Put on the top salt plate gently and slowly squeeze together to spread the mull uniformly. Clamp the two plates firmly together in a metal cell holder. (The cell holder consists of two metal plates, one containing a rectangular center slit 1/4 inch wide x 5/8 inch long, the other with a center hole 1 inch in diameter. The two plates are clamped together by means of threaded studs and nuts.) Examine the assembled cell by holding it up to the light. It should appear smooth, free of any air bubbles, and not in contact with the spacer. Adjust the amplification of the spectrophotometer to full-scale deflection for one microvolts, set the slit opening to about 0.300 and run the spectrum from 9.4 to 10.7 microns, using an automatic slit-control mechanism and taking a zero reading (shutter closed) at the beginning and at the end of the run. Draw a base line between two points, one on each side of the absorption band (10.1 microns) and calculate the base-line optical density, using the following formula.

$$D_b = \log \frac{I_b}{I_p}$$

where

- $D_b$ = base-line optical density,
- $I_b$ = distance from the zero line to the maximum absorption of the band.
- $I_p$ = distance from the zero line to the base line, measured at the same wavelength as $I_b$.

Using known mixtures of penicillin G working standard and penicillin O working standard, prepare a standard curve by plotting the optical density obtained against the percent penicillin O. Obtain the percent penicillin O in the sample under test from this standard curve.

§ 141a.6 Sodium penicillin, calcium penicillin, potassium penicillin, penicillin X. Dissolve the contents of a 100,000 unit ampoule in about 20 milliliters of ice cold distilled water. Transfer quantitatively to a 100-milliliter volumetric flask, using a zero reading (shutter closed) at the beginning and at the end of the run. Draw a base line between two points, one on each side of the absorption band (10.1 microns) and calculate the base-line optical density, using the following formula.

$$D_b = \log \frac{I_b}{I_p}$$

where

- $D_b$ = base-line optical density,
- $I_b$ = distance from the zero line to the maximum absorption of the band.
- $I_p$ = distance from the zero line to the base line, measured at the same wavelength as $I_b$.

Shake the mixture vigorously for one minute. Allow the layers to separate and filter the chloroform through a small pledge of cotton, moisten with chloroform, into a second 125-milliliter separatory funnel. Shake the combined NaHCO3 extracts give a pH of 7.0, and make to 100 milliliters with water. Make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0 and assay as directed in § 141a.1 (f) or (h) where $e$-milligrams of water equivalent to 1 ml. Karl Fischer reagent.

§ 141a.7 Penicillin in oil and wax.

(a) Potency. Proceed as directed in § 141a.1 except paragraph (f) thereof and, in lieu of the directions in § 141a.1 (d) prepare sample as follows: Liquefy the sample by warming, thoroughly mix, and then extrude approximately 10 milliliters of peroxide-free ether. Transfer to a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the material with the ether. Shake with a 25-milliliter portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-milliliter quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. If the label represents the potency of the penicillin in oil and wax and to a blending jar containing 100 milliliters of 1 percent phosphate buffer at pH 6.0. Using a high-speed blender, blend this mixture for 1 minute and then make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. If the label represents the potency of the penicillin in oil and wax as 200,000 units per milliliter or less, it is satisfactory if it is 90 percent or more of the potency so represented; if represented as 201,000 units per milliliter, it is satisfactory if it is 90 percent or more of the potency so represented.

(b) Sterility. Transfer aseptically directly to test tubes of the medium the entire contents of single-dose containers or the equivalent of approximately 300 milligrams (activity) from each multiple-dose container, and proceed as directed in § 141a.2.

(c) Moisture.—(1) Reagents.—(i) Karl Fischer reagent. Preserve the reagent in glass-stoppered bottles and use from an all glass automatic burette, protecting the solution from the moisture in the air.

(ii) Water-methanol solution. Use methanol containing approximately 1 mg. of per milliliter. Store the solution in a glass bottle attached to an automatic burette and protect from moisture in the air at all times.

2) Standard Karl Fischer reagent. Add a known volume of the Karl Fischer reagent to a suitable titrating vessel which has been previously dried at 100 C. and cooled in a desiccator. Introduce a mechanism and two platinum electrodes which are connected to a suitable electrometric apparatus for measurement of the endpoint. Start the stirrer and titrate with the water-methanol solution until the end-point is reached. Calculate the milliliters of Karl Fischer reagent equivalent to each milliliter of water-methanol.

Add an accurately weighed quantity of water (approximately 50 milligrams) to a dry titrating vessel, add an excess of the Karl Fischer reagent and back titrate with the water-methanol solution as above. Calculate the water equivalent to each milliliter of the Karl Fischer reagent. Standardize the Karl Fischer reagent in this manner daily.

§ 141a.1 Potency. Proceed as directed in § 141a.1 except paragraph (a) thereof and, in lieu of the directions in § 141a.1 (d) prepare sample as follows: Liquefy the sample by warming, thoroughly mix, and then extrude approximately 10 milliliters of peroxide-free ether. Transfer to a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the material with the ether. Shake with a 25-milliliter portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-milliliter quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. If the label represents the potency of the penicillin in oil and wax as 200,000 units per milliliter or less, it is satisfactory if it is 90 percent or more of the potency so represented; if represented as 201,000 units per milliliter, it is satisfactory if it is 90 percent or more of the potency so represented.

(ii) Water-methanol solution.

(a) Procedure. Transfer 1.0 milliliter of the penicillin in oil and wax to a dry titrating vessel, add 10 milliliters of dry chloroform and an excess of the Karl Fischer reagent and back titrate with the water-methanol solution until the end-point is reached. Transfer 10 milliliters of the dry chloroform used to a dry titrating vessel, add an excess of the Karl Fischer reagent, and titrate with the water-methanol as above. Calculate the milliliters of Karl Fischer reagent equivalent to 10 milliliters of water-methanol.

% moisture = \( \frac{(a - b - v) \times 100}{4X1000} \)

where

- $b$ = milliliters Karl Fischer reagent equivalent to 10 ml of chloroform.
- $a$ = volume of the sample in milliliters.

(d) Measurement of penicillin particle size. Vigorously shake the container to obtain an even suspension of the penicillin particles and immediately withdraw a reasonably representative portion of the drug into a clean, dry, tuberculin syringe using a dry 18-gauge needle, Discard approximately the first 5 drops of the mixture extruded from the needle and then extrude approximately 1 milliliter of the remaining mixture into a test tube containing 3 to 4 milliliters of light mineral oil. Thoroughly mix the contents of the tube and by means of a bacteriological loop (2 millimeters wide, 22 gauge wire) immediately place one loopful of the suspension on each ruled chamber of a bright line hemocytometer. (It is not necessary to use a
cover slip.) Confirm by means of the low power objective of the microscope the even dispersion of particles over the ruled areas of both chambers and repeat with another loopful of the suspension if even dispersion is not obtained.

Use a magnification of 600 diameters and a calibrated ocular micrometer to measure the penicillin particles. For the purpose of measurement and calculation, the predominant type of crystals observed shall be considered constant. Center a large penicillin particle in the microscopic field; measure the particle and all other particles in the field and repeat this operation on other fields until at least 200 particles are measured. Particles of less than 5 microns in length are disregarded. The grouping of the particles by length, the midpoint, the ratio of the midpoints, and the square of the ratio of the midpoints for each group are tabulated below:

<table>
<thead>
<tr>
<th>Group</th>
<th>Length (microns)</th>
<th>Midpoint</th>
<th>Ratio of Midpoints</th>
<th>(Stated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5-14</td>
<td>9.5</td>
<td>1.60</td>
<td>1.93</td>
</tr>
<tr>
<td>2</td>
<td>15-29</td>
<td>22.0</td>
<td>2.31</td>
<td>3.34</td>
</tr>
<tr>
<td>3</td>
<td>30-42</td>
<td>36.0</td>
<td>4.16</td>
<td>5.68</td>
</tr>
<tr>
<td>4</td>
<td>43-64</td>
<td>53.5</td>
<td>6.89</td>
<td>9.80</td>
</tr>
<tr>
<td>5</td>
<td>65-94</td>
<td>78.0</td>
<td>10.0</td>
<td>13.10</td>
</tr>
<tr>
<td>6</td>
<td>95-124</td>
<td>106.5</td>
<td>15.8</td>
<td>20.70</td>
</tr>
<tr>
<td>7</td>
<td>125-154</td>
<td>142.5</td>
<td>20.5</td>
<td>28.76</td>
</tr>
<tr>
<td>8</td>
<td>155-184</td>
<td>172.5</td>
<td>25.5</td>
<td>35.33</td>
</tr>
<tr>
<td>9</td>
<td>185-214</td>
<td>203.5</td>
<td>30.5</td>
<td>42.74</td>
</tr>
<tr>
<td>10</td>
<td>215-250</td>
<td>238.0</td>
<td>35.5</td>
<td>49.89</td>
</tr>
</tbody>
</table>

Calculate the percent particles in each group from the total number measured. Determine the percent relative weight for each group as follows:

\[
\text{Relative weight} = \frac{\text{number of particles}}{\text{total number of particles}} \times 100
\]

When examined by the method described in this section not less than 50 percent of the total relative weight of the penicillin in the drug consists of penicillin having a particle size of not less than 50 microns in length.

§ 141a.8 Penicillin ointment—(a) Potency. Proceed as directed in § 141a.1, except paragraph (c) of that section, and in lieu of § 141a.9, (d) prepare the sample by one of the following techniques:

(1) Extraction. Place a representative portion of the sample (usually approximately 1 gram, accurately weighed) or the entire contents of a single-dose container in a separatory funnel containing 50 milliliters of peroxide-free ether. If the sample consists of substantially more than 1 gram, use 100 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 50 milliliters of 1-percent phosphate buffer, pH 6.0, and shake. If the sample consists of substantially more than 1 gram, use 50 milliliters of buffer. Allow the layer to separate. Remove the buffer layer and repeat the extraction with new portions of buffer at least three times and any additional times necessary to ensure complete extraction of the antibiotic. Centrifuge and make the proper estimated dilutions with buffer.

(2) Tablets that contain benzathine penicillin G or penicillin V. Proceed as directed in § 141a.12 (a).

§ 141a.11 Penicillin with aluminum hydroxide gel—(a) Sodium penicillin, calmette penicillin, potassium penicillin. Proceed as directed in §§ 141a.1, 141a.2, 141a.5, and 141a.5 (a) and (b) if crystalline penicillin, § 141a.5 (c) and (d) if crystalline penicillin G, § 141a.5 (a) (c).

(b) Aluminum hydroxide gel. Thoroughly wash the aluminum hydroxide gel and transfer aseptically 1.0 and 0.1-milliliter portions in triplicate to sterile Petri dishes. Pour into each Petri dish 20 milliliters of nutrient agar, described in § 141a.1 (b) which has been melted and cooled to 45°C. Thoroughly mix the aluminum hydroxide gel and melted agar. Allow the agar to solidify, invert the Petri dishes, and incubate for 48 hours at 32°C. Count the number of colonies appearing on the plates and calculate therefrom the number of viable bacteria per milliliter of the aluminum hydroxide gel.

§ 141a.12 Penicillin troches—(a) Potency. Proceed as directed in § 141a.1, except paragraph (d) thereof and, in lieu of the directions in § 141a.9, prepare sample as follows:

(1) If the troche does not contain a mastectomy substance, proceed as directed in § 141a.9 (a).

(2) If the troche contains paraffin as a mastectomy substance, place the troches in a Pyrex funnel containing 75 ml of N-hexane; shake until the troches are dissolved. Shake with a 25-milliliter portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-milliliter quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0.

(3) If the troche contains gum as a mastectomy substance, cut each of five troches into fine pieces and place in a bowl; blending jar containing 100 milliliters of a 50 percent acetone-water solution. Using a high-speed blender, blend for 5 to 5 minutes. Add an additional 100 milliliters of a 50 percent acetone-water solution to the blender and blend for an additional 5 to 5 minutes, and then make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0.

The average potency of the troche is satisfactory if it contains not less than 86% of the number of units per tablet that it is represented to contain.
(b) Moisture. Proceed as directed in §141a.5 (a) if it contains a non-volatile substance proceed as directed in §141a.7 (a) using 1.0 to 2.0 grams dissolved in 10 milliliters of dry chloroform.

§ 141a.13 Penicillin dental cones—(a) Potency. Proceed as directed in §141a.1, except paragraph (i) thereof and, in lieu of the directions in §141a.1, prepare sample using 5 cones as directed in §141a.9 (a) The average potency of the cone is satisfactory if it contains not less than 65 percent of the number of units per cone it is represented to contain.

§ 141a.14 Penicillin with vasoconstrictor—(a) Penicillin used in the packaged combination—(1) Potency. Unless it is penicillin tablets, proceed as directed in §141a.1, §141a.9 (a), except prepare the sample using

§ 141a.15 Penicillin for surface application—(a) Potency. Proceed as directed in §141a.9 (a) using the contents of 15 immediately containers.

§ 141a.16 Tablets aluminum penicillin—(a) Potency. Proceed as directed in §141a.9 (a), using citrate buffer at pH 6.5 for making working dilutions of the working standards and for the sample under test in lieu of phosphate buffer. The citrate buffer is of the following composition:

<table>
<thead>
<tr>
<th>Grams</th>
<th>Citric acid</th>
<th>55.9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (pellets)</td>
<td>28.25</td>
<td></td>
</tr>
<tr>
<td>Sodium citrate</td>
<td>988.0</td>
<td></td>
</tr>
</tbody>
</table>

Make up to 4000 ml. with distilled water.

(b) Moisture. Proceed as directed in §141a.5 (a) 

§ 141a.17 Penicillin sulfonylamide powder—(a) Potency. Proceed as directed in §141a.9 (a), except prepare the samples as follows: Accurately weigh 0.5 gram from each of the immediate containers and dissolve in 100 milliliters of distilled water. From this solution make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0.

(b) Moisture. Proceed as directed in §141a.5 (a) 

(c) Sterility. Transfer aseptically directly to the tubes of the medium approximately 0.5 gram from each container tested and proceed as directed in §141a.2. 

§ 141a.18 Penicillin vaginal suppositories—(a) Potency. Proceed as directed in §141a.1 except paragraph (i) thereof and in lieu of the directions in §141a.1 (d) prepare sample as follows:

Place 5 suppositories in a separatory funnel containing 150 milliliters of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the material with the ether. Shake with a 50-milliliter portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 50-milliliter quantities of buffer. Combine all extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The sample may also be prepared as follows: Place 5 suppositories in a glass blending jar containing 200 milliliters of 1 percent phosphate buffer at pH 6.0. Use a high-speed blender blend for 3 minutes and make the proper estimated dilution in 1 percent phosphate buffer at pH 6.0. The average potency of the sample is satisfactory if it contains not less than 65 percent of the number of units it is represented to contain.

(b) Moisture. Proceed as directed in §141a.9 (a) using a weighed suppository dissolved in 10 milliliters of dry chloroform and 2 milliliters of methanol from the titrating burette. (Correct for the amount of moisture in the solvents used.)

§ 141a.19 Buffered crystalline penicillin—(a) Potency. Proceed as directed in §141a.1 except paragraph (i) thereof and in lieu of the directions in §141a.1 (d) prepare samples as follows:

Place the contents of 12 capsules and the empty capsules into a 500-milliliter volumetric flask. Add approximately 300 milliliters of 1 percent phosphate buffer at pH 6.0, shake until the powder has dissolved and the capsules have gelatinized and make to 500 milliliters with the phosphate buffer. Make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The average potency of the sample prepared with pectin hydrolysate is satisfactory if it contains not less than 65 percent of the number of units per capsule it is represented to contain.

(b) Moisture. Proceed as directed in §141a.9 (a) using the contents of 4 capsules.

§ 141a.22 Penicillin bougies—(a) Potency. Proceed as directed in §141a.9 (a) 

(b) Moisture. Proceed as directed in §141a.7 (a) using 1.0 to 2.0 grams of bougies dissolved in 10 milliliters of dry chloroform if it contains the excipient polyethylene glycol. If it does not contain the excipient polyethylene glycol, proceed as directed in §141a.5 (a)

§ 141a.23 Crystalline penicillin and epinephrine in oil—(a) Potency. Proceed as directed in §141a.7 (a) except the provisions for warming the sample. When examined by the method described in this section the potency of crystalline penicillin and epinephrine in oil is satisfactory if it is 90 percent or more of the potency represented.

(b) Sterility. Proceed as directed in §141a.7 (b) 

(c) Epinephrine. Proceed as directed in §141a.3, but in lieu of the directions for preparation of sample in paragraph (b) thereof, prepare sample as follows:

Suspend approximately 60 milligrams in 20 milliliters of pyrogen-free sterile physiological salt solution, adding the salt solution in approximately 1-milliliter aliquots and mixing thoroughly

§ 141a.24 Aluminum penicillin—(a) Potency. Proceed as directed in §141a.1 (a) using citrate buffer as prepared in §141a.19 (a) in lieu of phosphate buffer.

(b) Sterility. Proceed as directed in §141a.2.

(c) Pyrogens. Proceed as directed in §141a.3, but in lieu of the directions for preparation of sample in paragraph (b) thereof, prepare sample as follows:

Potential. Proceed as directed in § 141a.1, except use physiological salt solution as the diluent. Proceed as directed in § 141a.3, except use physiological salt solution as the diluent. Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter. Proceed as directed in § 141a.5 (a).

(c) Pyrogens. Proceed as directed in § 141a.3, except use physiological salt solution as the diluent. Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter. Proceed as directed in § 141a.5 (a).

Pipettes. Proceed as directed in § 141a.1, except use physiological salt solution as the diluent.

(c) Pyrogens. Proceed as directed in § 141a.3, except use physiological salt solution as the diluent. Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter. Proceed as directed in § 141a.5 (a).

Pipette. Proceed as directed in § 141a.7 (e).

§ 141a.25 Procaine penicillin—(a) Potency. Proceed as directed in § 141a.1, except use physiological salt solution as the diluent. Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter. Proceed as directed in § 141a.5 (a).

(b) Moisture. Proceed as directed in § 141a.26 (c).

§ 141a.29 Procaine penicillin for inhalation therapy—(a) Potency. Proceed as directed in § 141a.1, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter. Proceed as directed in § 141a.4, except use physiological salt solution as the diluent.

(b) Moisture. Proceed as directed in § 141a.5 (a), except if it is procaine penicillin. Proceed as directed in § 141a.26 (a).

§ 141a.20 Ephedrine penicillin—(a) Potency. Proceed as directed in § 141a.1, except use physiological salt solution as the diluent.

(b) Moisture. Proceed as directed in § 141a.26 (c).
(b) Procaine penicillin. Proceed as directed in § 141a.5 (d).

§ 141a.33 Procaine penicillin and buffered penicillin powder. Proceed as directed in §§ 141a.1 and 141a.5 (a).

§ 141a.34 Procaine penicillin and crystalline penicillin in oil. (a) Total potency. Proceed as directed in § 141a.27 (a) or by the iodometric assay procedure described in § 141a.5 (d) (1) using in the latter procedure a 0.6-milliliter aliquot of the solution prepared as follows: Introduce 1 milliliter of the well-shaken sample, by means of a hypodermic syringe, into a 50-milliliter volumetric flask. Make to 50 milliliters with chloroform–absolute alcohol (1:1) solvent and shake well.

(b) Crystalline penicillin. Proceed as directed in § 141a.32 (b), except prepare the sample as follows: Introduce 1 milliliter of the well-shaken sample, by means of a hypodermic syringe, into a 30-milliliter centrifuge tube equipped with a screw cap. Add 10.0 milliliters of chloroform and 10.0 milliliters of a 20 percent sodium sulfate solution, shake well for about 1 minute and centrifuge to obtain a clear upper layer.

(c) Procaine penicillin. The difference between the total penicillin as determined by paragraph (a) of this section and the crystalline penicillin as determined by paragraph (b) of this section represents the amount of procaine penicillin present.

(d) The procaine penicillin and the crystalline penicillin content of the batch are satisfactory when assayed by the methods described in this section if each is not less than 85 percent of that which it is represented to contain.

(e) Sterility. Proceed as directed in § 141a.7 (b) except in the case of multiple-dose containers use approximately 400 milligrams (activity) from each container, in lieu of 300 milligrams.

(f) Moisture. Proceed as directed in § 141a.7 (c).

§ 141a.35 Penicillin–streptomycin ointment, penicillin–dihydrostreptomycin ointment—(a) Potency.—(1) Penicillin content. Proceed as directed in § 141a.8 (a) its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per gram of ointment that is represented to contain.

(2) Streptomycin content. Proceed as directed in § 141b.10 (b) and (c) of this chapter, except paragraph (k) of that section, and in lieu of the directions in § 141b.101 (e) and (j) (3), test a representative portion of the sample (usually approximately 1 gram, accurately weighed) or the entire contents of a single-dose container prepared by one of the following methods:

(i) To assay by the cup-plate method. Use either extraction.

(a) Extraction. Place the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. If the sample consists of substantially more than 100 milliliters of ether. Shake the sample and ether until homogeneous. Add 20

(2) Odometric assay for total penicillin in the solution for assay. Determine the quantity of penicillin in the solution for assay by the iodometric assay procedure described in § 141a.5 (d) (3).

(3) Colorimetric determination of procaine penicillin in the solution for assay. Transfer an aliquot of the solution for assay to a 50-milliliter volumetric flask. Determine the quantity of penicillin in this solution by the following method:

(a) Reagents.—(a) Sodium nitrite solution. Dissolve 0.1 gram of sodium nitrite in 100 milliliters of distilled water. Prepare fresh solution every week and store under refrigeration.

(b) Ammonium sulfamate solution. Dissolve 0.5 gram of ammonium sulfamate in 100 milliliters of distilled water and store under refrigeration.

(c) N-(1-naphthyl)-ethylenediamine solution. Dissolve 0.1 gram of N-(1-naphthyl)-ethylenediamine dihydrochloride in 100 milliliters of distilled water.

Prepare fresh solutions every week and store under refrigeration.

(d) Standards. Transfer, respectively, 1.0, 2.0, 3.0, and 5.0 milliliters of the standard solution containing 27.55 milligrams of procaine hydrochloride U. S. P. in a liter of distilled water (each milliliter of the standard solution is equivalent to 60 units of procaine penicillin).

(II) Standards. Transfer, respectively, 1.0, 2.0, 3.0, and 5.0 milliliters of the standard solution and 5.0 milliliters of distilled water to each of six 50-milliliter volumetric flasks. Add 4.0, 3.0, 2.0, and 1.0 milliliters of water to the first four flasks, respectively, to give each a volume of 5.0 milliliters.

(III) Procedure. To each flask of the standards and the solution for assay add 5.0 milliliters of 4N HCl, 1.0 milliliter of the sodium nitrite solution, 1.0 milliliter of the ammonium sulfamate, and 1.0 milliliter of the N-(1-naphthyl)-ethylenediamine solution. Mix and let stand for 10 minutes before each addition. Make each flask to volume with distilled water.

Determine the absorbency of the colored solutions at 550 mμ in a suitable photo electric colorimeter. The curve is usually balanced so that the zero concentration reads zero absorbancy. Plot the standard curve on coordinate paper. Obtain the procaine penicillin content of the solution for assay by determining the points on the standard curve corresponding to its absorbancy.

(4) The content of buffered crystalline penicillin in one dose of the product is calculated as follows:

\[A = (B - C)F\]

where

\[A = \text{buffered crystalline penicillin content of the product.}\]

\[B = \text{total number of units of penicillin per milliliter as determined in subparagraph (2) of this paragraph.}\]

\[C = \text{number of units of procaine penicillin per milliliter as determined in subparagraph (3) of this paragraph.}\]

\[F = \text{appropriate dilution factor depending on the dilution factor with preparation of the solution for assay.}\]

The content of buffered crystalline penicillin in the batch is satisfactory when determined by the method described in paragraph (c) of this section if less than 85 percent of that which it is represented to contain.

(c) Procaine penicillin. The procaine penicillin content of the batch is the difference between the total penicillin content determined by the method described in paragraph (a) or paragraph (d) of this section and the content of the buffered crystalline penicillin determined by the method described in paragraph (c) of this section.

The procaine penicillin content of the batch is satisfactory when determined by the method described in this paragraph if it is not less than 85 percent of that which it is represented to contain.

(d) Total potency of a one-dose container. Wash out the material remaining in the 10-milliliter volumetric flask referred to in paragraph (b) (1) of this section with 1-percent phosphate buffer, pH 6.0. Dilute to give a concentration of approximately 5,000 units per milliliter, and assay by the iodometric method described in § 141a.5 (d) (1). Obtain the total potency by adding the number of units found in this solution (units per milliliter×volume) to the number of units found (units per milliliter×volume) in the solution assayed in accordance with paragraph (b) (2) of this section.

(2) Determination of the quantity of procaine penicillin in the solution for assay by the iodometric assay procedure described in § 141a.5 (d) (1). Proceed as directed in §§ 141a.1 and 141a.5 (a).

(3) Percent sodium sulfate solution almost to the mark, centrifuge sufficiently to see the meniscus, make to volume with 20-percent sodium sulfate solution, shake well, and centrifuge to obtain a clear or reasonably clear solution. Dilute a 0.5-milliliter aliquot of this clear solution with 1-percent phosphate buffer, pH 6.0, to give a solution for assay of approximately 2,000 units per milliliter.

(2) Iodometric assay for total penicillin in the solution for assay. Determine the quantity of penicillin in the solution for assay by the iodometric assay procedure described in § 141a.5 (d). (1) (3) and (4).}

(2) Iodometric assay for total penicillin in the solution for assay. Determine the quantity of penicillin in the solution for assay by the iodometric assay procedure described in § 141a.5 (d). (1) (3) and (4).
milliliters of 0.1 N potassium phosphate buffer, pH 8.0, and shake. If the sample consists of substantially more than 1 gram, use 50 milliliters of buffer. Allow the layers to separate. Remove the buffer layer and repeat the extraction with new portions of buffer at least three times and any additional times necessary to ensure complete extraction of the antibiotic. Combine the extractives and make up to an appropriate measured volume with buffer. To a suitable aliquot add sufficient penicillinase and let stand for 30 minutes at 37°C. To inactivate the penicillin. After inactivation, make the proper estimated dilution with buffer at pH 8.0.

(ii) To assay by the turbidimetric method. Place the sample in a separatory funnel containing approximately 10-milliliter portions of peroxide-free ether. If the sample consists of substantially more than 1 gram, use 100 milliliters of ether. Shake the sample and ether until homogeneous. Add 50-milliliter portions of distilled water, and shake. If the sample consists of substantially more than 1 gram, use 50 milliliters of water. Allow the layers to separate. Remove the aqueous layer and repeat the exact 10-milliliter portion of distilled water. Make the proper extractives and distilled water. Make the proper estimated dilutions with buffer at pH 8.0. Remove the aliquot and, if the ratio of the content of penicillin to the content of streptomycin is equal to or greater than 1.0 unit for each microgram, add sufficient penicillinase and let stand for 30 minutes at 37°C. To inactivate the penicillin. Make the proper estimated dilutions with distilled water. If its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(2) Streptomycin content. Using 12 boulées, proceed as directed in § 141b.101 of this chapter, except paragraph (d) of that section, and if the cup-plate method is used, replace the buffer to the plate buffer (pH 7.8–8.0) for dissolving the sample in lieu of sterile distilled water as directed in § 131b.101 (e) of this chapter and add sufficient penicillinase to the solution under test to completely inactivate the penicillin present. If the turbidimetric method is used, inactivation with penicillinase is not necessary unless the ratio of the content of penicillin to the content of streptomycin is equal to or greater than 1.0 unit for each microgram. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.23 (b).

§ 141b.37 Penicillin bacitracin ointment—(a—Penicillin—(1) Penicillin content. Proceed as directed in § 141a.3 (a), except the last sentence of that paragraph. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units of the sample into 1.0 milliliter of buffer. If its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units it is represented to contain.

(b) Bacitracin content. Proceed as directed in § 141b.402 (a) of this chapter, except that sufficient penicillinase is added to the sample under test to completely inactivate the penicillin present. Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units it is represented to contain.

(3) Streptomycin content. Using 1 milliliter as the test sample proceed as directed in § 141b.55 (a) (2). Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(3) Dihydrostreptomycin content. Proceed as directed in § 141b.55 content. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(b) Moisture. Using 1 milliliter as the test sample proceed as directed in § 141b.7 (c).

§ 141a.39 Penicillin and streptomycin, penicillin and dihydrostreptomycin—(a) Penicillin—(1) Sodium or potassium penicillin content. Proceed as directed in § 141a.22 (b), except prepare the sample as follows: Add the indicated amount of distilled water to the sample containing the contents of a vial of the sample and shake vigorously for 1 minute. To a suitable aliquot of the suspension or solution add a 0.1-milliliter volume of a 5 percent aqueous solution of sodium or potassium penicillin content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) Streptomycin content. Proceed as directed in § 141b.101 (c) or § 141a.35 (d), except that in the turbidometric assay one drop of 1.5 N HCl is added to the blank immediately before the addition of the 0.01 N HCl. The procaine penicillin content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(3) Dihydrostreptomycin content. Proceed as directed in § 141b.101 (f) and (i) of this chapter.

(3) Dihydrostreptomycin content. Proceed as directed in § 141b.101 (j) and (k) of this chapter.

(5) Pyrogens. Proceed as directed in § 141b.6, using as a test dose 0.5 milliliter of a solution of the sample containing 1.0 milligram of streptomycin or dihydrostreptomycin per milliliter.

(6) Moisture. Proceed as directed in § 141b.25 (e).

(1) pH. Proceed as directed in § 141b.5 (e).

(b) Use the solution or suspension recommended for use in preparing the sample in lieu of the directions for preparing the sample in subparagraph (3) thereof prepare the sample and calculate as follows: Accurately weigh about 1 gram of the sample into a dry, 50-milliliter volumetric flask. Add an exact 10 milliliters of the Karl Fischer reagent and back titrate immediately with water-methanol solution until the end point is reached. The entire operation from the addition of the Karl Fischer reagent and back titrate until the end point is reached should not exceed 1 minute.

\[
\text{Percent moisture} = \left( \frac{W_1 - W_2}{W_1} \right) \times 100
\]

where \(W_1\) = weight of sample in milligrams.

§ 141a.41 Penicillin—bacitracin mixture—(a) Penicillin content. Proceed as directed in § 141a.12.
(a) Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per troche that is represented to contain.

(b) Bacitracin. Proceed as directed in § 141e.403 (a) of this chapter, except that sufficient penicillinase is added to the solution under test to completely inactivate the penicillin present. Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per troche that is represented to contain.

(b) Sterility. Proceed as directed in § 141a.5 (a)

§ 141a.42 Crystalline penicillin and bacitracin. (a) Potency. (1) Content of penicillin. Proceed as directed in § 141a.1. Its content of penicillin is satisfactory if it contains not less than 85 percent and not more than 115 percent of the number of units it is represented to contain.

(2) Content of bacitracin. Proceed as directed in § 141e.401 (a) of this chapter, except that sufficient penicillinase is added to the sample under test to completely inactivate the penicillin present. Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units it is represented to contain.

(b) Sterility. Proceed as directed in § 141a.5 (b) using a solution prepared as directed in the labeling for the drug.

§ 141a.43 E-Phenamene penicillin G. (a) Potency. Proceed as directed in § 141a.1, except in lieu of paragraph (d) dissolve the sample by adding 0.5 milliliter of a solution containing 250 units of bacitracin per milliliter. Use physiological salt solution as the diluent and inject 2.0 milliliters per kilogram of a solution containing 80% units per milliliter.

(d) Pyrogens. Proceed as directed in § 141a.2, except prepare the sample in 5 milliliters of redistilled methanol. Further dilute this solution with sufficient 1 percent phosphate buffer pH 6.0 to give a concentration of 2.0 milligrams per milliliter.

(1) Specific rotation. Accurately weigh approximately 128 milligrams of the sample in a 25-milliliter glass-stoppered volumetric flask and dissolve in about 15 milliliters of water-acetone (1-1) at 20° C. Dilute to 25 milliliters with water-acetone (1-1) at 20° C. and mix thoroughly. Transfer the solution to a 200-millimeter tube, determine the angular rotation in a suitable polarimeter, using sodium light or a 5,893 Angstrom filter, and calculate the specific rotation. The determination must be completed within 1½ hour from the time the solution is prepared.

§ 141a.44 1-Phenamene penicillin G m-ol. (a) Potency. Proceed as directed in § 141a.27 (a) except use the last sentence thereof. If it is represented to contain less than 300,000 units per milliliter, its potency is satisfactory if it contains not less than 85 percent of the number of units so represented. If it is represented to contain 300,000 units per milliliter, its potency is satisfactory if it contains not less than 90 percent of the number of units so represented.

(b) Sterility. Proceed as directed in § 141a.7 (b)

(c) Moisture. Proceed as directed in § 141a.5 (c)

§ 141a.45 E-Phenamene penicillin G for aqueous injection. (a) Potency. Proceed as directed in § 141a.43 (a). Its potency is satisfactory if it contains not less than 90 percent of the number of units it is represented to contain.

(b) Sterility. Proceed as directed in § 141a.7 (b) except prepare the sample in 5 milliliters of redistilled methanol before diluting with sterile distilled water to make an appropriate stock solution.

(d) Toxidity. Proceed as directed in § 141a.5 (d) except prepare the sample in 5 milliliters of redistilled methanol before diluting with sterile distilled water to make an appropriate stock solution.

(e) Microscopical test for crystallinity. Proceed as directed in § 141a.5 (e)

(a) Heat stability. Proceed as directed in § 141a.5 (d) (1) except prepare the sample as follows: Dissolve the sample in 5 milliliters of redistilled methanol. Further dilute this solution with sufficient 1 percent phosphate buffer pH 6.0 to give a concentration of 2.0 milligrams per milliliter.

§ 141a.46 Procaine penicillin in streptomycin sulfate solution, procaine penicillin in dihydrostreptomycin sulfate solution. (a) Potency. (1) Procaine penicillin content. Proceed as directed in § 141a.1, except paragraph (l) thereof. If the iodometric assay is used, 1 drop of the 1.2 N HCl is added to the blank immediately before the addition of the 0.01 N I2. Its content of procaine penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) Sterility. Proceed as directed in § 141a.39 (d)

(e) pH. Proceed as directed in § 141a.5 (b), using the undiluted aqueous suspension.

§ 141a.47 Benzathine penicillin G. (a) Potency. Proceed as directed in § 141a.1, except if the bioassay method is used dissolve the sample to be tested in sufficient dimethyl formamide or formamide prior to diluting with phosphate buffer solution. If the iodometric method is used proceed as directed in § 141a.5 (d), except in preparing the sample solution add 0.5 milliliter of dihydrostreptomycin per milliliter, and make a suspension of 2 milligrams per milliliter in 1 percent phosphate buffer at pH 6.0. Shake well, pipette 2.0 milliliters into a 125-milliliter glass-stoppered Erlenmeyer flask, add 10 milliliters 0.01 N iodine and immediately titrate with 0.01 N Na2S2O3. In preparing the sample solution for incinination dissolve a weighed sample (30-60 milligrams) in sufficient 1 N NaOH to give 2.0 milligrams per milliliter. Pipette a 2.0-milliliter aliquot into a 125-milliliter glass-stoppered Erlenmeyer flask, add 10 milliliters 0.01 N HCl and 10 milliliters 0.01 N iodine. Allow to stand for 15 minutes and titrate the excess iodine with 0.01 N Na2S2O3. In calculating the results regard the difference in liters multiplied by 661.8, divided by 4, as the units per milliliter.

(b) Sterility. Proceed as directed in § 141a.3, except prior to sterilization add 0.5 milliliter of 20% sodium acetate solution, 30 milliliters 1.2 N HCl and 10 milliliters 0.01 N iodine to each tube of thygoclate and Sabouraud's medium, and after sterilization add sufficient penicillinase to each tube of Sabouraud's medium to completely inactivate the penicillin used in the test.
During the period of incubation, shake the tubes at least once daily.

(4) Potency. Proceed as directed in § 141a.2, except use physiological salt solution as the diluent and inject 0.25 milliliter of a suspension containing 4,000 units per milliliter.

(b) Microscopic test for crystallinity. Proceed as directed in § 141a.5 (c) (d) Penicillin G content. Dissolve 50 milligrams of the sample, accurately weighed, in absolute methyl alcohol and make up to a volume of 100 milliliters with absolute methyl alcohol. With a suitable spectrophotometer, determine the optical density of the solution in a 1-centimeter cell at 263 mp compared with absolute methyl alcohol as a blank. Multiply the optical-density figure obtained by the appropriate factor to obtain the optical-density value of a 1-percent solution. The E 263 value of the sample multiplied by 100, divided by 7.0, represents the percent penicillin G in the sample.

§ 141a.43 Benzathine penicillin G oral suspension, benzathine penicillin G for oral suspension (a) Potency. Proceed as directed in § 141a.4 (b).

(b) pH. Proceed as directed in § 141a.5 (b) using the undiluted aqueous suspension or the suspension prepared as directed in the labeling of the drug.

(c) Moisture. Proceed as directed in § 141a.2, except use physiological salt solution as the diluent and inject 0.5 milliliter of a suspension containing 4,000 units per milliliter.

§ 141a.49 Penicillin streptomycin-bacitracin ointment, penicillin-dihydrostreptomycin-bacitracin ointment—(a) Potency. (1) Content of penicillin, streptomycin, and dihydrostreptomycin. Proceed as directed in § 141a.35 (a) (2) Bacitracin content. Proceed as directed in § 141e.402 (a) of this chapter, except that:

(1) Sufficient penicillin is added to the sample under test to completely inactivate the penicillin present.

(ii) If streptomycin is present add sufficient 0.5 percent semicarbazide solution (pH 6.5-7.0) to the appropriate factor to room temperature for 30 minutes.

(iii) If dihydrostreptomycin is present use the test organism the Food and Drug Administration dihydrostreptomycin-resistant strain of M. flavus (P. C. 19 R. D.) which is grown and maintained in media containing 500 mg/mg of dihydrostreptomycin per milliliter of media, or calculate from the quantity of dihydrostreptomycin found, using the method prescribed by subparagraph (1) of this paragraph, the quantity of dihydrostreptomycin that would be present in the sample if diluted to contain 1 unit of bacitracin Gabaed potency per milliliter. Prepare the bacitracin standard curve by adding the standard bacitracin-streptomycin to each concentration of bacitracin used for the curve. Use this standard curve to calculate the bacitracin content of the sample.

§ 141a.50 Penicillin streptomycin dental cone, penicillin-dihydrostreptomycin dental cone—(a) Potency. Proceed as directed in § 141a.8 (b) (1) Optical density figure. Proceed as directed in § 141a.35 (a) (2) Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(d) Moisture. Proceed as directed in § 141a.5 (c)

(1) pH. Proceed as directed in § 141a.5 (b) using a saturated aqueous solution prepared by adding 500 milligrams per milliliter.

(2) Sterility. Proceed as directed in § 141a.5 (c) (2) (pH 7.9) except use physiological salt solution as the diluent.

(g) Microscopic test for crystallinity. Proceed as directed in § 141a.5 (c) (d) Penicillin G content. Accurately weigh approximately 50 milligrams of the sample and dissolve in 2.0 milliliter potassium phosphate buffer, pH 9.0 (one part of 0.1 M KPF 6 and 11.65 parts of 0.1 M NaH 2 PO 4 ). Allow to stand at room temperature for not less than 1.5 hours and not more than 2 hours. Transfer a 0.5-milliliter aliquot to a 0.5-milliliter glass-stopped test tube. Place the tube in an ice bath and add 10.0 milliliters of chloroform (previously washed with water) After cooling, adjust the pH of the aqueous phase to 9.0 by adding 0.5 milliliter of 1-6 HPO 4 . Shake the tube thoroughly for 2 minutes, centrifuge, and withdraw the lower chloroform layer with the aid of a 10-millimeter hypodermic syringe and a 3-inch needle. Superficially dry the chloroform by filtering through a pledget of cotton, using a U-shaped funnel to reduce evaporation during filtration. Determine the optical density of the filtered chloroform solution in a 1-centimeter cell at 263 mp and 200 mp, using a suitable spectrophotometer. Treat the working standard of sodium penicillin G in the same manner, using an accurately weighted sample of approximately 50 milligrams.

§ 141a.61 Diethylaminoethyl cester penicillin G hydrochloride. (a) Potency. Proceed as directed in § 141a.1, except prepare the sample as follows: Dissolve in 0.1 M potassium phosphate buffer (PH 7.5-8.0) to make a stock solution of 0.5 milligrams per milliliter (estimated). Allow to stand at room temperature for not less than 1.5 hours and not more than 2 hours and then dilute an aliquot with 1-percent potassium phosphate buffer (pH 6.0) to 1.0 unit (estimated), or proceed by the iodometric method described in § 141a.8 (d) (1), except prepare the sample as follows: Dissolve a weighed sample (approximately 50 milligrams) in 2.0 milliliters of redistilled methanol. Further dilute this solution with 1-percent phosphate buffer (pH 6.0) to give a concentration of 2,000 units per milliliter.

§ 141a.62 Diethyiaminoethyl cester penicillin G hydrochloride for aqueous injection—(a) Potency. If the bioassay method is used, proceed as directed under § 141a.61 (a) If the iodometric method is used, proceed as directed under § 141a.8 (d) (1) (i) Its potency is satisfactory if it contains not less than 90 percent of the number of units that it is represented to contain.

(b) Sterility. Use the entire contents of single-dose containers or the equivalent of approximately 300 milligrams (activity) from each multiple-dose container, and proceed as directed in § 141a.8.

(c) Moisture. Proceed as directed in § 141a.5 (a)

§ 141a.63 Penicillin streptomycin implantation pellets, penicillin-dihydrostreptomycin implantation pellets—(a) Potency. Proceed as directed in § 141a.9 (a). Its content of penicillin is satisfactory if it contains not less than 90 percent of the number of units that it is represented to contain.

(b) Sterility. Proceed as directed in § 141a.2, except use physiological salt solution as the diluent.
RULES AND REGULATIONS

The extinction coefficient of the sample in the particular cell being used is calculated as follows:

\[ E = \frac{D \times 5}{W} \]

where \( E \) = extinction coefficient.

Using an accurately weighed sample of about 200 milligrams of the potassium penicillin G working standard in the procedure, determine its extinction coefficient in the particular cell being used.

Obtain the percent chloroprocaine penicillin G in the sample under test by the following calculation:

\[ \text{Standard} \times \% \text{ penicillin G} = \text{sample} \times \% \text{ chloroprocaine penicillin G} \]

(c) Chloroprocaine penicillin G content. Proceed as directed in § 141a.5 (g), except prepare the sample as follows: Accurately weigh approximately 500 milligrams of the sample in a 25-milliliter glass-stoppered test tube. Add 6 milliliters of distilled water and 6.0 milliliters of amyl acetate. Place the tube in an ice bath for 5 minutes and then add 4 milliliters of 1-4 HPO₄. Shake vigorously for 2 minutes, centrifuge for 1 minute to separate the layers, and withdraw 5.0 milliliters of the amyl acetate layer. Place this in a 250-milliliter Erlenmeyer flask and evaporate to dryness by directing a stream of air into the flask. Dissolve the residue in 2.0 milliliters of 2.6 percent KOH.

Calculate the percent of penicillin G in the sample from the equation:

\[ \text{(5.10)} \times (50) = \% \text{ penicillin G} \]

(Wt. sample milligrams) (0.689)

\[ = \% \text{ penicillin G} \]

§ 141a.57 Chloroprocaine penicillin O for aqueous injection. For the determination of potency, sterility, moisture, pyrogens, toxicity, and pH, proceed as directed in § 141a.59.

§ 141a.58 Penicillin - streptomycin vaginal suppositories, penicillin-dihydrostreptomycin vaginal suppositories.—(a) Potency.—(1) Penicillin content. Proceed as directed in § 141a.10 (e) (1). Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) Sterptomycin content. Using 5 suppositories, proceed as directed in § 141a.35 (a) (2), except that 150 milliliters of peroxide-fre ether is used in the extraction. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(c) Dihydrostreptomycin content. Proceed as directed in subparagraph (2) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.15 (b).

§ 141a.59 Penicillin - streptomycin dental paste, penicillin-dihydrostreptomycin - bacitracin dental
The page contains a series of paragraphs and sections discussing the preparation and analysis of penicillin solutions, with specific emphasis on the determination of potency and the dilution factor. The text includes references to specific sections of regulations or guidelines, such as §141a.49(a) and §141a.50, and mentions the use of iodometric and colorimetric procedures for analysis. The text is technical and detailed, focusing on the procedural steps for the determination of penicillin content and the establishment of potency levels.

The page also contains references to specific units of measurement and concentrations, such as milligrams, units, and milliliters. The text is structured in a way that each paragraph builds upon the previous one, providing a comprehensive guide for the analysis of penicillin solutions.

The overall content of the page is dedicated to the methodological aspects of penicillin analysis, including the preparation of solutions, the execution of tests, and the interpretation of results to ensure the potency and efficacy of the antibiotic.
to in subparagraph (3) (i) (a) of this paragraph, or combine the contents remaining in the 50-milliliter volumetric flask and in the centrifuge tube referred to in subparagraph (3) (i) (b) of this paragraph. Disperse the material by adding 10 milliliters of 1 N NaOH for each 50,000 units of benzathine penicillin and allow to stand 15 minutes. Add 1 milliliter of 1.25 N HCl for each milliliter of 1 N NaOH and then dilute with distilled water to give a concentration of approximately 2,000 units per milliliter. Place 2.0 milliliters in a 125-milliliter glass-stoppered Erlenmeyer flask, add 10 milliliters of 0.01 N iodine, allow to stand for 15 minutes, and then titrate with 0.01 N sodium thiosulfate as directed in § 141a.5 (d) (1). For the blank determination, prepare a separate sample as directed in subparagraph (3) (i) (a) or (b) of this paragraph and in the first sentence of this subparagraph, then dilute with 1 percent phosphate buffer, pH 6.0, to give a concentration of approximately 2,000 units per milliliter. The total penicillin content is equal to the sum of the number of units found in this assay (units per milliliter×volume) and the number of units per milliliter×volume) in the solution for assay in subparagraph (3) (ii) of this paragraph.

(b) Procaine penicillin content of a single-dose container. Make suitable dilutions of the NaOH-activated solution prepared in subparagraph (3) of this paragraph to obtain approximately 60 units of procaine penicillin per milliliter. Determine the procaine penicillin content (units per milliliter×volume) of this solution by the colorimetric procedure described under § 141a.32 (b) (3). To this value add the procaine penicillin content (units per milliliter×volume) of the solution for assay, as found in subparagraph (3) (iii) of this paragraph, to obtain the procaine penicillin content of the single-dose container. The content of procaine penicillin in the batch is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(b) (ii) Sterility. Proceed as directed in § 141a.47 (c) (4). (c) Pyrogens. Proceed as directed in § 141a.47 (d).

(d) Toxicity. Proceed as directed in § 141a.47 (e).

(e) Moisture. Proceed as directed in § 141a.26 (a).

(f) pH. Proceed as directed in § 141a.47 (f).

§ 141a.56 Benzathine penicillin G and benzathine penicillin G for aqueous injection (a) Total potency. Benzathine penicillin G content, procaine penicillin content. Proceed as directed in § 141a.61 (a) (1), (2), (3), (4), (b) (i) Sterility, toxicity, pyrogens. Proceed as directed in § 141a.47 (c), (4), (c)

(d) pH. Proceed as directed in § 141a.5 (b), using the undiluted aqueous suspension or the suspension prepared as directed in the labeling for the drug.

(d) Moisture (dry mixture of the drug). Proceed as directed in § 141a.26 (e).

§ 141a.63 Penicillin - bacitracin - neomycin ointment; penicillin-bacitracin-neomycin in oil. (a) Potency. Proceed as directed in § 141a.37 (a).

(b) Neomycin content. Proceed as directed in § 141a.41 (a). (2) Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that is represented to contain.

(c) Penicillin content. Proceed as directed in § 141a.9 (a). (2) Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that is represented to contain.

(d) Streptomycin content. Proceed as directed in § 141a.36 (a). (2) Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

§ 141a.64 Penicillin - streptomycin tablets, penicillin-dihydrostreptomycin neomycin in oil. (a) Potency. Proceed as directed in § 141a.9 (a). (2) Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (a).

§ 141a.65 Procaine penicillin-streptomycin-neomycin in oil; procaine penicillin-dihydrostreptomycin-neomycin in oil; procaine penicillin-streptomycin-neomycin ointment; procaine penicillin-dihydrostreptomycin-neomycin ointment. (a) Potency. Proceed as directed in § 141a.38 (a) (1) and (2). (c) Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) Streptomycin content. Proceed as directed in § 141a.37 (a). (1) Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

§ 141a.66 Capsules procaine penicillin G in oil. (a) Potency. Proceed as directed in § 141a.33 (a) (1) of this chapter, except prepare the sample as follows: Place 12 capsules in a blending jar containing 40 milliliters of absolute alcohol and 260 milliliters of distilled water. After blending for 1 minute with a high-speed blender, add 260 milliliters of distilled water. Blend again for 1 minute and make the proper estimated dilutions in 1-percent phosphate buffer at pH 8.5. Its potency is satisfactory if it contains not less than 85 percent of the number of units per capsule that is represented to contain.

(b) Moisture. Use an accurately weighed sample of approximately 1 gram of the capsule contents, proceed as directed in § 141a.7 (c).

§ 141a.67 Procaine penicillin and benzathine penicillin G in streptomycin sulfate solution; procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution. (a) Potency. Proceed as directed in § 141a.61 (a) (1) and (2) except that in the iodometric assay one unit of I2(M) is added to the blank immediately, before the addition of the 0.01 N iodine.

(b) Benzathine penicillin G content. The difference between the total penicillin potency and the procaine penicillin content determined under subparagraph (1) of this paragraph represents the benzathine penicillin G content.
benzathine penicillin G content is satisfactory if it is not less than 85 percent of that which is represented to contain.

(3) Streptomycin content. Proceed as directed in § 141b.101 (j) and (k) of this chapter.

Cry & streptomycin content. Proceed as directed in § 141b.108 (g) of this chapter.

(b) Sterility. Proceed as directed in § 141b.4f (b) except that no control tube is used in the test for bacteria.

d) Toxicity. Proceed as directed in § 141a.39 (c).

d) Pyrogens. Proceed as directed in § 141a.39 (c).

e) pH. Proceed as directed in § 141a.5 (b) using the undiluted aqueous suspension.

§ 141a.68 Benzathine penicillin G and streptomycin, benzathine penicillin G and dihydrostreptomycin-(a) Potency-(1) Content of benzathine penicillin G. Proceed as directed in § 141a.47 (a). Its content of benzathine penicillin G is satisfactory if it contains not less than 80 percent of the number of units that it is represented to contain.

(2) Streptomycin content. Proceed as directed in § 141b.101 (j) of this chapter. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) Dihydrostreptomycin content. Proceed as directed in § 141b.108 (a) of this chapter. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) Sterility. Use the entire contents of single-dose containers or the equivalent if approximately 0.5 gram (combined activity) for each multiple-dose container, and proceed as directed in § 141a.47 (b) except that no control tube is used in the test for bacteria.

d) Toxicity, pyrogens, pH. Proceed as directed in § 141a.39 (c) (d) and (f).

§ 141a.69 Crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, potassium penicillin G oral suspension—(a) Potency. Proceed as directed in § 141a.1, except § 141a.1 (i) and in lieu of the directions in § 141a.1 (d) prepare the sample as follows: By means of a hypodermic syringe, introduce 5 milliliters of the well-shaken undiluted aqueous solution of potassium penicillin G into 15 milliliters of a high-speed blender containing 244 milliliters of 1-percent phosphate buffer at pH 6.0 and 1.0 milliliter of a 10-percent aqueous solution of polysorbate 80. Blend the mixture for 3 to 5 minutes. Make the proper estimated dilutions in 1-percent phosphate buffer at pH 6.0. Its potency is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.7 (a).

§ 141a.70 Tablets benzathine penicillin G and crystalline penicillin—(a) Potency—(1) Total potency. Proceed as directed in § 141a.9 (a) (2) Its total potency is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(2) Crystalline penicillin content. Place 5 tablets in a blending jar and add thereto sufficient distilled water to give a concentration of 5,000 units of crystalline penicillin per milliliter. Blend for 2 minutes with a high-speed blender, filter, remove a 10-milliliter aliquot of the clear solution from 15 milliliters of 1.0 percent phosphate buffer at pH 6.0. Remove a 2-milliliter aliquot of this solution and assay by the hemodialysis assay procedure described in § 141a.5 (d) (1). Its content of crystalline penicillin is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(b) moisture. Proceed as directed in § 141a.5 (a).

§ 141a.71 Penicillin - streptomycin powder penicillin-dihydrostreptomycin powder—(a) Potency—(1) Penicillin content. Use an accurately weighed sample of approximately 1 gram and proceed as directed in § 141a.1, except paragraph (i) of that section. The penicillin content of the powder is satisfactory if it contains not less than 65 percent of the number of units that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.39 (e).

§ 141a.73 Dibenzy lam ine penici llin and potassium penicillin powder, buffered—(a) Total potency. Proceed as directed in § 141a.1, using 5 milliliters of the preparation, reconstituted as directed in the labeling.

(b) Potassium penicillin content. Centrifuge approximately 10 milliliters of the reconstituted preparation to obtain a clear solution and proceed as directed in § 141a.1, using 5 milliliters of the clear solution. The potency of the clear solution is regarded as the potassium penicillin content. The potassium penicillin is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(2) Dibenzy lam ine penicillin content. The difference between the total potency as determined by paragraph (a) of this section and the potassium penicillin as determined by paragraph (b) of this section represents the amount of dibenzy lam ine penicillin present. The content of dibenzy lam ine penicillin is satisfactory if it is not less than 85 percent of that which it is represented to contain.

§ 141a.74 Benzathine penicillin and streptomycin in oil, dibenzylamine penicillin and dihydrostreptomycin in oil—(a) Potency—(1) Penicillin content. Proceed as directed in § 141a.27 (a) except the last centents thereof. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(b) Streptomycin content. Using 1.0 milliliter as the test sample, proceed as directed in § 141a.36 (a) (2). Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(d) Moisture. Proceed as directed in § 141a.26 (e).

§ 141a.75 Dihydrostreptomycin content. Using 1.0 milliliter as the test sample, proceed as directed in § 141a.36 (a) (3). Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.
(b) Moisture Using 10 milliliters of the test sample, proceed as directed in § 141a 7 (c).

§ 141a 75 Hydramamine penicillin G—
(a) Potency Proceed as directed in § 141a 1, except if the bioassay method is used prepare the sample as follows:
Dilute 10 milliliters of the sample in methanol and dilute with methanol to 1,000 units per milliliter (estimated). By means of a volumetric pipette, add a 0.25-milliliter aliquot to a 1,000-milliliter volumetric flask containing approximately 500 milliliters of 1-percent phosphate buffer, pH 6.0, and swirl the flask for 5 minutes. Make to a volume of 1,000 milliliters with 1-percent phosphate buffer pH 6.0. If the iodometric method is used accurately weigh 30-60 milligrams of the sample to be tested in a 50-milliliter Erlenmeyer flask and dissolve in sufficient chloroform USP to give a concentration of 2.0 milligrams per milliliter. Pipette 20 milliliters of this solution into a 125-milliliter glass-stoppered Erlenmeyer flask, add 10 milliliters of 0.01 N NaOH, and titrate immediately with 0.01 N Na₂SO₄ for the blank determination. Toward the end of the titration, add 1 drop of starch solution or about 50 milliliters of CCl₄. Continue the titration by the addition of 0.01-0.03-milliliter portions of 0.01 N Na₂SO₄ shaking vigorously after each addition. 10 milliliters of the original chloroform solution add 10 milliliters of 1 N NaOH and shake well immediately and 5 minutes later. Fill up the portion of the sample above the 10 milliliters of the original chloroform solution add 10 milliliters of 1 N NaOH and shake well immediately and 5 minutes later. Fill up the flask by means of a volumetric pipette 20 milliliters of the upper NaOH layer into a 125-milliliter glass-stoppered Erlenmeyer flask and add 20 milliliters of 1.2 N HCl and 10 milliliters of 0.01 N NaOH. Stop the flask after 15 minutes titrate the excess iodine with 0.01 N Na₂SO₄.

Units of hydramamine penicillin G per milligram

\[ \text{Difference in titers} \times \text{potency of F D A working standard in units per milligram} = \frac{4}{F} \times F \]

where F = the number of milliliters of 0.01 N NaOH absorbed for each 10 milligrams of the Food and Drug Administration sodium penicillin G working standard.

(b) Toxicity Proceed as directed in § 141a 4, except use physiological salt solution as the diluent and inject 0.25 milliliter of a suspension containing 4,000 units per milliliter.

(c) Moisture Proceed as directed in § 141a 26 (c).

(d) pH Proceed as directed in § 141a 5 (b) using a saturated aqueous solution prepared by adding approximately 60 milligrams per milliliter.

(e) Microscopical test for crystallinility Proceed as directed in § 141a 5 (c).

(f) Penicillin G content Accurately weigh a glass weighing bottle of approximately 10-milliliter capacity together with its top a stirring rod and a medium-porosity immersion filter stick. Transfer to the weighing bottle approxi- mately 225 milligrams of the sample to be tested and weigh. Add 15 milliliters of pyridine and stir until solution is complete. Add 0.25 milliliter of N-ethylpipеридин и держала unt until precipitation begins. When precipitation is complete dilute with 2.5 milliliters of petroleum ether stir well, and allow to stand for 15 minutes. Attach the filter stick to a vacuum line equipped with a suitable trap and wash the liquid from the precipitate. Add 2.5 milliliters of petroleum ether to the precipitate and wash the liquid from the precipitate. Repeat the procedure twice. Add 2.5 milliliters of petroleum ether. Leave the stirring rod and the filter stick in the bottle dry for 30 minutes in a vacuum desiccator stopper and weigh.

Percent of hydramamine penicillin G

\[ \text{Milligrams of N-ethylpiperidine penicillin precipitate} \times 141.4 \]

\[ \text{Weight of sample in milligrams} \]

(g) Extinction coefficient Accurately weigh approximately 100 milligrams of the sample, dissolve in absolute methanol and make to 100 milliliters. Determine the extinction coefficient of the sample at the absorption peak at 276 millioncrons using a suitable ultraviolet spectrophotometer and 1-centimeter quartz cells. Set the instrument to 100 percent transmission. Add 0.01 N NaOH to the solution and titrate with dilute methanol. If a recording spectrophotometer is used record the ultraviolet absorption spectrum from 240-300 millimicrons. If a nonrecording spectrophotometer is used, determine the absorbancy of the sample at the absorption peak at 276 millioncrons using a slit width of 0.4 millimeter or less. (The exact position of the peak should be determined for the particular instrument used.) Calculate the E₄₀ of the value of the sample at the absorption peak at 276 millioncrons.

§ 141a 76 Hydramamine penicillin G oral suspension—(a) Potency Proceed as directed in § 141a 1, except if the bioassay method is used prepare the sample as follows: Place 10 milliliters of the sample to be tested in a 100-milliliter volumetric flask and dilute to volume with methanol. By means of a volumetric pipette add a 10-milliliter aliquot of this solution to a sufficient volume of 1-percent phosphate buffer pH 6.0 to give a solution having a concentration of 1 unit per milliliter (constantly swirling the flask during the addition). If the iodometric method is used dilute 1 milliliter of the sample with a 1.25-milliliter glass-stoppered Erlenmeyer flask. Add 10 milliliters of 0.01 N NaOH and titrate immediately with 0.01 N Na₂SO₄ for the blank determination. Dilute a 1-milliliter aliquot of the sample with 1.0 N NaOH to produce a suspension containing 2,000 units per milliliter (estimated) and add approximately half that amount of chloroform USP. Shake immediately and again after 5 minutes. Fifteen minutes after the initial shaking, pipette 20 milliliters of the upper NaOH layer into a 125-milliliter glass-stoppered Erlenmeyer flask and add 0 milliliters of 0.01 N HC₁ and 10 milliliters of 0.01 N NaOH. After 15 minutes titrate the excess iodine with 0.01 N Na₂SO₄.

Units of penicillin per milliliter of suspension

\[ \text{Difference in titers} \times \text{potency of F D A working standard in units per milligram} \times \text{volume of 2,000 units per milliliter suspension} = \frac{F}{X} \times X \]

where F = the number of milliliters of 0.01 N NaOH absorbed by 1.0 milliliter of the Food and Drug Administration sodium penicillin G working standard.

(b) pH Proceed as directed in § 141a 5 (b) using the undiluted aqueous suspension.

§ 141a 77 Capsules crystalline penicillin G (capsules crystalline penicillin G potassium capsule crystalline penicillin G sodium)—(a) Potency Use the contents of 12 capsules and proceed as directed in § 141a 1 except § 141a 1 (i) and except if it contains a vegetable oil, prepare the sample as follows: Place 12 capsules in a blending jar containing 1.0 milliliter of a 10-percent aqueous solution of polysorbate 80 and sufficient 1-percent phosphate buffer pH 6.0 to give a volume of 250 milliliters. Using a high-speed blender, blend for 3 to 5 minutes, then add 250 milliliters of buffer and blend for an additional minute. Make further dilutions to 1 unit per milliliter (estimated) with 1-percent phosphate buffer pH 6.0. The sample with 1.0-milliliter capsules crystalline penicillin G is satisfactory if it is not less than 85 percent of the number of units per capsule they are represented to contain.

(b) Moisture Use the contents of 4 capsules and proceed as directed in § 141a 5 (a) except if it contains a vegetable oil proceed as directed in § 141a 7 (c).

§ 141a 78 Benzathine penicillin G in oil—(a) Potency Proceed as directed in § 141a 1 except paragraph (i) of that section, and in lieu of the directions in § 141a 1 (d) prepare the sample as follows: Place a representative quantity (usually 1.0 milliliter) of a multiple-dose
container, or the entire contents of a single-dose container, in a blending jar containing sufficient dimethyl formamide (previously adjusted to a pH of 6.5±0.5 with concentrated HSO₄) to give a final volume of 100 milliliters. Using a high-speed blender, blend the mixture for 2 minutes and then make the proper estimated dilutions in a 1.0-percent phosphate buffer at pH 6.0. The potency is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) Sterility. Proceed as directed in § 141a.47 (b).
(c) Moisture. Proceed as directed in § 141a.17 (c).

§ 141a.79 Benzathene penicillin G and procaine penicillin G in oil—(a) Potency—(1) Total penicillin content. Proceed as directed in § 141a.79 (a) (2). The streptomycin content is satisfactory if it contains not less than 1.0 milliliter of a multiple-dose container, or the entire contents of a single-dose container, as directed in § 141a.35 (a) (2). The dihydrostreptomycin content is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(5) Dihydrostreptomycin content. Using a representative quantity (usually 1.0 milliliter) of a multiple-dose container, or the entire contents of a single-dose container, proceed as directed in § 141a.35 (a) (5). The dihydrostreptomycin content is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(b) Toxicity. Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter into the peritoneal cavity of rabbits. Proceed as directed in § 141a.26 (c). The procaine penicillin content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(3) Benzathene penicillin G content. The benzathene penicillin G content is the difference between the total penicillin content as determined in subparagraph (1) of this paragraph and the procaine penicillin content as determined in subparagraph (2) of this paragraph. The benzathene penicillin G content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) Sterility. Proceed as directed in § 141a.47 (b).
(c) Moisture. Proceed as directed in § 141a.17 (c).

§ 141a.80 Benzathene penicillin G-procaine penicillin G-streptomycin G in oil; benzathene penicillin G-procaine penicillin G-dihydrostreptomycin G in oil—(a) Potency—(1) Total penicillin content. Proceed as directed in § 141a.79 (a) (1). The total penicillin content is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(2) Procaine penicillin content. Proceed as directed in § 141a.79 (a) (2). The procaine penicillin content is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(b) Sterility. Proceed as directed in § 141a.47 (b).
(c) Moisture. Proceed as directed in § 141a.17 (c).

§ 141a.81 Penicillin V (phenoxymethyl penicillin)—(a) Potency. Proceed as directed in § 141a.1, except use the penicillin V working standard as the standard of comparison. If the iodometric assay method is used, proceed as directed in § 141a.5 (d) (1) except determine the factor F as the number of milliliters of 0.01 N NaOH absorbed by 1.0 milligram of penicillin V working standard.

### Table: Units of penicillin V per milligram

<table>
<thead>
<tr>
<th>Units of penicillin V per milligram</th>
<th>Milligrams in 2.0 milliliters tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute method. Determine the absorbance of the sample at the absorption peak at 276 nm, using a suitable ultraviolet spectrophotometer and quartz cells. Set the instrument to the 100 percent transmission with absolute methanol. If a recording spectrophotometer is used, determine the absorbance (or a solution containing 20 milligrams per 100 milliliters) at the 276 nm absorption peak, using a slit width of 0.5 millimeters or less. The exact position of the peak should be determined for the particular instrument used. Proceed as directed in § 141a.5 (c).</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Percent penicillin V</th>
<th>Absorbance: 0.0033</th>
</tr>
</thead>
<tbody>
<tr>
<td>1% penicillin V per tablet</td>
<td>100 mg tablets</td>
</tr>
</tbody>
</table>
Penicillin V units per tablet = \(276 \times \text{average weight of each tablet} \times 1,695,000\),
where \(276 \times \text{observed absorbance of chloroform solution}\).

\(E_v = \text{specific absorbance}\ (\text{noted} \times \text{a} = 15\%\) of penicillin V standard in chloroform similarly treated.

The penicillin V content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(3) Penicillin G content. The penicillin G content of the combined extractives with sufficient penicillinase at least three times and any additional times that may be necessary to ensure complete extraction of the antibiotic. Combine the extracts and inactivate the penicillin with sufficient penicillinase at 37°C, for 30 minutes. Make the proper estimated dilutions in 10-percent potassium phosphate buffer, pH 6.0, to give a concentration of 10 units per milliliter (estimated).

(ii) The standard curve is prepared in the following concentrations: 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15 units per milliliter in a 10- to 100-potassium phosphate buffer, pH 6.0. The pH of each milliliter concentration is used as the reference point. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.26 (e)

§141a.85 Capsules penicillin V—(a) Potency. Dissolve the contents of 12 capsules in 1-percent phosphate buffer, pH 6.0, and proceed as directed in §141a.1, except use the penicillin V working standard as the standard of comparison. The average potency of capsules penicillin V is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(b) Moisture. Use the contents of 4 capsules and proceed as directed in §141a.26 (e)

§141a.88 Procaine penicillin-streptomycin-polymyxin in oil procaine penicillin-dihydrostreptomycin-polymyxin in oil—(a) Potency. Proceed as directed in §141a.8 (a) its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(2) Streptomycin content. Proceed as directed in §141b.129 (a) (1) of this chapter, except use the streptomycin in the combined extractives with sufficient penicillinase at 37°C for 30 minutes. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(3) Dihydrostreptomycin content. Proceed as directed in subparagraph (2) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(4) Polymyxin content. Proceed as directed in §141b.112 (b) (1) of this chapter, with the following exceptions:

(i) In lieu of the directions for the preparation of the sample described in §141b.112 (b) (vii) of this chapter, prepare the following: Place a convenient sized representative quantity of the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 25 milliliters of 10-percent potassium phosphate buffer, pH 6.0, containing 2 grams of KH₂PO₄ and 8 grams of KH₂PO₄, in each 100 milliliters, and shake. Remove the buffer layer and repeat the extraction with 25-milliliter portions of buffer at least three times and any additional times that may be necessary to ensure complete extraction of the antibiotic. Combine the extracts and inactivate the penicillin with sufficient penicillinase at 37°C, for 30 minutes. Make the proper estimated dilutions in 10-percent potassium phosphate buffer, pH 6.0, to give a concentration of 10 units per milliliter (estimated)

(ii) The standard curve is prepared in the following concentrations: 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15 units per milliliter in a 10- to 100-potassium phosphate buffer, pH 6.0. The pH of each milliliter concentration is used as the reference point. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.8 (b)

PART 141B—STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) AND STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN-) CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

Sec. 141b.101 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; potency

141b.102 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; potency

141b.103 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; potency

141b.104 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; potency

141b.105 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; hithamine.

141b.106 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride.

141b.107 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride.

141b.108 Dihydrostreptomycin sulfate, crystalline dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride.

141b.109 Streptomycin sulfate tablets, dihydrostreptomycin tablets.

141b.110 Streptomycin for topical use.

141b.111 Streptomycin sulfate solution, dihydrostreptomycin sulfate solution, crystalline dihydrostreptomycin sulfate solution.

Sec. 141b.112 Streptomycin—polymyxin—bactrocin tablets.

141b.113 Streptomycin syrup, streptomycin and kaolin in gel, dihydrostreptomycin syrup, dibydrostreptomycin and kaolin in gel; potency.

141b.114 Streptomycin—bactrocin—polymyxin gauze pads.

141b.115 Streptomycin oto with antifungal agent, dihydrostreptomycin oto with antifungal agent.


141b.117 Streptomycin for inhalation therapy, dihydrostreptomycin for inhalation therapy.

141b.118 Dihydrostreptomycin—streptomycin—polymyxin sulfa.

141b.119 Streptomycin sulfa otio veterinary.

141b.120 Streptomycin sulfa powder oral veterinary; streptomycin sulfate granules oral veterinary.

141b.121 Streptomycin-salicyclic acid—isonicotinyl hydrazine sulfate.

141b.122 Dihydrostreptomycin—streptomycin sulfa solution.

141b.123 Streptomycin-sulfate-vanadium with kaolin and petuin, streptomycin-sulfate-vanadium with penicillin and petuin.

141b.124 Streptomycin hydrochloride solution oral veterinary; streptomycin sulfa solution oral veterinary.

141b.125 Dihydrostreptomycinc—streptomycin sulfa with isonicotinyl acid hydrazone.

141b.126 Streptomycin-erythromycin ointment.

141b.127 Streptomycin—chlorotetracyclinda ments, oral veterinary; streptomycin—chlorotetracyline—chlor- amphenicol—bacitracin dental cement.

141b.128 Streptomycin-sodium sulfathiazole solution veterinary; dihydrostreptomycin-sodium sulfathiazole solution veterinary.

141b.129 Streptomycin-polymyxin-nemycin ointment; dihydrostreptomycin-polymyxin-neomycin ointment.


§141b.101 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; potency—(a) Cylinders (cups) Use cylinders described under §141a.1 (a) of this chapter.

(b) Culture media. Using ingredients that conform to the standards prescribed by the U. S. P. or N. F., make nutrient agar for the seed and base layers:

Bovine extract.----------------- 1.5 gm.

Yeast extract.----------------- 3.0 gm.

Peptone.------------------------ 5.0 gm.

Agar------------------------ 15.0 gm.

Distilled water q. e. 1,000.0 ml.

pH 7.8 to 8.0 after sterilization.

(c) Working standard. Keep the working standard (obtained from the U. S. Food and Drug Administration) at room temperature in tightly stoppered vials, which in turn are kept in larger stoppered vials containing anhydrous magnesium perchlorate. Dry an appropriate
ate amount of the working standard as described in § 141a.5 (a) of this chapter (the most stable standard solution, a potency of 780 micrograms per milligram). Dissolve the weight of dry working standard obtained in 0.05 M potassium phosphate buffer (pH 6.0). Keep this buffer at a temperature of about 15° C., do not use it later than 30 days after it is made.

(d) Standard curve. Prepare daily in 0.10 M phosphate buffer (pH 7.8 to 8.0) from the stock solution described in paragraph (c) of this section, 60 concentrations of 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, and 1.5 micrograms per milliliter solutions. A total of 27 plates is used in the preparation of the standard curve, three plates for each solution except the 1.0 mcg./ml. solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill 3 cylinders with the 1.0 mcg./ml. standard and the other 3 cylinders with the concentration under test. Perform 81 microgram determinations and 9 determinations for each of the other points on the curve. After the plates have incubated read the diameters of the circles of inhibition obtained. Use the diameters of the 1.0 mcg./ml. concentration and the readings of the point tested for each set of 3 plates and average also all 81 readings and the 9 determinations for each point on the curve. Calculate the average value obtained for each point to the nearest 0.1% and compare the mg.

Preparation of standard curve. After the plates have incubated for 24 hours at 37° C., wash the spores in sterile distilled water and heat for 30 minutes at 65° C. Wash the spore suspension three times with sterile distilled water, heat again for 30 minutes at 65° C. and resuspend in sterile distilled water.

(i) Grow the organism for 5 days at 37° C. in a Roux bottle containing 300 milliliters of agar medium described in subparagraph (b) of this section. Incubate overnight at 37° C. Maintain the spore suspension at approximately 15° C. Determine by appropriate tests the quantity of spore suspension to be added to each 100 milliliters of agar for the secondary layer of the plate that will give sharp, clear zones of inhibition.

Preparation of vegetative suspension. If a suspension of the test organism is to be used in lieu of the spore suspension described in subparagraph (d) of this paragraph, prepare such suspension as follows: Using 2.0 milliliters of sterile distilled water, wash the organism from an agar slant (which has been incubated for 24 hours at 37° C.) onto the agar surface of a Roux bottle containing 300 milliliters of nutrient agar prepared as described in § 141a.1 (b) (1) of this chapter. Incubate for 24 hours at a temperature of approximately 15° C. Suspend the resultant growth in 50 milliliters of sterile distilled water and homogenize the suspension. Determine by appropriate tests the quantity of suspension to be added to each 100 milliliters of agar for the secondary layer that will give sharp, clear zones of inhibition.

Preparation of plates. Add 21 milliliters of agar described in paragraph (b) of this section to each Petri dish (20 x 100 millimeters). Melt the agar to be used for the secondary layer, cool to 50° C., and add the spore suspension prepared in paragraph (d) of this section. Mix thoroughly and add 4 milliliters to each of the plates containing the 21 milliliters of the uninoculated agar. Tilt the plates back and forth to assure that the inoculated agar evenly covers the surface.

Plate assay. Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius. Use three plates for each sample. Fill three cylinders on each plate with the 1.0 mcg./ml. standard and three cylinders with the 1.0 mcg./ml. estimated sample. Incubate the plates for 16 to 18 hours at 37° C. and measure the diameter of each circle of inhibition.

Estimation of potency. Average the zone readings of the standard and average the zone readings of the sample on the three plates used. If the sample gives a larger average zone size than the average of the standard, subtract the difference between them from the 1.0 mcg./ml. zone size of the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 mcg./ml. value on the curve. From the curve read the potency corresponding to these corrected values of zone sizes.

Turbidimetric assay. In lieu of the plate assay method described in paragraph (i) of this section the sample may be assayed for potency by the following turbidimetric procedure.

(1) Test culture and media. Employ the agar described in paragraph (b) of this section (adjusted to a final pH 7.0) for maintaining the test organism, which is Bacillus subtilis (American Type Culture Collection (ATCC) No. 141a.1 (b) (1) of this chapter. Prepare a daily inoculum (estimated) per milliliter solution to a potency of 1,000 micrograms per milliliter, but modified by the addition of 300 milligrams of MnSO₄·H₂O per liter. Suspend the growth in 50 milliliters of sterile isotonic saline solution, centrifuge, and wash the resultant suspension three times with sterile distilled water. Decant the supernatant liquid. Reconstitute the sediment and heat-shock the suspension to be added to each 100 milliliters of agar for the secondary layer that will give sharp, clear zones of inhibition.

(2) Preparations of working stock solutions. Add 0.10 M phosphate buffer (pH 7.8) to 1,000 micrograms per milliliter solution prepared from the stock solution described in paragraph (c) of this section to 100-milliliter volumetric flasks containing sterile distilled water and bring to volume with the working stock solutions tabulated below. These 9 flasks are well stoppered and maintained at approximately 15° C. for 1 month. Prepare the final dilutions daily by adding 4.2 milliliters of each of these 9 working stock solutions to 9.5 milliliters of sterile distilled water. Add 1.0 milliliter of each final dilution to each of six tubes having an average diameter of approximately 125 millimeters (total 54 tubes). Add 0.0 milliliters of inoculated broth described in subparagraph (i) of this paragraph to each tube and place immediately in a 37° C. water bath for 3 to 4 hours. The final concentration of strep-
tomycin per milliliter of broth is also included in the table below.

<table>
<thead>
<tr>
<th>Amount of standard solution (1.090 mg streptomycin or equivalent)/mL</th>
<th>Working concentration (micrograms/ml)</th>
<th>Final concentration (micrograms/ml) after addition of distilled water to broth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ml.</td>
<td>Micrograms</td>
<td>Micrograms</td>
</tr>
<tr>
<td>6.0</td>
<td>70</td>
<td>1.8</td>
</tr>
<tr>
<td>7.0</td>
<td>80</td>
<td>2.4</td>
</tr>
<tr>
<td>8.0</td>
<td>90</td>
<td>3.0</td>
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<tr>
<td>9.0</td>
<td>100</td>
<td>3.6</td>
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<td>110</td>
<td>3.9</td>
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<tr>
<td>11.0</td>
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<td>130</td>
<td>3.9</td>
</tr>
<tr>
<td>13.0</td>
<td>140</td>
<td>3.6</td>
</tr>
<tr>
<td>14.0</td>
<td>150</td>
<td>3.0</td>
</tr>
</tbody>
</table>

(3) Preparation of sample. Dilute the sample under test with sterile distilled water to contain 100 micrograms per milliliter (estimated). To 4.2 milliliters of the sample add 9.6 milliliters sterile distilled water. Add 1.0 milliliter of this dilution to each of six 16 milliliters by 125 millimeter tubes (outside dimensions). Add 9.0 milliliters of the inoculated broth described in subparagraph (1) of this paragraph to each tube and place immediately in a 37° C. water bath for 3 to 4 hours. A control tube containing 1.0 milliliter of distilled water and 9.0 milliliters of the inoculated broth is similarly incubated. After incubation, add 0.5 milliliter of formalin diluted 1:3 to each tube and read the light transmission in a photo-electric colorimeter, using a broad band filter having a wave length of 5,300 angstrom units.

(4) Determination of potency. Average the light transmission readings for each concentration of the standard. Plot these values on cross section paper, employing average light transmission readings as the ordinate, and streptomycin concentration per milliliter of broth as the abscissa. Prepare the standard curve by connecting successive points with a straightedge. Since the final concentration of streptomycin per milliliter of broth is equivalent to the concentration per milliliter of the working stock solution (see table in subparagraph (2) of this paragraph) the latter concentrations for each concentration level of the standard may be expressed as percent and substituted on the abscissa of the standard curve. If this is done the percent potency of the sample under test may be read directly from the standard curve.

(a) Potency. The potency of streptomycin is satisfactory, when assayed by the methods described in this section, if the immediate controls contain 99 percent of the number of grams they are represented to contain.

(4) Rules and Regulations

§ 141b.103 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; toxicity. Proceed as directed in § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 2 mg/ml.

§ 141b.104 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; pyrogens. Proceed as directed in § 141a.6 of this chapter, using as a test dose 1.0 milliliter per kilogram of a solution containing 10 mg/ml.

§ 141b.105 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; histamine. Use a healthy adult cat as the test animal. Determine weight and place under general anesthesia by employing sufficient (150 mg./kg.) sodium phenobarbital administered intraperitoneally. Surgically expose the femoral vein and separate it completely from all surrounding structures, including the vagus nerve, by blunt dissection and cannulate. Introduce 0.2 percent epinephrine into the femoral vein. Start the recording kymograph and inspect the tracings for amplitude of excursion and relative stability of pressure. Determine the sensitivity of the animal by injecting into the femoral vein standard solutions of histamine made to contain the equivalent of 1.0 microgram of histamine base per milliliter. Make injections at not less than 5-minute intervals using doses of 0.15 microgram of histamine base per kilogram. Repeat these injections, disregarding the first series of readings, until the drop given by equivalent doses of histamine is relatively uniform. The fall in blood pressure given by 0.1 mg./kg. of histamine base (not less than 20 millimeters of mercury) is subsequently employed as the standard in testing samples. The histamine standard is supplied on request. Inject 3 mg./kg. of the sample of streptomycin per milliliter maintaining the five minute injection schedule. If a significant drop is encountered the dose is repeated after the animal has been re-tested with the standard histamine. The animal may be used as long as it remains reasonably stable and responsive to histamine. The product is satisfactory if the fall in blood pressure obtained with 3 milligrams of streptomycin per kilogram of body weight is no greater than the fall obtained with 0.1 microgram of histamine base per kilogram of body weight. (Dogs may be substituted for cats in this test provided the ratio of the doses of streptomycin and histamine employed is the same.)

§ 141b.106 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride—(a) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

(1) pH. Proceed as directed in § 141a.5 (b) of this chapter, using a solution with a concentration of 0.2 gm./ml.

§ 141b.107 Streptomycin ointment, dihydrostreptomycin ointment; potency—

(a) Streptomycin content. Proceed as directed in § 141b.103 except paragraphs (f) and (g) thereof, and in lieu of the directions in § 141b.103 (a), prepare the sample as follows:

Accurately weigh the tube and contents and squeeze approximately 1.0 gram into a blending jar containing 1.0 milliliter of 0.10 M potassium phosphate buffer (pH 7.8 to 8.0). Re-wet the tube to obtain weight of ointment used in the test. Using a high-speed blender, blend the mixture 3 minutes. Set aside a portion of the mixture to contain 100 micrograms of streptomycin base (estimated) per milliliter. Transfer 10 milliliters of this solution to a 100-milliliter flask and make up to volume with 0.10 M potassium phosphate buffer (pH 7.8 to 8.0) Use this last dilution in the assay for potency. The potency of streptomycin ointment is satisfactory if it contains not less than 85 percent of the number of micrograms of streptomycin base per gram it is represented to contain.

(b) Dihydrostreptomycin content. Prepare as directed in paragraph (a) of this section, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of micrograms of dihydrostreptomycin base per gram it is represented to contain.

§ 141b.108 Dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride—(a) Potency. Using the dihydrostreptomycin working standard as a standard of comparison, proceed as directed in § 141b.103 (b). The content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of micrograms of dihydrostreptomycin base per gram it is represented to contain.

(b) Content of streptomycin sulfate or streptomycin hydrochloride—(1) Reagents. (i) 10 percent ferric chloride stock solution. Dissolve 2 grams of FeCl₃·6H₂O in 50 milliliters 0.1 N HCl.

(ii) 0.25 percent ferric chloride solution—Dilute 2.5 milliliters of 10 percent ferric chloride in 0.1 N HCl to 100 milliliters with 0.01 N HCl. Prepare the solution fresh daily.

(2) Standard curve. Prepare a stock aqueous solution of the Food and Drug Administration working standard containing 1.0 milligrams streptomycin base per milliliter. Store this standard solution in the refrigerator and use for no longer than 3 weeks. Transfer 1.0, 2.0, 3.0, 4.0, and 5.0 milliliters of this standard solution and 10 milliliters of distilled water to each of six 25-milliliter volumetric flasks. Add 0.0, 0.5, 1.0, and 2.0 milliliters of distilled water to the first three flasks, respectively, to give each a total volume of 10 milliliters. To each add 2.0 milliliters of 1 N NaOH and then heat the flasks in a boiling water bath for 10 minutes. Cool the flasks in ice water for 3 minutes and add the contents with 2.0 milliliters of 1.2 N HCl. To each flask add 5.0 milliliters of 0.35 percent ferric chloride reagent, make to volume with distilled water, and mix thoroughly.

Transfer the colored solutions to 2.0-centimeter absorption cells and measure the percent light transmission at 560 mp in a suitable photoelectric colorimeter. Set the colorimeter at 100 percent light transmission for the zero concentration.
and then obtain the percent light transmission of the sample. Prepare a standard curve on semilog paper, plotting the percent light transmission on the logarithmic ordinate scale and the concentration of streptomycin base on the abscissa.

(3) Procedure. Dilute the contents of a 1-gm vial to 50 milliliters with distilled water (dilute vials containing larger quantities to make solutions having the same concentration) and transfer a 10-milliliter aliquot of this solution to a 25-milliliter volumetric flask, add 2.0 milliliters of 1 N NaOH and heat in a boiling water bath for 10 minutes. Cool in ice water for 5 minutes and acidify the solution with 2.0 milliliters of 1.2 N HCl. Add 5.0 milliliters of 0.25 percent ferric chloride reagent. Make to volume with distilled water. Transfer 2.0 milliliters of this solution to a 25-milliliter volumetric flask, add 2.0 milliliters of 0.1 N NaOH, and heat in a boiling water bath for 10 minutes. Cool in a boiling water bath for 10 minutes, and acidify the solution with 2.0 milliliters of 1.2 N HCl. Add 5.0 milliliters of 0.25 percent ferric chloride reagent. Make to volume with distilled water. Transfer the colored solution to a 2.0-centimeter absorption cell and measure the percent light transmission at 500 μm in a suitable photoelectric colorimeter. Set the colorimeter at 0.1 percent light transmission for the zero concentration and then obtain the percent light transmission of the sample. The concentration of streptomycin obtained directly from the standard curve at the percent light transmission of the sample is the concentration of streptomycin present in the sample.

(e) Sterility. Proceed as directed in § 141b.102.

(2) Toxicity, pyrogens, humidity, moisture, pH, crystallinity. Proceed as directed in §§ 141b.103, 141b.104, 141b.105, 141b.106, and 141a.5 (a) of this chapter.

§ 141b.109 Streptomycin tablets, dihydrostreptomycin tablets—(a) Potency—(1) Streptomycin content. Using 12 tablets, proceed as directed in § 141b.101, except paragraphs (j) and (k) of that section, and use 0.10 M potassium phosphate buffer (pH 7.8-8.0) for dissolving the sample in lieu of sterile distilled water as directed. (e) The average potency of streptomycin tablets is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(2) Dihydrostreptomycin content. Proceed as directed in subparagraph (1) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. The average potency of dihydrostreptomycin tablets is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

§ 141b.110 Streptomycin for topical use—(a) Potency. Proceed as directed in § 141b.101, except paragraph (k) thereof. The potency of streptomycin for topical use is satisfactory if the immediate containers are represented to contain:

1. Less than 500 milligrams and contain 85% or more of the number of milligrams it is represented to contain;
2. More than 500 milligrams and contain 90% or more of the number of milligrams so represented.

(b) Sterility, toxicity, pyrogens, histamine, moisture, pH. Proceed as directed in §§ 141b.102 to 141b.108.

§ 141b.111 Streptomycin sulfate solution, dihydrostreptomycin sulfate solution, crystalline dihydrostreptomycin sulfate solution. (a) If it is streptomycin sulfate solution, proceed as directed in §§ 141b.101, 141b.104, 141b.105, and 141b.106 (b), and for the toxicity test proceed as directed in § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 1.5 milligrams per milliliter.

(b) If it is dihydrostreptomycin sulfate solution or crystalline dihydrostreptomycin sulfate solution, proceed as directed in § 141b.106, except in lieu of the directions in § 141b.106 (a) to determine the streptomycin content as follows:

(1) Preparation of standard. Prepare a standard aequous solution of the Food and Drug Administration working standard containing 0.25 milligram of streptomycin base per milliliter. Transfer 1.0, 1.5, and 2.0 milliliter aliquots of this solution to test tubes. Add 0.5, 1.0, and 0.5 milliliter of 0.1 N NaOH, and heat in a boiling water bath for 10 minutes. Cool in ice water for 5 minutes and acidify the solution with 2.0 milliliters of 1.2 N HCl. Add 5.0 milliliters of 0.25 percent ferric chloride reagent. Make to volume with distilled water.

(2) Preparation of sample. Dilute 1.0 milliliter of streptomycin solution to the test tube, heat in a boiling water bath for 10 minutes, cool in ice water for 5 minutes, and acidify the solution with 2.0 milliliters of 1.2 N HCl. Add 5.0 milliliters of 0.25 percent ferric chloride reagent. Make to volume with distilled water.

(3) Blank. Use 2.0 milliliters of distilled water.

(4) Procedure. To each tube containing 2.0 milliliters, add, in turn, 5.0 milliliters of 0.1 N NaOH, mix thoroughly, and immediately determine the optical density at 532 μm in a suitable spectrophotometer. Set the spectrophotometer at 532 μm and measure the percent light transmission of the blank similarly treated. Return the solution to the test tube, heat in a boiling water bath for 10 minutes, cool in ice water for 5 minutes, and acidify the solution to come to room temperature. Determine the optical density at 532 μm. The difference in reading before and after heating is the optical density of the aliquot.

(c) Preparations of working standards. Prepare a standard curve. The concentration of streptomycin in the sample solution obtained directly from the standard curve times 1,250, divided by the number of milligrams of dihydrostreptomycin in the original dihydrostreptomycin solution, equals the percent of streptomycin.

§ 141b.112 Streptomycin-polymyxin-bacitracin tablets—(a) Tablets—(1) Potency—(i) Streptomycin content. Proceed as directed in § 141b.109 (a) (1) of this paragraph, except that sufficient semi-carbazide 0.5 percent solution (pH 8.0) is added to inactivate (1 hour at room temperature) the streptomycin contained in the solution. Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

(b) Polymyxin used in making the tablets—(1) Potency—(a) Cylinders (cmps). Use cylinders described under § 141a.1 (a) of this chapter.

(c) Culture medium. Using ingredients that conform to the standards prescribed, if any, by the U. S. P. or N. F., make nutrient agar for the seed and base layers.

(1) Seed layer. For seed layer make the following changes in the medium described in (a) of this subdivision.

(2) Base layer.

Acid ______________ 12.0 gm.

Oxidized agar (add 100 gm. after boiling) ______________ 10.0 gm.

Final pH ______________ 7.3.

In lieu of preparing the medium from the individual ingredients as specified, it may be prepared from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such medium. Minor modifications of the specified individual ingredients are permissible if the resulting medium possesses growth-promoting properties at least equal to the described.

(iii) Working standard. Weigh out a sufficient quantity of the working standard (obtained from the Food and Drug Administration) to contain 1,300 units per milliliter stock solution by diluting with 1-percent phosphate buffer, pH 6.0. This solution may be used for 2 weeks if kept in the refrigerator.

(b) Standard curve. Prepare daily a standard curve as directed in § 141b.101 (d) with the following exceptions: Using a solution of the polymyxin working standard in 1-percent phosphate buffer, pH 6.0, prepare volumetrically the following concentrations: 60, 70, 80, 90, 100, 110, 120, 130, 140, and 150 units per milliliter stock solution by diluting with 1-percent phosphate buffer, pH 6.0. The 160 units per milliliter is used as the reference point.

(v) Preparation of test organism. The test organism is Bacillus subtilis (American Type Culture Collection 13780) which is maintained on seed described under subdivision (ii) (a) of this subparagraph. Incubate a Roux bottle containing this agar, subdivide it, and add it to a suitable medium. Minor modifications of the seed agar are permissible if the resulting medium possesses growth-promoting properties at least equal to the described.

(1) Standard curve. Proceed daily a standard curve as directed in § 141b.101 (d) with the following exceptions: Using a solution of the polymyxin working standard in 1-percent phosphate buffer, pH 6.0, prepare volumetrically the following concentrations: 60, 70, 80, 90, 100, 110, 120, 130, 140, and 150 units per milliliter stock solution by diluting with 1-percent phosphate buffer, pH 6.0. The 160 units per milliliter is used as the reference point.

(v) Preparation of test organism. The test organism is Bacillus subtilis (American Type Culture Collection 4407) which is maintained on seed described under subdivision (ii) (a) of this subparagraph. Incubate a Roux bottle containing this agar, subdivide it, and add it to a suitable medium. Minor modifications of the seed agar are permissible if the resulting medium possesses growth-promoting properties at least equal to the described.
pension to 50-percent light transmission using a filter having a wave length of 589 nanometers. Proceed as directed in §141a.7 of this chapter. For the sample and calculate as follows: Freeze the container as described in paragraph (a) of this section. After freezing, open the container and remove a 20-gram sample in an atmosphere of 0.1 percent CO₂ and 0.1 percent O₂. Place this sample in a dry titrating vessel, immediately add an excess of Karl Fischer reagent, and back-titrator with water-methanol solution until the endpoint is reached.

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For the sample to be tested to a final concentration of 100 units per milliliter and proceed as directed in §141b.101 (ch) and (d).

Toxicity. Proceed as directed in §141a.4 of this chapter, using 0.5 milliliter of a solution prepared by diluting the sample to approximately 1,500 units per milliliter with physiological salt solution.

**§ 141b.113 Streptomycin syrup, streptomycin and kaolin in gel, dihydrostreptomycin and kaolin in gel; potency.** Proceed as directed in §141b.101, except paragraph (k) thereof, and except if it is dihydrostreptomycin use the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 95 percent of the number of milligrams of streptomycin or dihydrostreptomycin per milliliter that it is represented to contain.

**§ 141b.114 Streptomycin-bacitracin-polyoxymycin gauze pads—(a) Potency.** Proceed as directed in §141b.112 (a) (1), except soak the sample for not less than 1 hour with frequent agitation.

**§ 141b.115 Streptomycin otic with antifungal agent, dihydrostreptomycin otic with antifungal agent—(a) Potency.** Proceed as directed in §141b.101, except paragraph (k) thereof, and if it is dihydrostreptomycin otic with antifungal agent use the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 95 percent of the number of milligrams of streptomycin or dihydrostreptomycin per milliliter that it is represented to contain.

**§ 141b.116 Streptomycin-kaolin-pecein-aluminium hydroxide gel powder veterinary—(a) Potency—(1) Streptomycin content.** Proceed as directed in §141b.101, except paragraph (k) of that section. Its potency is satisfactory if it contains not less than 95 percent of the number of milligrams of streptomycin it is represented to contain.

**Dihydrostreptomycin content.** Proceed as directed in subparagraph (1) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of dihydrostreptomycin it is represented to contain.

**§ 141b.117 Streptomycin for inhalation therapy, dihydrostreptomycin for inhalation therapy—(a) Potency—(1) Streptomycin content.** Proceed as directed in §141b.101, except if it is packaged with inert gases proceed as follows: Use not less than 5 immediate containers. Place one-half the number of such containers in a suitable sharp freezing unit having a temperature not higher than —30° C. After freezing, cut open the containers and transfer the contents of each to a suitably sized and allowed gas to evaporate. After gas has evaporated, wash and dry the residue remaining in the container into the beaker with not less than 10 milliliters of sterile distilled water. Let stand for not less than 15 minutes, with frequent agitation. Repeat the procedure for each of these solutions and proceed as directed in §141b.101 to determine the average total quantity of streptomycin in each container. Expel the drug from each of the remaining containers as directed in its labeling. After all gas (with drug) has been expelled, cut, open the containers and place each in a large beaker containing 500 milliliters of sterile distilled water. Let stand for not less than 15 minutes, with frequent agitation. Remove an aliquot and proceed as directed in §141b.101 to determine the average total quantity of streptomycins in each container. The quantity of streptomycin expelled is determined by subtracting the average amount of the residue found from the average total quantity contained in the remaining containers. Its potency is satisfactory if it contains not less than 90 percent, or 85 percent if it is packaged with inert gases, of the number of milligrams of streptomycin that it is represented to contain.

**§ 141b.118 Dihydrostreptomycin sulfate—(a) Potency.** Proceed as directed in §141b.101 (a) of this chapter. Its total potency is satisfactory if it contains not less than 90 percent of the combined number of milligrams of dihydrostreptomycin and streptomycin that it is represented to contain.

**Content of streptomycin sulfate.** Proceed as directed in §141b.108 (b), making appropriate dilutions so that the aliquot used for each determination contains 5.0 milligrams of streptomycin (estimated) and modify the calculations in accordance with the dilutions made. Its content of streptomycin is satisfactory if it contains not less than 95 percent and not more than 55 percent of the total potency as determined under paragraph (a) of this section.

**Sterility, toxicity, pyrogens, histamine, moisture, pH.** Using the total potency of the sample for preparing dilutions and weighings, proceed as directed in §§141b.103, 141b.104, 141b.105, 141b.106, and 141b.108.

**§ 141b.119 Streptomycin sulfate oral veterinary—(a) Potency.** Proceed as directed in §141b.101.

**Toxicity.** Proceed as directed in §141b.107.

**Moisture.** Using a 1-gram sample, proceed as directed in §141a.5 (a) of this chapter.

**pH.** Proceed as directed in §141b.106 (b).

**§ 141b.120 Streptomycin sulfate powder oral veterinary; streptomycin sulfate granules oral veterinary—(a) Potency.** Proceed as directed in §141b.101. Its content of streptomycin is satisfactory if it contains not less than 90 percent of the number of milligrams of streptomycin per gram it is represented to contain.

**Moisture.** Using a 1-gram sample, proceed as directed in §141a.5 (a) of this chapter.

**§ 141b.121 Streptomycyspolidene isonicotinyl hydrazide sulfate—(a) Potency—(1) Streptomycin content.** Dilute the sample with hydrochloric acid solution pH 1.5 to 1.600 micrograms per milliliter (estimated streptomycin activity). Heat at 50° C. for 30 minutes, cool rapidly and proceed as directed in §141b.101. The streptomycin potency of streptomycyspolidene isonicotinyl hydrazide sulfate is satisfactory if the immediate contents contain 90 percent of the streptomycin activity they are represented to contain.

**Isonicotinyl acid hydrazide content—(1) Reagents.** (a) FP. Proceed as directed in §141b.103, 141b.105, 141b.106, 141b.108 (b), and 141a.5 (c) of this chapter.

**End of this chapter:** Proceed as directed in §141a.7 (o) of this chapter, but in lieu of the directions for preparing the sample in paragraphs (2) and (3) of this section prepare the sample and calculate as follows: Freeze the container as described in paragraph (a) of this section. After freezing, open the container and remove a 10-gram sample in an atmosphere of 0.1 percent CO₂ and 0.1 percent O₂. Place this sample in a dry titrating vessel, immediately add an excess of Karl Fischer reagent, and back-titrator with water-methanol solution until the endpoint is reached.

Percent moisture: 
\[ \frac{(Q_t - Q_f) \times 100}{Q_t} \]

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The text appears to be extracted from a section discussing the potency and preparation of pharmaceuticals, specifically streptomycin and related compounds. It includes methods for assaying potency, preparing solutions, and determining various properties such as moisture, pH, and toxicity. The section also covers the preparation of plates for testing and the calculation of potency. The text is technical and detailed, typical of regulatory or pharmaceutical literature.
and 15 grams of KBr in sufficient water to make 1,000 milliliters.
(b) Concentrated hydrochloric acid.
(c) 20-percent potassium iodide solution.
(d) 0.05 N Na₂SO₃ (accurately standardized against KIO₃).

(ii) Preparation of sample. Place an accurately weighed sample of approximately 250 milligrams or an aliquot of a solution containing 250 milligrams of streptomycylidine isonicotinyl hydrazine sulfate into a 250-milliliter iodine flask. Add sufficient water to give a volume of 25 milliliters.

(iii) Blank. Add 25 milliliters of distilled water to a 250-milliliter iodine flask.
(iv) Procedure. To each iodine flask containing the sample and blank, add 25 milliliters of 0.1 N KBrO₃-KBr solution and 5 milliliters of concentrated HCl. Stopper the flasks, and place distilled water in the wells around the stopper. Allow the flasks to stand for 15 minutes at room temperature, and then add 5 milliliters of 20-percent potassium iodide solution to each flask. Titrate the liberated iodine with 0.05 N Na₂SO₃, using starch as an indicator.

(v) Calculations.

Percent isonicotinic acid hydrazide = \( \frac{(B-S) \times 100}{W} \)

Where:
- B = milliliters of Na₂SO₃ required for the blank
- S = milliliters of Na₂SO₃ required for the sample
- N = normality of the Na₂SO₃
- W = milligrams of sample.

(b) Extinction coefficient. Accurately weigh approximately 100 milligrams of the sample, dissolve in distilled water, and make to 100 milliliters. Dilute a 5-milliliter aliquot of this solution to 100 milliliters, allow to stand at room temperature for 15 minutes, and, using a suitable spectrophotometer, determine the optical density of the solution in a 1-centimeter cell at 250 millimicrons compared with distilled water as a blank.

(c) Toxicity. Proceed as directed under § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 1,000 micrograms of streptomycin active per milliliter.

(d) Sterility. Proceed as directed under § 141a.5 of this chapter, using the equivalent of approximately 0.5 gram streptomycin activity, except that neither penicillinase nor the control tube is used in the test for bacteria.

(e) Pyrogen, histamine, moisture, pH, and crystallinity. Proceed as directed under §§ 141b.104, 141b.105, 141b.106, and 141a.5 (c) of this chapter.

§ 141b.122 Streptomycin-sulfate solution—(a) Combined potency of dihydrostreptomycin and streptomycin; content of streptomycin. Proceed as directed in § 141b.118 (a) and (b).

(b) Sterility, toxicity, pyrogen, histamine, moisture, pH. Proceed as directed in the labeling of the drug and as directed under §§ 141b.102, 141b.103, 141b.104, and 141b.105.

(c) pH. Using the undiluted solution, proceed as directed in § 141a.5 (b) of this chapter.

§ 141b.123 Streptomycin—pencilin-sulfonamide with kaolin and pectin, dihydrostreptomycin—pencilin-sulfonamide with kaolin and pectin—(a) Potency—(1) Streptomycin content. Proceed as directed in § 141b.101. Its potency is satisfactory if it contains not less than 90 percent of the number of milligrams of streptomycin per milliliter that it is represented to contain.

(b) Toxicity. Proceed as directed in § 141b.103.

(c) ph. Proceed as directed in § 141b.106 (b).

§ 141b.125 Streptomycin-erythromycin ointment—(a) Ointment—(1) Potency—(1) Streptomycin content. Proceed as directed in § 141b.101 (a) through (d) except prepare the sample as follows: Place a representative quantity of the ointment (usually an entire container) in a blending jar containing approximately 225 milliliters of chloroform. Using a high-speed blender, blend the mixture for 3 minutes. Transfer the blended material to a large Buchner funnel (at least 10 centimeters in diameter) fitted with a highly retentive filter paper and attached to a vacuum line. Apply vacuum long enough to insure removal of chloroform from the filter cake. Place the filter cake and the paper in a blending jar containing 250 milliliters of 0.1 M phosphate buffer, pH 6.0, and blend for 10 minutes. Filter the blended material through a fast, porous, filter paper. Dilute the filtrate to obtain a solution for assay containing 1.0 microgram per milliliter. Its potency is satisfactory if it contains not less than 85 percent of the number of micrograms per gram that it is represented to contain.

(b) Toxicity. Proceed as directed in § 141b.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 1,000 micrograms of total potency per milliliter.

§ 141b.126 Streptomycin-erythromycin ointment—(a) Ointment—(1) Potency—(1) Streptomycin content. Proceed as directed in § 141b.101 (a) through (d) except prepare the sample as follows: Place a representative quantity of the ointment (usually an entire container) in a blending jar containing approximately 225 milliliters of chloroform. Using a high-speed blender, blend the mixture for 3 minutes. Transfer the blended material to a large Buchner funnel (at least 10 centimeters in diameter) fitted with a highly retentive filter paper and attached to a vacuum line. Apply vacuum long enough to insure removal of chloroform from the filter cake. Place the filter cake and the paper in a blending jar containing 250 milliliters of 0.1 M phosphate buffer, pH 6.0, and blend for 10 minutes. Filter the blended material through a fast, porous, filter paper. Dilute the filtrate to obtain a solution for assay containing 1.0 microgram per milliliter. Its potency is satisfactory if it contains not less than 85 percent of the number of micrograms per gram that it is represented to contain.
(ii) Erythromycin content—(a) cylinders (cups) Use cylinders described under § 141a.1 (a) of this chapter.

(b) Culture media. Prepare the culture media for the base and seed layers and for carrying the test organisms as directed in § 141a.1 (b) (1) of this chapter, except for the base and seed layers adjust the media to pH 8.0 after sterilization. Make up approximately 425 milliliters of polyethylene glycol. Using a high-speed blender, blend the mixture for 10 minutes and filter through a Buchner filter. Dilute the filtrate to 1.0 microgram per milliliter (estimated) in 0.1 N potassium phosphate buffer, pH 8.0, and proceed as directed in § 141a.101 (h) and (i) except that the incubation temperature is 30° C.

Its content of erythromycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(iii) Moisture. Proceed as directed in § 141a.7 (c) of this chapter.

(b) Erythromycin used in making the ointment—(1) Moisture. Proceed as directed in § 141a.36 (e) of this chapter. Use the value obtained to calculate the weight of the samples used for the determination.

(2) Potency. Proceed as directed in paragraph (a) (1) (ii) of this section, except in the preparation of the solution of the sample dissolve 25 milligrams (the anhydrous compound) in a small amount of methyl alcohol and then further dilute in 10.0 M potassium phosphate buffer, pH 8.0, to make a solution containing 1.0 microgram per milliliter (estimated).

(3) Toxicity. Proceed as directed in § 141d.305 (b) of this chapter, except administer orally to several animals of 1.0 milliliter of a suspension of the drug containing 30 milligrams per milliliter.

(e) pH. Using a saturated aqueous solution (100 milligrams per milliliter) proceed as directed in § 141a.5 (b) of this chapter.

(5) Color-identity test. Dissolve about 3 milligrams of the sample in 2 milliliters of acetone and add an equal volume of concentrated hydrochloric acid. A rapid color development takes place beginning with orange, changing to red, and finally resulting in a deep purple. Shake with 5 milliliters of chloroform. A portion of the purple color extracts into the chloroform layer.

§ 141b.127 Streptomycin-chlorotetracycline-chloramphenicol-bacitracin dental cement; dihydrostreptomycin-chlorotetracycline-chloramphenicol-bacitracin dental cement—(a) Potency—(1) Streptomycin or dihydrostreptomycin content—(i) Reagents. (a) Sodium nitroprusside solution, 10 percent (w/v)
(b) Potassium ferricyanide solution, 10 percent (w/v)
(c) Sodium hydroxide solution, 10 percent (w/v)
(d) Oxidized nitroprusside solution, 10 percent (w/v)

Mix equal volumes of the 10-percent sodium nitroprusside, 10-percent potassium ferricyanide, and 10-percent sodium hydroxide solutions in the order named. A deep-red color is formed which changes to a yellow green after standing at room temperature for approximately 15 minutes. Dilute 1.0 milliliter of this yellow-green solution with water to 10 millimeters and shake. This is the oxidized nitroprusside solution to be used in the test. It should be prepared fresh daily. Each of the 10-percent solutions described is stable for at least 2 months when stored in amber bottles.

(e) 0.3 percent piperedine in acetone. (f) Acetone.

(II) Preparation of standard. Prepare aqueous solutions of the working standard of streptomycin or dihydrostreptomycin containing 0.2 milligram per milliliter. Transfer 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, and 7.0 milliliter portions to small flasks. Add sufficient water to give each a 10-milliliter volume.

(iii) Preparation of sample. Place an accurately weighed portion of approximately 100 milligrams of the dental cement in a sintered-glass filter funnel and wash with three successive 5-milliliter portions of 0.3-percent piperedine in acetone. Remove any residual piperedine with two 5-milliliter portions of acetone and suck dry with vacuum. To the residue add the filter 10 milliliters of distilled water and 10 milliliters of the oxidized nitroprusside solution. Shake, allow the color to develop at room temperature for 5 minutes. Wash the growth off in about 1 liter of this yellow-green solution with water to 100 milliliters and shake. This is the oxidized nitroprusside solution to be used in the test. It should be prepared fresh daily. Each of the 10-percent solutions described is stable for at least 2 months when stored in amber bottles.

(IV) Blank. Use 10 milliliters of distilled water.

(v) Procedure. To each flask containing 10 milliliters of the standard solution add 10 milliliters of the oxidized nitroprusside solution and allow the color to develop at room temperature for 6 minutes. Determine the optical density of each of the standard solutions and the sample at 490 millimicrons, using a suitable spectrophotometer. The blank is used to set the instrument to zero optical density. The orange-red color produced is stable for 30 minutes. Prepare a standard curve on coordinate graph paper, plotting the optical density on the ordinate scale and the concentration of streptomycin or dihydrostreptomycin base on the abscissa. For the sample, the optical density found is used to obtain the concentration of streptomycin or dihydrostreptomycin directly from the standard curve. The potency of the sample, multiplied by the concentration found by the appropriate factors in accordance with the dilutions used, is the potency of dihydrostreptomycin. If it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(2) Chlorotetracycline content—(i) Reagents. Mix 8 volumes of 20-percent (w/v) KHPO₄ with 1 volume of 20-percent (w/v) KH₂PO₄.

(a) Coleman electronic photofluorometer (Model 12) or a similar instrument, equipped with filter b-1 for incident light and filter b-3 for emitted fluorescence.

(b) Matched 18 x 150-millimeter Pyrex test tubes.

(iii) Preparation of standards. Prepare the fluorometric standard by dissolving 30 milligrams of U. S. P. quinoline sulfate in 1 liter of 0.1 N H₂SO₄. Dilute 5 milliliters of this standard solution to 200 milliliters with 0.1 N H₂SO₄. Store these standards in the dark.

(b) Prepare solutions of the chlortetracline hydrochloride working stand-
ard to contain 5, 10, and 20 micrograms per 10 milliliters.

iv) Procedure. Using the diluted guinea pig standard, set the fluorometric reading at 35.0. Place a 50-milliliter portion of the clear solution in one of the matched test tubes and add 2.0 milliliters of water. Place a 10-milliliter portion of the clear solution in one of the matched test tubes and add 20.0 milliliters of water. Add 2 milliliters of 0.5 percent piperidine in acetone solution, using an Erlenmeyer suction flask and vacuum. Wash the residue with four 10-milliliter portions of distilled water. Withdraw undiluted vacuum, pool wash, and add 20.0 milliliters of water to give a bacitracin concentration of 2 units per milliliter. To a 10-milliliter portion of this solution add 2.0 milliliters of mixing of 8 parts of a 20-percent dibasic potassium phosphate solution and 1 part of a 20-percent monobasic potassium phosphate solution. Heat this solution with steam for 5 minutes and cool immediately. Adjust to pH 6.0 with approximately 1.5 milliliters of 1 N HCl and add enough sterile distilled water to give a final bacitracin concentration of 1 unit per milliliter. Assay by the method prescribed in § 141a.49 of this chapter, using the dihydrostreptomycin-resistant strain of M. flavus (P. C. I. 16 R. D.) for the calculation of streptomycin content.

v) Procedure. Take the residue in a 3-milliliter portion of ethyl acetate. Heat to boiling on a steam bath for 15 minutes and cool immediately. Wash the residue with one of the following ways: (i) Add 15 drops of concentrated HC1. Proceed as directed in § 141b.101 (j), inclusive, except prepare the sample as directed in subparagraph (1) of this paragraph, using the dihydrostreptomycin working standard as a principal of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

b) Proceed as directed in § 141b.112 (b) (1) with the following exceptions:

(i) In lieu of the directions for the preparation of the sample described in subdivision (vii) of § 141b.111 (d), prepare the sample as follows: Place a convenient sized representative quantity of the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 23 milliliters of 10-percent potassium phosphate buffer, pH 6.0, containing 2 grams of KH2PO4 and 8 grams of K2HPO4, in each 10-milliliter portions, and shake. Remove the buffer layer and repeat the extraction with 25-milliliter portions of buffer at least three times and any additional times that may be necessary to insure complete extraction of the antibiotic. Combine the extracts and make the proper estimated dilutions in 10-percent potassium phosphate buffer, pH 6.0, to prepare a dilution of 10 units per milliliter (estimated).

(ii) The standard curve is prepared in the following concentrations: 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15 units per milliliter in 10-percent potassium phosphate buffer, pH 6.0. The 10 units per milliliter concentration is used as the reference point. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(4) Neomycin content. Proceed as directed in § 141d.410 (b) (1) of this chapter, with the following exception:

(i) In lieu of the directions for the preparation of the sample described in § 141d.410 (b) (1) (vii) of this chapter, prepare the sample as directed in subparagraph (1) (i) of this paragraph by a blending technique as follows: Place a convenient sized representative quantity of the sample in a blending jar containing 1.0 milliliter of an exceptional aqueous solution of diocetyl sodium sulfosuccinate and sufficient 0.1 M potassium phosphate buffer, pH 8.0, to give a volume of 200 milliliters. Using a high-speed blender, blend for 5 minutes and then make the appropriate estimated dilutions with buffer.
(ii) Use as the test organism the Food and Drug Administration dihydrostreptomycin- (and streptomycin-) resistant strain of M. pyogenes var. aureus (P. C. L. 1209 R. D.) grown and maintained on media containing 1,000 micrograms of dihydrostreptomycin per milliliter of agar. Its content of neomycin is satisfactory if it contains not less than 85 percent of the labeled amount of micrograms per gram that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.8 (b) of this chapter.

PART 1410—CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE-(OR TETRACYCLINE-) CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

Sec. 1410.201 Chlortetracycline hydrochloride.
1410.202 Chlortetracycline ointment (chlortetracycline hydrochloride ointment), chlortetracycline calcium ointment, chlortetracycline calcium cream; tetracycline hydrochloride suspension (tetracycline hydrochloride in oil suspension)
1410.203 Chlortetracycline troches, tetracycline hydrochloride troches
1410.204 Chlortetracycline capsules (chlortetracycline hydrochloride capsules); tetracycline hydrochloride capsules
1410.205 Chlortetracycline powder (chlortetracycline hydrochloride powder); tetracycline hydrochloride powder.
1410.206 Chlortetracycline in p h a l m c; tetracycline hydrochloride ophthalmic.
1410.207 Chlortetracycline tablets; tetracycline tablets
1410.208 Chlortetracycline oto, tetracycline hydrochloride oto.
1410.209 Chlortetracycline dental cones.
1410.210 Chlortetracycline dental paste.
1410.211 Chlortetracycline surgical powder (chlortetracycline hydrochloride surgical powder); tetracycline hydrochloride surgical powder.
1410.212 Chlortetracycline ointments, suppositories (chlortetracycline hydrochloride suppositories); tetracycline hydrochloride suppositories.
1410.213 Chlortetracycline gauze packing.
1410.214 Chlortetracycline dressing.
1410.215 Chlortetracycline with vasoconstrictor.
1410.217 Chlortetracycline calcium oral drops, chlortetracycline calcium syrup; tetracycline syrup.
1410.218 Tetracycline hydrochloride.
1410.219 Crude chlortetracycline oral veterinary.
1410.220 Tetracycline.
1410.221 Tetracycline hydrochloride for injection.
1410.222 Tetracycline hydrochloride oral suspension; tetracycline calcium oral suspension.
1410.224 Tetracycline hydrochloride-nystatine capsule.
1410.225 Tetracycline hydrochloride-nystatine tablets.
1410.226 Tetracycline and vasoconstrictor suspension.
between them from the micrograms per milliliter unit value on the curve. From the curve read the potency corresponding to these corrected values of zone sizes.

(5) Turbidimetric assay. In lieu of the plate assay method described above, the sample may be assayed by the following turbidimetric method:

(i) Test culture and media. Employ the agar described in § 141a.1 (b) of this chapter for maintaining the test organism when necessary. Propionates var. aureus (P. C. 205-1 and American Type Culture Collection 6533-P) transfer the organism to fresh agar slants and inbute at 32°-35° C. overnight. For use in the assay, suspend daily the growth from a fresh slant in a small amount of nutrient broth prepared as in § 141a.1 (b) of this chapter and transfer to a flask containing sufficient nutrient broth warmed to 37° C. (about 150 milliliters) to give a light transmission reading of 85 percent using a filter at 5461-A and using a 0.1-millimeter filter having a light transmission of 100 percent.

(ii) Preparation and dilutions. Prepare a standard stock solution as directed in § 141c.213 (a) and if it is tetracycline hydrochloride, may be assayed by the following turbidimetric method: Prepare a standard curve by connecting successive points with a straightedge. Since the final concentration of tetracycline per milliliter of broth is equivalent to the concentration per milliliter of the standard solution used, the latter concentrations for each concentration level of the standard may be expressed as percent and substituted on the abscissa of the standard curve. Thus 0.06 microgram concentration is 100 percent, the 0.05 microgram concentration 83.3 percent, etc. If this is done the percent transmission per unit volume may be read directly from the standard curve.

(iii) Colorimetric assay. In lieu of the assay methods described above, the sample may be assayed by the following colorimetric method: Prepare an aqueous solution of 0.5 milligram per milliliter of the sample to be assayed. Transfer 2.0-milliliter aliquots to 1 of each of 25-milliliter volumetric flasks. Add 5.0 milliliters of 2 N HCl to one flask and 5.0 milliliters of distilled water to the other flask as a control blank. Heat both flasks in a boiling water bath for 5 minutes, then cool the flasks under tap water, add 5.0 milliliters of 2 N HCl to the control blank and immediately make up to mark with distilled water. Transfer the solutions to 1-centimeter colorimetric cells, set the photometric colorimeter at 100 percent light transmission for the blank, using a 440-mµ filter. Then replace this with the cell containing the unknown and read the percent transmission. Determine the concentration of the unknown solution by reference to a standard curve prepared by treating appropriate aliquots of a standard solution of tetracycline hydrochloride as described above.

(10) Chlortetracycline content. The potency of chlortetracycline is satisfactory, when assayed by the methods described in this section, if the immediate containers contain 85 percent of the number of grams they are represented to contain.

(b) Sterility. Using 40 milligrams from each container tested, proceed as directed in § 141a.2 of this chapter, except that neither pectinase nor the control tube is used in the test for bacteria.

(c) Toxicity. Proceed as directed in § 141a.4 of this chapter, using a test dose 0.5 milliliter of an aqueous solution containing 2 micrograms per milliliter, except if it is intended for use solely in the manufacture of a veterinary drug for nonparenteral use, use a test dose of 0.4 milliliter of said standard.

(d) Histamine. Proceed as directed in § 141a.163 of this chapter, using a test dose 0.5 milliliter of a solution containing 5 milligrams per milliliter prepared with the diluent recommended by the manufacturer in his labeling for the drug.

(e) Moisture. Proceed as directed in § 141a.5 (a) or § 141a.26 (e) of this chapter.

(f) pH. Proceed as directed in § 141a.5 (b) of this chapter, using an aqueous solution containing 10 milligrams per milliliter.

(b) Microscopical test for crystallinity. Proceed as directed in § 141a.5 (e) of this chapter.

§ 141a.202 Chlortetracycline ointment (chlortetracycline hydrochloride ointment), chlortetracycline ointment, chlortetracycline calcium ointment, chlortetracycline calcium cream; tetracycline hydrochloride ointment, tetracycline hydrochloride cream; chlortetracycline hydrochloride ointment—(a) Potency. If it is tetracycline hydrochloride ointment prepared as directed in § 141c.213 (a) and if it is chlortetracycline ointment prepared as directed in § 141c.201 (a) and (b) (3) of this chapter, using a test dose 0.5 milliliter of a solution containing 2 micrograms per milliliter of the buffer solution. The potency of the ointment is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.8 (b) of this chapter.

§ 141c.203 Chlortetracycline troches; tetracycline hydrochloride troches—(a) Potency. If it is tetracycline hydrochloride, proceed as directed in § 141c.213 (a) and if it is chlortetracycline hydrochloride troches proceed as directed in § 141c.201 (a) except § 141c.201 (a) (10) and (b) (3) of this chapter, using a test dose 0.5 milliliter of a solution containing 2 micrograms per milliliter of the buffer solution. The potency of the troches is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.8 (a) of this chapter.
§ 141c.204 Chlortetracycline capsules (chlortetracycline hydrochloride capsules) tetracycline hydrochloride capsules; tetracycline hydrochloride powder, (chlortetracycline hydrochloride powder) tetracycline hydrochloride powder; tetracycline hydrochloride powder—(a) Potency. Proceed as directed in §141c.203 (a) using an accurately weighed sample of approximately 2.0 grams of chlortetracycline or tetracycline that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (a) or §141a.26 (e) of this chapter.

§ 141c.205 Chlortetracycline powder (chlortetracycline hydrochloride powder) tetracycline hydrochloride powder—(a) Potency. Proceed as directed in §141c.203 (a) if it is chlortetracycline powder. If it is tetracycline powder, blend a 3.0-gram sample as directed in §141c.203 (a) or reconstitute in the immediate container as directed in the labeling directions. Transfer an appropriate aliquot of 1.0 milliliter to 50 milliliters to a 100-milliliter volumetric flask and make to mark with 0.01 milliliters of water to prepare the sample. Proceed as directed in §141c.205 (a) using 500 milliliters of distilled water to prepare the sample. The average potency of the sample is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (a) or §141a.26 (e) of this chapter.

§ 141c.208 Chlortetracycline oto tetracycline hydrochloride oto—(a) Potency. If it is chlortetracycline proceed as directed in §141c.203 (a) and if it is tetracycline hydrochloride proceed as directed in §141c.218 (a) (b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

§ 141c.209 Chlortetracycline dental cones—(a) Potency. Proceed as directed in §141c.203 (a) using an accurately weighed sample of approximately 2.0 grams of chlortetracycline or tetracycline that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

§ 141c.210 Chlortetracycline dental paste—(a) Potency. Proceed as directed in §141c.203 (a) using an accurately weighed sample of approximately 2.0 grams of chlortetracycline or tetracycline that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.8 (b) of this chapter.

§ 141c.211 Chlortetracycline surgical powdertetracycline hydrochloride surgical powder—(a) Potency. If it is chlortetracycline proceed as directed in §141c.203 (a) and if it is tetracycline proceed as directed in §141c.218 (a) (b) Sterility. Proceed as directed in §141b.108 (c) of this chapter.

(c) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

§ 141c.212 Chlortetracycline suppositorystetracycline hydrochloride suppositories tetracycline hydrochloride suppositories—(a) Potency. If they are tetracycline hydrochloride suppositories, proceed as directed in §141c.218 (a) and if they are chlortetracycline suppositories, proceed as directed in §141c.203 (a) except subparagraph (b) (iii) of §141c.203 (a) prepare the sample as follows: Place three suppositories into a separatory funnel and add 50 milliliters of 1.0 percent of peroxide-free ether. Shake the suppositories and ether until homogeneous. Shake with a 50-milliliter portion of the buffer solution. Remove the ether layer and repeat the extraction with three 50-milliliter quantities of buffer. Combine the extracts and centrifuge an aliquot at 2,000 r. p. m. for 5 minutes. Remove an aliquot of the supernatant and make the proper estimated dilutions in the buffer solution. The average potency of the suppository is satisfactory if it contains not less than 85 percent of the number of milligrams of chlortetracycline or tetracycline hydrochloride that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.8 (b) of this chapter.

§ 141c.213 Chlortetracycline gauze packing—(a) Potency. Using three packings, obtain the average weight and average linear length per packing. As- say three packings by dissolving each in 500 milliliters of 0.1 N HCl and allow to soak with frequent agitation for not less than 2 hours. Use aliquots of these solutions and proceed as directed in §141c.201 (a) Calculate the average potency per gram and per linear foot. The average potency of the gauze packing is satisfactory if it contains not less than 85 percent of the number of milligrams per gram and per linear foot it is represented to contain.

(b) Sterility. Using individual gauze packing, proceed as directed in §141c.215 (a) except that neither penicillinase nor the control tube is used in the test for bacteria.

(c) Moisture. Proceed as directed in §141a.8 (b) of this chapter.

§ 141c.214 Chlortetracycline dressing—(a) Potency. Using individual dressings and appropriate volumes of peroxide-free ether and buffer solution, proceed as directed in §141c.203 (a) (b) Sterility. Using individual dressing, proceed as directed in paragraph (1) of this section, except that neither penicillinase nor the control tube is used in the test for bacteria.

(c) Moisture. Proceed as directed in §141a.8 (b) of this chapter.

§ 141c.215 Chlortetracycline with vasoconstrictor—(a) Potency. Proceed as directed in §141c.201 (a) (b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

§ 141c.217 Chlortetracycline calcium oral drops; chlortetracycline calcium syrup; tetracycline syrup—(a) Potency. If it is chlortetracycline calcium oral drops or chlortetracycline calcium syrup, proceed as directed in §141c.201 (a) and if it is tetracycline syrup use 1.0-milliliter aliquots of the sample and proceed as directed in §141c.206 (a). Its potency is satisfactory if each milliliter of the drug contains not less than 85 percent of the number of milligrams of chlortetracycline or tetracycline that it is represented to contain.

(b) pH. Using the undiluted sample, proceed as directed in §141a.5 (b) of this chapter.

(c) Toxicity. Administer orally, by means of a cannula or other suitable device, to each of 5 mice, within the weight range of 18 to 25 grams, a sufficient volume of the preparation to contain 25 milligrams if it is chlortetracycline or 50 milligrams if it is tetracycline. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with 5 unused mice weighing 20 grams (±0.5
§ 141c.218 Tetracycline hydrochloride.—(a) Potency. Acceptable tetracycline hydrochloride working standard as a standard of comparison and proceed as directed in § 141c.201 (a) except:

(1) Prepare the standard stock solution by dissolving an appropriate amount of the working standard in sufficient 0.01 N HCl to give a concentration of 1,000 micrograms per milliliter. This stock solution may be kept in the refrigerator for 1 week. Do not freeze.

(2) Further dilute the stock solution to contain 0.3 microgram per milliliter in H/10 monopotassium phosphate buffer pH 6.85 in lieu of 0.1 microgram per milliliter.

(3) Prepare 10 tubes each of the minimum (0.04 microgram per milliliter) and maximum (6.4 microgram per milliliter) concentrations diluted for the standard curve, and use these solutions to adjust the photocolorimeter.

(4) Use the 0.24 microgram per milliliter concentration of the standard curve as the reference point.

(5) Dilute the sample to be tested in sufficient 0.01 N HCl to give an appropriate stock solution. Further dilute in H/10 monopotassium phosphate buffer pH 6.85 to give an estimated concentration of 0.24 microgram per milliliter in lieu of 0.06 microgram per milliliter.

The potency of tetracycline hydrochloride for intravenous use is satisfactory if each immediate container contains not less than 90 percent of tetracycline hydrochloride that it is represented to contain.

(b) Sterility and toxicity. Proceed as directed in § 141a.201 (b) and (c).

(c) Pyrogens. Proceed as directed in § 141a.3 of this chapter, using as a test dose 1.0 milliliter per kilogram of an aqueous solution containing 500 micrograms per milliliter.

(d) Histamine, moisture, pH, and crystallinity. Proceed as directed in § 141c.201 (a), (c), and (f) and § 141a.5 (c) of this chapter.

(e) Extinction coefficient. Dissolve approximately 40 milligrams of the sample, accurately weighed, in approximately 150 milliliters of distilled water by mixing thoroughly. Dilute to exactly 250 milliliters with distilled water and mix thoroughly. Transfer a 10.0-milliliter aliquot of this solution to a 100-milliliter volumetric flask, add about 75 milliliters of distilled water and 5.0 milliliters of 5 N NaOH, and then make to 100 milliliters with water and mix thoroughly. Exactly 5 minutes after the addition of the NaOH, determine the absorbency of the solution at 380 mp compared with distilled water as a blank. Use a suitable spectrophotometer for the absorbency measurements.

\[ \text{Absorbancy at } 380 \text{ mp} \times \frac{2000}{\text{weight of sample in milligrams}} \]

§ 141c.219 Crude chlortetracycline oral veterinary.—(a) Potency. Accurately weigh approximately 3.0 grams of the sample and place in a blender jar containing 200 milliliters of an acetic-acetone solution prepared with 1 part 4 N HCl, 6 parts distilled water, and 13 parts acetone. Blend for 3 minutes. Using an aliquot of the liquid, make the proper estimated dilutions in H/10 monopotassium phosphate buffer pH 6.85, shake well, and proceed as directed in § 141c.201 (a) (6). Its content of chlortetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of grams that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

§ 141c.220 Tetracycline.—(a) Moisture. Proceed as directed in § 141a.26 (e) of this chapter. Use the value obtained to calculate the weighed samples used as Paragraphe (b) (i) and (b) (ii) of this section to the anhydrous compound.

(b) Potency. Using 40 milligrams (as the anhydrous compound) of sample, proceed as directed in § 141c.218 (a) except:

(1) It contains not less than 85 percent of the number of grams that it is represented to contain.

(2) Its content of penicillin is satisfactory if it contains not less than 90 percent of the number of milligrams of tetracycline hydrochloride that it is represented to contain.

(3) Its content of streptomycin or dihydrostreptomycin is satisfactory if it contains not less than 95 percent of the number of milligrams of streptomycin per gram of ointment that it is represented to contain.

(c) Crystallinity. Proceed as directed in § 141a.5 (c) of this chapter.

(d) Extinction coefficient. Proceed as directed in § 141c.218 (e) except dissolve 40 milligrams (as the anhydrous compound) in 2.0 milliliters 0.1 N HCl and dilute to 250 milliliters with distilled water.

§ 141c.221 Tetracycline hydrochloride for use in ophthalmic preparations.—(a) Potency. Reconstitute the sample as directed on the label or labeling. Using a suitable syringe, withdraw a one-dose aliquot and place in a 100-milliliter volumetric flask. Dilute to the mark with water and mix thoroughly. Exactly 5 minutes after the addition of water, determine the absorbency of the solution at 380 mp compared with distilled water as a blank. Use a suitable spectrophotometer for the absorbency measurements.

\[ \text{Weight of sample in milligrams} \times \frac{2000}{\text{Absorbancy at } 380 \text{ mp}} \]

§ 141c.223 Chlortetracycline-neomycin-streptomycin-penicillin ointment; chlortetracycline - neomycin - dihydrostreptomycin-penicillin ointment; tetracycline hydrochloride-neomycin-dihydrostreptomycin-penicillin ointment.—(a) Potency. Place an accurately weighed sample of approximately 1 gram in an extraction funnel prepared by fusing a ground-glass joint to the top of a medium-porosity sintered-glass filter (1.5 cm diameter). Wash with five 10-milliliter portions of warm iso-octane and draw off the octanol base under vacuum. Discard the iso-octane washings. Wash the residue with three 10-milliliter portions of chloroform and draw off under vacuum, combine the extracts, and make to mark in a 250-milliliter volumetric flask with absolute alcohol. Make the proper estimated dilutions in 1-percent phosphate buffer, pH 6.0, and proceed as directed in § 141a.1 of this chapter. Its content of penicillin is satisfactory if it contains not less than 65 percent of the number of units per gram of ointment that it is represented to contain.

(b) Tetracycline content. Wash the residue with three 10-milliliter portions of chloroform and draw off under vacuum, combine the extracts, and make to mark in a 250-milliliter volumetric flask with absolute alcohol. Make the proper estimated dilutions in 1-percent phosphate buffer, pH 6.0, and proceed as directed in § 141a.1 of this chapter. Its content of tetracycline is satisfactory if it contains not less than 95 percent of the number of milligrams per gram of ointment that it is represented to contain.

(c) Neomycin content. The residue remaining after the chromatography described in subparagraph (2) of this paragraph and proceed as directed in § 141c.218. Its content of tetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(d) Streptomycin content. The residue remaining after the chromatography described in subparagraph (2) of this paragraph and proceed as directed in § 141c.218. Its content of chlortetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.
volumetric flask and make to mark with distilled water. Using an aliquot of this aqueous solution, proceed as directed in § 141a.65 (a) to (iii) or (iv) of this chapter. The content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(5) Streptomycin content. Using an aliquot of the aqueous solution prepared in subparagraph (a) of this paragraph, prepare two solutions by diluting it with distilled water. Using an aliquot of this solution with 1-percent phosphate buffer, pH 6.0, to make concentrations of 5, 10, 15, 20, 30, 40, and 50 units per milliliter, respectively. A total of 18 plates is used in the preparation of the standard curve, three plates for each concentration, except the 20 units per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of the three plates fill three cylinders with the 20 units per milliliter standard and the other three cylinders with the organism suspension at the standard concentration under test. Thus, there will be 54 twenty-unit determinations and nine determinations for each of the other concentrations on the curve. Incubate the plates for 18 hours at 37°C. and measure the diameter of each zone of inhibition. Average the readings of the 20 units per milliliter concentration and the readings of the concentration tested for each set of three plates, and average also all 54 readings of the 20 units per milliliter concentration. The average of the 54 readings of the 20 units per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 20 units per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 16 units per milliliter concentration the average of the 54 readings of the 20 units per milliliter concentration is 15.8 millimeters and the average of the 20 units per milliliter concentration of this set of three plates is 16.0 millimeters, the correction is +0.2 millimeter. If the average of the 15 units per milliliter concentration of those same three plates is 15.0 millimeters, the corrected value is then 15.2 millimeters. Plot these corrected values, including the average of the 20 units per milliliter concentration on two-cycle semilog paper, using the concentration in micrograms per milliliter as the abscissa. Draw the standard curve through these points.

(b) Make nutrient broth for preparing an inoculum of the test organism:

Peptone 10 grams.
Yeast extract 5 grams.
Bovine extract 3 grams.
Sodium chloride 10 grams.
Dextrose 10 grams.
Agar 15 grams.
Distilled water to make 1,000 milliliters.

(b) Make nutrient broth for preparing an inoculum of the test organism:

Peptone 10 grams.
Yeast extract 5 grams.
Bovine extract 3 grams.
Sodium chloride 10 grams.
Dextrose 10 grams.
Agar 15 grams.
Distilled water to make 1,000 milliliters.

(b) Make nutrient broth for preparing an inoculum of the test organism:

Peptone 10 grams.
Yeast extract 5 grams.
Bovine extract 3 grams.
Sodium chloride 10 grams.
Dextrose 10 grams.
Agar 15 grams.
Distilled water to make 1,000 milliliters.

(b) Make nutrient broth for preparing an inoculum of the test organism:

Peptone 10 grams.
Yeast extract 5 grams.
Bovine extract 3 grams.
Sodium chloride 10 grams.
Dextrose 10 grams.
Agar 15 grams.
Distilled water to make 1,000 milliliters.

(b) Make nutrient broth for preparing an inoculum of the test organism:

Peptone 10 grams.
Yeast extract 5 grams.
Bovine extract 3 grams.
Sodium chloride 10 grams.
Dextrose 10 grams.
Agar 15 grams.
Distilled water to make 1,000 milliliters.

(b) Make nutrient broth for preparing an inoculum of the test organism:

Peptone 10 grams.
Yeast extract 5 grams.
Bovine extract 3 grams.
Sodium chloride 10 grams.
Dextrose 10 grams.
Agar 15 grams.
Distilled water to make 1,000 milliliters.

(b) Make nutrient broth for preparing an inoculum of the test organism:

Peptone 10 grams.
Yeast extract 5 grams.
Bovine extract 3 grams.
Sodium chloride 10 grams.
Dextrose 10 grams.
Agar 15 grams.
Distilled water to make 1,000 milliliters.

(b) Make nutrient broth for preparing an inoculum of the test organism:

Peptone 10 grams.
Yeast extract 5 grams.
Bovine extract 3 grams.
Sodium chloride 10 grams.
Dextrose 10 grams.
Agar 15 grams.
Distilled water to make 1,000 milliliters.

(b) Make nutrient broth for preparing an inoculum of the test organism:

Peptone 10 grams.
Yeast extract 5 grams.
Bovine extract 3 grams.
Sodium chloride 10 grams.
Dextrose 10 grams.
Agar 15 grams.
Distilled water to make 1,000 milliliters.
sample gives a larger zone size than the average of the standard, add the difference between them to the 20 units per milliliter zone size in the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 20 units per milliliter value on the curve. From the curves read an approximate value at this point and determine the weight to these corrected values of zone sizes.

(2) Toxicity. Inject intraperitoneally each of 5 mice, within the weight range of 18 grams to 25 grams, with 0.5 milliliters of a suspension of the drug containing 1,500 units per milliliter in a 0.5 percent aqueous solution. If no animal dies within 48 hours, the sample is not toxic. If one or more of the animals die within 48 hours, repeat the test with 5 unused mice weighing 20 grams (+0.5 gram) each; if all animals survive the repeat test, the sample is nontoxic.

(3) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

(4) pK. Proceed as directed in §141a.5 (b) of this chapter, using a 3-percent aqueous suspension of the drug.

(5) pH. Weigh approximately 1.0 gram of the sample in a 25-milliliter glass-stoppered volumetric flask, dissolve the sample and dilute to volume with distilled water made at 20° C. Transfer the solution to a 200-millimeter tube, determine the angular rotation in a suitable polarimeter, using sodium light or a 436 Angstrom unit filter, and calculate the specific rotation.

§ 141c.225 Tetracycline hydrochloride-nystatin tablets—(a) Tablets—(1) Potency—(i) Tetracycline hydrochloride content. Proceed as directed in §141c.224 (a) (1) (i) Its content of tetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(ii) Nystatin content. Proceed as directed in §141c.224 (a) (1) (ii) Its content of nystatin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(iii) Moisture. Proceed as directed in §141a.5 (a) or §141a.26 (e) of this chapter.

(b) Nystatin used in making the tablets. Proceed as directed in §141c.224 (b) of this chapter.

§ 141c.226 Tetracycline and vasconstrictor suspension—(a) Potency. Proceed as directed in §141c.218 (a) (1) Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) pH. Using the undiluted sample, proceed as directed in §141a.5 (b) of this chapter.

§ 141c.227 Chlortetracycline spray dresses (chlortetracycline hydrochloride spray dressings)—(a) Potency. Spray the entire contents of the well shaken sample into a large tared beaker, place in a vacuum desiccator, evacuate, and allow to stand at room temperature for 16 to 18 hours. After the gas has volatilized, accurately weigh the beaker and contents and determine the weight of the ointment ejected when used as directed in its labeling. Remove a representative quantity (usually 1 gram) of the ointment from the beaker, accurately determine its weight, and place in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Proceed as directed in §141c.219 (b) of this chapter.

§ 141d.308 Chloramphenicol ophthalmic.

§ 141d.309 Chloramphenicol palmitate.

§ 141d.310 Chloramphenicol palmitate-dihydrochloride.

§ 141d.311 Chloramphenicol palmitate-streptomycin oral suspension.

Part 1 4 1 d—Chloramphenicol and Chloramphenicol-Containing Drugs; Tests and Methods of Assay

Sec. 141d.301 Chloramphenicol.

141d.302 Chloramphenicol capsules; potency.

141d.303 Chloramphenicol ophthalmic.

141d.304 Chloramphenicol palmitate.

141d.305 Chloramphenicol palmitate oral suspension.

141d.307 Chloramphenicol solution; chloramphenicol for aqueous injection.

141d.308 Chloramphenicol otic; chloramphenicol topical.

141d.309 Chloramphenicol-streptomycin capsules; chloramphenicol-streptomycin palmitate capsules.

141d.310 Chloramphenicol tablets.

141d.311 Chloramphenicol palmitate-streptomycin oral suspension; chloramphenicol-streptomycin palmitate oral suspension.


141d.301 Chloramphenicol—(a) Potency—(1) Cylinders (cups). Use cylinders described under §141a.1 (a) of this chapter.

(2) Culture media. Use the medium described under §141a.1 (b) (1) of this chapter for both the seed layer and the base layer. Use the nutrient broth described under §141a.1 (b) (3) of this chapter for preparing a suspension of the test organism.

(3) Working standard. Prepare the working standard by weighing out carefully appropriate amounts of the chloramphenicol working standard and dilute in 1 percent phosphate buffer pH 6.0 to give a solution containing 50 micrograms per milliliter. Keep this stock solution at a temperature of 15° C or less and use for only 1 month. The standard may first be dissolved in a small amount of ethyl alcohol to facilitate solution.

141c.501 Chloramphenicol—(b) Cylinders (cups) Use cylinders described under §141a.1 (a) of this chapter.

(2) Culture media. Use the medium described under §141a.1 (b) (1) of this chapter for both the seed layer and the base layer. Use the nutrient broth described under §141a.1 (b) (3) of this chapter for preparing a suspension of the test organism.

(3) Working standard. Prepare the working standard by weighing out carefully appropriate amounts of the chloramphenicol working standard and dilute in 1 percent phosphate buffer pH 6.0 to give a solution containing 50 micrograms per milliliter. Keep this stock solution at a temperature of 15° C or less and use for only 1 month. The standard may first be dissolved in a small amount of ethyl alcohol to facilitate solution.

4 Preparation of sample. Prepare the sample to be tested by dissolving in a small amount of ethyl alcohol and then further dilute in 1 percent phosphate buffer pH 6.0 to make an appropriate stock solution.

6 Preparation of suspension. The test organism is Sarcina lutea (P. C. I. 1001). Maintain the test organism on slants of nutrient agar prepared as in subparagraph (2) of this paragraph and transfer to a fresh agar slant once a week. Prepare a suspension of the test organism by inoculating a Roux bottle containing nutrient broth. Use the suspension so obtained to inoculate the surface of a layer of agar containing 500 milliliters of nutrient agar. Spread the suspension over the entire surface with the aid of sterile glass beads. Incubate for 24 hours at 26° C. Wash the growth from the agar surface with 150 milliliters of water and make the nutrient broth prepared as in subparagraph (2) of this paragraph. If an aliquot of this bulk suspension, when diluted to 50 percent of the number of gram-seconds of light transmission in a suitable photoelectric colorimeter equipped with a filter having a wavelength of 6500 Ångstrom units, is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution so that an aliquot of the adjusted suspension diluted 1:10 gives 10 percent light transmission. (The adjusted bulk suspension only, and not the 1:10 dilution of it, is used in preparing the seed layer.) The bulk suspension may be used in the test for 1 month. Add 1 to 1.5 milliliters of the adjusted bulk suspension to 100 milliliters of agar which has been melted and cooled to 43° C.

6 Preparation of plates. Add 21 milliliters of the agar prepared as in subparagraph (2) of this paragraph to each Petri dish (90×15 mm Petri dishes). Dissolve the agar, and allow to harden. Use the plates the same day they are prepared. Add 4 milliliters of the inoculum prepared as in subparagraph (2) of this paragraph to each plate, tilting the plates back and forth to spread the inoculated agar evenly over the surface.

7 Assay. Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.3-centimeter radius. Use three plates for each sample. Fill three cylinders on each plate with the 50 micrograms per milliliter standard and three cylinders with the 50 micrograms per milliliter (estimated) sample, alternating standard and sample. At the same time prepare standard curves from solutions of the standard of 30.0, 35.0, 40.0, 45.0, 50.0, 55.0, 60.0, 65.0, and 70.0 micrograms per milliliter. A total of 24 plates is used in the preparation of the standard curves. Use three plates per standard curve except the 50 micrograms per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill three cylinders with the 50 micrograms per milliliter standard and the other three cylinders with the concentration of the standard under test.
Thus, there will be seventy-two 50-microgram determinations and nine determinations for each of the other points on the curve. Incubate the plates for 16 to 18 hours at 35°C, and measure the diameter of each circle of inhibition. Average the readings of the 50 micrograms per milliliter concentration and the readings of the point tested for each set of three plates, and average also all 72 readings of the 50 micrograms per milliliter concentration. The average of the 72 readings of the 50 micrograms per milliliter concentration is the correction point for the selected sample zone, and the corrected value obtained for each point to the figure it would be if the 50 micrograms per milliliter readings for that set of three plates were the same as the correction point. Thus, if in correcting the 40 micrograms per milliliter concentration the average of the 72 readings of the 50 micrograms per milliliter is 17.0 millimeters, and the average of these three plates is 17.0 millimeters, the corrected concentration of these same three plates is 17.0 millimeters, the corrected value is then 17.2 millimeters.

Plot these values, including the average of the 50 micrograms per milliliter concentrations on two-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points.

To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 50 micrograms per milliliter unit zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 50 micrograms per milliliter unit zone value on the curve.

From the curves read the potencies corresponding to these corrected values of zone sizes.

(8) Spectrophotometric Method. In lieu of the plate-assay method described above, the following method may be used:

Dissolve 20 milligrams of the sample, accurately weighed, in 100 milliliters of distilled water, warming to hasten solution. Cool to room temperature, dilute to exactly 1,000 milliliters with distilled water, and mix. With a suitable spectrophotometer determine the optical density of the solution in a 1-centimeter cell at 278 mμ compared with distilled water as a blank. Multiply the optical density figure obtained by the appropriate factor to obtain the optical density value of a 1 percent solution.

The E1% value of the sample multiplied by 100, divided by 298, represents the percent potency.

(9) Chloramphenicol Content. The potency of chloramphenicol is satisfactory, when assayed by the methods described in this section, if the immediate containers contain 85 percent of the number of grams they are represented to contain.

(b) Sterility. Proceed as directed in § 141c.201 (b) of this chapter.

(c) Toxicity. Proceed as directed in § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 5 milligrams per milliliter. Use physiological salt solution as the diluent.

(d) Pyrogens. Proceed as directed in § 141a.3 of this chapter, using as a test dose 1.0 milliliter per kilogram of a solution containing 5 milligrams per milliliter. Use physiological salt solution as the diluent.

(e) Histamine. Proceed as directed in § 141b.105 of this chapter, using as a test dose 0.6 milliliter of a solution containing 5 milligrams per milliliter prepared by application of heat.

(f) pH. Proceed as directed in § 141a.5 (b) of this chapter using a saturated aqueous solution.

(g) Specific Rotation. Accurately weigh approximately 1.25 grams of the sample and determine the rotation in a 25-milliliter volumetric flask and dilute to 100 milliliters with absolute alcohol, warming if necessary. Dilute the solution to 25 milliliters with absolute alcohol and mix thoroughly. Transfer the solution to a 200-millimeter tube, determine the angle of rotation in a suitable polarimeter, using sodium light or a 5893 Angstrom filter, and calculate the specific rotation.

(h) Melting Point. Proceed as directed by the U. S. P.

(i) Extinction Coefficient. Proceed as directed in paragraph (a) of this section.

§ 141d.303 Chloramphenicol capsules; potency—(a) Bioassay method. Proceed as directed in § 141d.301 (a) except subparagraph (1) thereof. The potency of chloramphenicol ophthalmic will be satisfactory if it contains not less than 85 percent of the number of milligrams of chloramphenicol per capsule that it is represented to contain.

§ 141d.303 Chloramphenicol ointment—potency. Proceed as directed in § 141d.301 (a), except subparagraphs (8) and (9) thereof, and in lieu of the directions in § 141d.301 (a) (4) prepare the sample by one of the following methods:

(a) Place an accurately weighed representative sample (0.5 gram) in a separatory funnel containing 10 milliliters of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the ointment and ether. With a 15-milliliter portion of 1-percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with two additional 15-milliliter portions of buffer. Combine the extracts and dilute to 50 milliliters with 1-percent phosphate buffer. Make proper estimated dilutions in 1-percent phosphate buffer at pH 6.0.

The potency of chloramphenicol ointment is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

§ 141d.304 Chloramphenicol ophthalmic solution—(a) Potency. Proceed as directed in § 141d.301 (a), except subparagraphs (8) and (9) thereof. The potency of chloramphenicol ophthalmic is satisfactory if it contains not less than 85 percent of the number of milligrams of chloramphenicol it is represented to contain.

(b) pH. Proceed as directed in § 141a.5 (b) of this chapter, using a solution prepared as directed in the labeling of the drug.

(c) Sterility. Proceed as directed in § 141a.2 of this chapter, except that:

(1) Use 0.5 milliliter of the suspension of the sample prepared according to label directions, and do not use physiological saline for the control tube in the test for bacteria.

(2) In lieu of the last sentence of § 141a.2 (b) of this chapter, the batch meets the requirements of the test for bacteria if no tube shows growth.

(3) In lieu of the last sentence of § 141a.2 (b) of this chapter, the batch meets the requirements of the test for molds and yeasts if no tube shows growth.

§ 141d.305 Chloramphenicol palatable—(a) Potency. Dissolve 50 milligrams of the sample in absolute ethanol and make to 100 milliliters with volumetric flask with absolute alcohol. Transfer a 5-milliliter aliquot to another 50-milliliter volumetric flask and make to volume with absolute alcohol. With a suitable spectrophotometer determine the optical density of the solution in a 1-centimeter cell at 278 mμ compared with
with absolute ethanol as a blank. Multiply the optical density figure obtained by the appropriate factor to obtain the optical density value of 1-per cent solution. The $E_{10}^{1}cm$ value of the sample multiplied by 178, divided by 178, represents the micrograms per milligram of chloramphenicol.

(b) Toxicity. Administer orally, by means of a cannula or other suitable device, to each of 10 mice, with the weight range of 18 to 25 grams, 1.0 milliliter of a suspension containing 60 milligrams per milliliter in 10 percent acetic acid solution. If no animal dies within 48 hours, repeat the test with 5 unused mice weighing 20 grams (+0.5 gram) each; if all animals survive the repeat test the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with 5 unused mice weighing 20 grams (+0.5 gram) each; if all animals survive the repeat test the sample is nontoxic.

(c) Melting point. Proceed as directed by the U. S. P.

(d) Extinction coefficient. Proceed as directed in paragraph (a) of this section.

§ 141d.306 Chloramphenicol ophthalmal oral suspension—(a) Potency. Using a hypodermic syringe, transfer 1.0 milliliter of the suspension to a separatory funnel containing 10 milliliters of water and 25 milliliters of chloroform. Shake for 1 minute, allow the layers to separate, and filter the lower chloroform layer through a pledget of cotton. Transfer the portion of the clear chloroform filtrate to a 100-milliliter volumetric flask, make to volume with absolute ethanol, and mix. With a suitable spectrophotometer, determine the absorbance of this solution on a suitable spectrophotometer or 273 mµ against a blank of distilled water. The optical density at 273 mµ, $C = 25,000 \times 0.575$, 278

where:

$C =$ the number of milligrams of chloramphenicol in 1.0 milliliter of the chloramphenicol ophthalmal suspension

$A =$ the absorbance of the solution at 271 millimicrons

$25,000 =$ dilution factor

$0.575 =$ the factor for converting chloramphenicol palmitate to chloramphenicol

$278 =$ extinction coefficient of chloramphenicol palmitate at 271 millimicrons.

The potency of chloramphenicol palmitate oral suspension is satisfactory if it contains not less than 85 percent of the number of milligrams in each milliliter that it is represented to contain.

(b) pH. Using the undiluted suspension, proceed as directed in § 141d.5 (b) of this chapter.

§ 141d.307 Chloramphenicol solution; chloramphenicol for aqueous injection—(a) Potency—(1) Chloramphenicol solution. Proceed as directed in § 141d.301 (a) except subparagraphs (b) and (d) of that paragraph, and in lieu of the directions in subparagraph (d) of that paragraph dilute the sample in sufficient 1.0-per cent phosphate buffer pH 6.0 to make an appropriate stock solution.

(2) Chloramphenicol for aqueous injection. Proceed as directed in § 141d.301 (a) except subparagraph (g) of that paragraph, and in lieu of the directions in subparagraph (d) of that paragraph prepare the sample as follows: Add the amount of water indicated in the labeling of the drug to the vial, and shake well. Remove 1.0 milliliter of the suspension, transfer to a 50-milliliter volumetric flask, and make to volume with absolute alcohol. Quickly remove 1.0 milliliter and make to the proper estimated dilution in 1.0-per cent phosphate buffer pH 6.0. In case the spectrophotometric method is used, proceed as follows: Add to the vial a fixed amount of water indicated in the labeling of the drug and shake vigorously until a uniform suspension is obtained. Transfer an aliquot of this suspension, equivalent to 1.0 gram of chloramphenicol, to an appropriate stoppered volumetric flask, add about 500 milliliters of distilled water, and heat on a steam bath until solution of the chloramphenicol is complete; let it cool to room temperature and dilute to exactly 1,000 milliliters with distilled water. Mix thoroughly, and transfer exactly 5 milliliters of this solution to a 250-milliliter glass-stoppered volumetric flask. Dilute to exactly 250 milliliters with distilled water and mix thoroughly. Measure the absorbancy of this solution on a suitable spectrophotometer at 273 mµ against a blank of distilled water. The optical density at 273 mµ, $C = 500 \times 229$, is obtained. Transfer an aliquot of this solution into a 1-centimeter quartz cell at 273 mµ, $C = 500 \times 229$, and transfer an amount of powder containing 500 milligrams (estimated) of chloramphenicol to a 1,000-milliliter glass-stoppered volumetric flask. Add 50 milliliters of redistilled methanol to the flask and shake for at least 1 minute. Make to volume with distilled water and mix thoroughly. Transfer exactly 10 milliliters of this solution into a 250-milliliter glass-stoppered volumetric flask. Make to mark and mix thoroughly. Determine the absorbancy of this solution on a suitable spectrophotometer in a 1-centimeter quartz cell at 276 millimicrons against a blank of distilled water.

<table>
<thead>
<tr>
<th>Milligrams of chloramphenicol per tablet:</th>
<th>Absorbancy: 500 X average weight in milligrams</th>
<th>Weight of powder tested in milligrams</th>
</tr>
</thead>
</table>
| 141d.309 Chloramphenicol ophthalmal; chloramphenicol topical—(a) Potency. Using 1.0 milliliter, proceed as directed in § 141d.303 (a) its potency is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.17 (c) of this chapter.

(c) pH. Dilute the drug with an equal volume of distilled water and proceed as directed in § 141a.5 (b) of this chapter.

§ 141d.309 Chloramphenicol-streptomycin capsules; chloramphenicol-dicyodextrin capsules—(a) Potency. Proceed as directed in § 141d.302 (a) or (b) its content of chloramphenicol is satisfactory if it contains not less than 85 percent of the number of milligrams per capsule that it is represented to contain.

(2) Content of streptomycin. Using 10 capsules, proceed as directed in § 141b.101 of this chapter, except paragraphs (a) through (d) and (f) of that section. If the content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per capsule that it is represented to contain.

(3) Content of dicyodextrin. Proceed as directed in paragraph (2) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per capsule that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (c) of this chapter.

§ 141d.310 Chloramphenicol tablets—(a) Bioassay method. Proceed as directed in § 141d.302 (a)

(b) Spectrophotometric assay method. Weigh accurately a counted number of not less than 10 tablets and determine the average weight at paracetamol. Reduce 10 tablets to a fine powder in a mortar and transfer an amount of powder containing 500 milligrams (estimated) of chloramphenicol to a 1,000-milliliter glass-stoppered volumetric flask. Add 50 milliliters of redistilled methanol to the flask and shake for at least 1 minute. Make to volume with distilled water and mix thoroughly. Transfer exactly 10 milliliters of this solution into a 250-milliliter glass-stoppered volumetric flask. Make to mark and mix thoroughly. Proceed as directed in § 141d.302 (a) or (b) its content of chloramphenicol is satisfactory if it contains not less than 85 percent of the number of milligrams per tablet that it is represented to contain.
§ 141d.311 Chloramphenicol palmitate-streptomycin oral suspension, chloramphenicol palmitate-dihydrostreptomycin oral suspension—(a) Potency—(1) Chloramphenicol content. Proceed as directed in § 141d.306 (a) its content of chloramphenicol is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(2) Streptomycin or dihydrostreptomycin content. Proceed as directed in § 141b.101 of this chapter except § 141b.101 (b), if it contains dihydrostreptomycin use the dihydrostreptomycin working standard as the standard of comparison. Its content of streptomycin or dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) pH. Using the undiluted suspension, proceed as directed in § 141a.5 (b) of this chapter.

PART 141—BACTRACIN AND BACTRACIN-CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

Sec. 141a.401 Bacitracin.

141a.402 Bacitracin ointment; zinc bacitracin ointment.

141a.403 Bacitracln tablets; zinc bacitracin tablets.

141a.404 Bacitracin troches; zinc bacitracin troches.

141a.405 Bacitracin with vasoconstrictor.

141a.406 Bacitracin-tyrothricin troches; zinc bacitracin-tyrothricin troches.

141a.407 Bacitracin-tyrothricin ointment.

141a.408 Bacitracin ophthalmic.

141a.409 Bacitracin ointment.

141a.410 Bacitracin-neomycin tablets; zinc bacitracin-neomycin tablets.

141a.411 Bacitracin-neomycin ointment.

141a.412 Bacitracln-polymyxin tablets.

141a.413 Bacitracin-neomycin troches; zinc bacitracin-neomycin troches.

141a.414 Bacitracin-neomycin with vasoconstrictor.

141a.415 Bacitracin-polymyxin troches; zinc bacitracin-polymyxin troches.

141a.416 Bacitracin-polymyxin troches; zinc bacitracin-polymyxin troches; zinc bacitracin-neomycin-polyoxymyxin troches.

141a.417 Bacitracin-tyrothricin- Neomycin troches; zinc bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches.

141a.418 Bacitracin-tyrothricin-neomycin ointment.

141a.419 Bacitracin-neomycin—polyoxymyxin troches; zinc bacitracin-neomycin—polyoxymyxin troches.

141a.420 Bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches.

141a.421 Bacitracin-neomycin—polyoxymyxin ointment.

141a.422 Bacitracin—polyoxymyxin—neomycin ointment.

141a.423 Soluble bacitracin methylene disalicylate.

141a.424 Bacitracin—neomycin—polyoxymyxin with vasoconstrictor.

141a.425 Bacitracin powder.

141a.426 Tablets bacitracin methylene disalicylate and streptomycin sulfoxide oral veterinary.


§ 141a.401 Bacitracin—(a) Potency—(1) Plate assay. Using the standard curve technique, proceed as directed in

§ 141a.1 (b) of this chapter, with the following exceptions:

(i) Use the bacitracin working standard to prepare a 1-percent bacitracin phosphate buffer to make an appropriate stock solution. The stock solution when refrigerated may be used for 2 weeks. The stock solution may also be frozen for 3 months and thawed by rinsing in small aliquots. Each aliquot should be sufficient for 1 day's use only. Make all dilutions of the stock solution for the assay with 1-percent phosphate buffer.

(ii) Dissolve the sample to be assayed in 1-percent phosphate buffer and make dilutions with the same solvent to one unit per milliliter (estimated).

(iii) The test organism is Micrococcus flavus, which is maintained at a refrigerator temperature on slants of nutrient agar prepared as directed in § 141a.1 (b) (1) of this chapter. Inoculate a Roux bottle containing this agar from a stock slant of the organism and incubate 18 hours at 32° ± 3° C. Wash off the cells from the agar in 25 ml of phosphate buffered physiological saline solution. If an aliquot of this bulk suspension, when diluted 1:50 in physiological saline solution, gives 75 percent light transmission in the light transmission with the micrococcus photoelectric colorimeter equipped with a filter having a wavelength of 6,500 Angstrom units, the bulk suspension is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution so that an aliquot of the adjusted suspension diluted 1:50 gives 75 percent light transmission. (The adjusted bulk suspension only after the 1:50 dilution of it, is used in preparing the seed layer.) Add 0.3 to 0.5 milliliter of the adjusted bulk suspension to 100 milliliters of agar which has been melted and cooled to 48° C.

(ii) Turbidimetric assay. In lieu of the plate-assay method described above, the sample may be assayed for potency by the following turbidimetric method:

(i) Test culture agar. Employ the agar described in § 141a.1 (b) (2) of this chapter (adjusted to a final pH 7.0) for maintaining the test organism, with the Staphylococcus aureus (PCF) strain (ATCC 12503) Transfer stock cultures every 2 weeks for test purposes. On the day of test transfer the growth from a stock slant to approximately 100 milliliters of nutrient broth (§ 141a.1 (b) (2) of this chapter) Incubate the inoculated broth until the culture has grown sufficiently to give a light transmission reading of 80–90 percent, using a filter having a light transmission peak at 6500 Angstrom units. This culture may be held over night at refrigerator temperature if desired. Prepare the "daily" inoculum described above to each tube of the standard and unknown series and place immediately in a 32° ± 2° C. water bath for 4 hours. After incubation for 4 hours of formalin to each tube, and estimate the turbidity of each in a photoelectric colorimeter, using a broad-band filter having a wave length of 6300 Angstrom units.

(iv) Estimation of potency. Average the six colorimeter readings at each standard level. Plot the average turbidity figures of the standard on semilog graph paper, employing units per tube as the abscissa (log scale) and light transmission as the ordinate. Connect the points with a straightedge. Average the six samples readings and read in units per tube from the curve. The quot should be sufficient for 200 units per milliliter, or 200 units per milliliter. The inject dose 1.0 milliliter per kilogram of solution containing 300 units per milliliter. Use physiological salt solution as the diluent.

(v) Toxicity. Inject intravenously each of five mice within the weight range of 18–25 grams with 0.5 milliliter of a solution of the sample prepared by diluting with sterile physiological salt solution to 200 units per milliliter. The injection should be made over a period of not more than 5 seconds. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with five unused mice weighing 20 grams (±0.5 gram) each. If all animals survive the repeat test the sample is nontoxic.

(a) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

(b) pH. Proceed as directed in § 141a.5 (b) of this chapter, using a solution containing 10,000 units per milliliter.

§ 141a.402 Bacitracin ointment; zinc bacitracin ointment—(a) Potency. Proceed as directed in § 141a.401 (a), except § 141a.401 (a) (3) and in lieu of the directions in § 141a.401 (a) (1), (iii), prepare the sample as directed in § 141a.1 (a) (2) of this chapter. Its content of zinc bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.8 (b) of this chapter.

§ 141a.403 Bacitracln tablets; zinc bacitracin tablets—(a) Potency. Pro-
ceed as directed in §141a.401 (a) except §141a.401 (a) (3) and in lieu of the directions in §141a.401 (a) (1) (ii) place 5 tablets in a blending jar and add thereto 125 milliliters of 1-percent phosphate buffer pH 6.0. After blending with a high-speed blender, add an additional 125 milliliters of buffer to the blender. Blend again for 1 minute and make the proper estimated dilutions with phosphate buffer pH 6.0. The content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

§141a.401 Bacitracin troches; zinc bacitracin troches—(a) Potency. Proceed as directed in §141a.403 (a). The average potency of the troche is satisfactory if it is not less than 85 percent of the number of units per troche that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

§141a.405 Bacitracin with vasoconstrictor—(a) Potency. Proceed as directed in §141a.401 (a) except subparagraph (3) thereof. The potency of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per container that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

§141a.407 Bacitracin—lyothromin troches; zinc bacitracin—lyothromin troches—(a) Potency. Proceed as directed in §141a.401 (a) (its) content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per troche that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

§141a.408 Bacitracin ophthalmic—(a) Potency. Proceed as directed in §141a.401 (a)

(b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

(c) pH. Proceed as directed in §141a.5 (b) of this chapter, using a solution prepared as directed in the labeling for the drug.

(d) Sterility. Proceed as directed in §141a.2 of this chapter, except that:

(1) Do not use penicillinase or the control tube in the test for bacteria if no tube shows growth.

(2) In lieu of the last sentence of §141a.2 (b) of this chapter, the batch meets the requirements of the test for bacteria if no tube shows growth.

§141a.409 Bacitracin-polyoxymycin—(a) Potency—(1) Bacitracin content. Proceed as directed in §141a.402 (a) Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(b) Polyoxymycin content. Proceed as directed in §141a.410 (b) (1) of this chapter, except in lieu of the directions in subdivision (vii) for the preparation of the sample, prepare the sample as follows: Accurately weigh approximately 5 grams of the sample and place into a high-speed blender that contains approximately 50 milliliters of peroxide-free ether. Shake with a high-speed blender, add an additional 125 milliliters of buffer to the blender. Blend again for 1 minute and make the proper estimated dilutions with phosphate buffer pH 6.0. The content of polyoxymycin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.8 (b) of this chapter.

§141a.410 Bacitracin—neomycin tablets; zinc bacitracin—neomycin tablets—(a) Tablets—(1) Potency—(i) Bacitracin or zinc bacitracin content. Proceed as directed in §141a.401 (a) (its) content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(ii) Neomycin content. Proceed as directed in §141a.401 (a) except subparagraph (3) thereof. The potency of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of milligrams of activity that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

(b) Neomycin used in making the tablets—(1) Potency—(i) Curtain and cover (cup) Use cylinders described under §141a.1 (a) of this chapter.

(ii) Culture medium. Use the medium described in §141a.1 (b) (1) of this chapter for both the base and seed layers, except its pH after sterilization is 7.8 to 8.0.

(iii) Working standard. Dry the working standard (obtained from the Food and Drug Administration) for 5 hours at 100° C. and a pressure of 3 millimeters or less and weigh out a sufficient quantity to make a convenient stock solution. Further dilute volumetrically this solution with 0.1 percent phosphate buffer pH 8.0. After a period of 1 hour at 30° C. and a pressure of 3 millimeters or less, may be used for a period not exceeding 1 month.

(iv) Standard curve. Prepare daily from the stock solution a standard curve as directed in §141b.101 (d) of this chapter, using solutions of the neomycin working standard in phosphate buffer, pH 7.8 to 8.0. The stock solution, when tested at a temperature of approximately 15° C., or less, may be used for a period not exceeding 1 month.

(b) Polyoxymycin content. Using an aliquot of the solution prepared in accordance with the procedure for the bacitracin content, proceed as directed in §141a.409 (b) (4). Its content of polyoxymycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (b) of this chapter.

§141a.412 Bacitracin—polyoxymycin tablets—(a) Potency—(1) Bacitracin content. Proceed as directed in §141a.403 (a). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) Polyoxymycin content. Using an aliquot of the solution prepared in accordance with subparagraph (1) of this paragraph, proceed as directed in §141b.112 (a) (iv) of this chapter. Its content of polyoxymycin is satisfactory if it contains not less than 85 percent of the
number of units it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.413 Bacitracin-neomycin troches; zinc bacitracin-neomycin troches—(a) Potency—(1) Content of bacitracin and zinc bacitracin. Proceed as directed in § 141e.405 (a). Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) Neomycin content. Proceed as directed in § 141e.410 (a) (1) (i) Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.414 Bacitracin-neomycin with vasconstrictor—(a) Potency—(1) Bacitracin content. Proceed as directed in § 141e.405 (a). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) Neomycin content. Proceed as directed in § 141e.410 (b) (1). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.415 Bacitracin-polymyxin troches; zinc bacitracin-polymyxin troches—(a) Potency—(1) Polymyxin content. Dissolve 5 troches in a small amount of 1-percent phosphate buffer pH 6.0, then add sufficient buffer to give a concentration of 100 units per milliliter and proceed as directed in § 141b.112 (b) (1) of this chapter. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) Contaminants. Proceed as directed in (2) Contaminants. Using an aliquot of the solution prepared in subparagraph (1) of this paragraph, proceed as directed in § 141e.401 (a) (1). Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.416 Bacitracin methylene disalicylate—(a) Potency. Proceed as directed in § 141e.401 (a) (1), except in lieu of the directions for preparing the sample in § 141e.401 (a) (4) (i) prepare the sample as follows: Place an accurately weighed sample of approximately 1 gram in a blending jar, add 50 milliliters of a 0.2-percent aqueous solution of polyethylene glycol 8000 and blend for 3 minutes in a high-speed blender. Allow the foam to subside, remove an aliquot of the solution, and dilute to 1 unit per milliliter with 1-percent phosphate buffer.

(b) Toxicity. Proceed as directed in § 141d.305 (b) of this chapter, using as the test dose 1 milliliter of a suspension containing 1,000 units of bacitracin activity per mouse.

(c) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

(d) pH. Prepare a saturated solution, using approximately 100 milligrams of the sample per milliliter and proceed as directed in § 141a.5 (b) of this chapter.

(e) Zinc content—(1) Reagents—(i) 8-hydroxyquinoline solution. Dissolve 1 gram of 8-hydroxyquinoline in 15 milliliters of acetic acid. Dilute to 100 milliliters with distilled water and filter if not clear. Do not use this solution if it is 2 weeks old.

(2) Procedure. Accurately weigh approximately 500 milligrams of the sample in a 400-milliliter beaker. Dissolve the sample in 5 milliliters of 10-percent acetic acid and dilute to about 100 milliliters with distilled water. Heat the solution to 70° C–80° C and then add 10 milliliters of the 8-hydroxyquinoline reagent. Slowly add the ammonium acetate solution until a pH of 4.0–5.1 is reached (usually about 20 milliliters is required). Heat just below the boiling point for 2–5 minutes and then allow to cool for 30–60 minutes. Filter through a tared Gooch crucible, wash the precipitate thoroughly with distilled water, and dry to constant weight at 120°C–140°C. Calculate the percentage of zinc content as follows:

Percent zinc = weight of precipitate × 18.40

weight of sample in milligrams

§ 141e.419 Bacitracin-neomycin-poly- myxin troches—(a) Potency—(1) Neomycin content. Proceed as directed in § 141e.410 (a) (1) (ii) Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams of activity that it is represented to contain.

(2) Polymyxin content. Proceed as directed in § 141e.415 (a) (1), except calculate from the quantity of polymyxin found (using the method prescribed in subparagraph (1) of this paragraph) the quantity of neomycin that would be contained in the sample if it contained 100 units of polymyxin (expressed as potency) per milliliter. Prepare the polymyxin standard curve by adding this calculated quantity of neomycin to each concentration of polymyxin used for the curve. Use this standard curve to calculate the polymyxin content of the sample. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(3) Content of bacitracin or zinc bacitracin. Using an aliquot of the solution prepared in subparagraph (2) of this paragraph, proceed as directed in § 141e.401 (a) (1) Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) Moisture. Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.420 Bacitracin-tyrothricin-neo- mycin troches; zinc bacitracin-tyrothricin-neomycin troches—potency and...
mucosa. Proceed as directed in §141e.413 (a) and (b). §141e.423 Bacitracin-neomycin-poly-
mixed tablets.—(a) Potency. Proceed as directed in §141e.409 (a). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per tablet that is represented to contain.

(2) Neomycin content. Proceed as directed in §141e.410 (a) (1) (ii) Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per tablet that is represented to contain.

(3) Polymyxin content. Proceed as directed in §141b.112 (a) (1) (ii) of this chapter, except calculate from the quantity of neomycin found (using the method prescribed in subparagraph (2) of this paragraph) the quantity of neomycin that would be present when the sample is diluted to contain 100 units of polymyxin (labeled potency) per milliliter. Prepare the polymyxin standard curve by adding this calculated quantity of neomycin to each concentration of polymyxin used for the curve. Use this standard curve to calculate from the quantity of polymyxin found in the sample as follows: Place an accurately weighed sample of approximately 1 to 5 grams in a 100-milliliter volumetric flask, dissolve in water, and dilute to 100 milliliters with water. Dilute a suitable aliquot with 1-percent phosphate buffer to a concentration of 1 unit per milliliter. Proceed as directed in §141e.415 (a) of this chapter. (c) pH. Proceed as directed in §141e.415 (b) of this chapter, using a solution containing 400 units per milliliter. §141e.424 Bacitracin-neomycin-poly-
myxin tablets.—(a) Potency. Proceed as directed in §141e.409 (a). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the bacitracin activity per pound that it is represented to contain.

(2) Neomycin content. Proceed as directed in §141e.401 (a). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain. (3) Polymyxin B content. Proceed as directed in §141b.112 (b) (1) of this chapter, except that: (I) Calculate from the quantity of polymyxin found in the sample as follows: Place an accurately weighed sample of approximately 1 to 5 grams in a 100-milliliter volumetric flask, dissolve in water, and dilute to 100 milliliters with water. Dilute a suitable aliquot with 1-percent phosphate buffer to a concentration of 1 unit per milliliter estimated) Its potency is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(b) Moisture. Proceed as directed in §141a.5 (a) of this chapter.

PART 146—GENERAL REGULATIONS FOR THE CERTIFICATION OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

§146.2 Definitions and interpretations. (a) Each of the several antibiotic substances (e. g. penicillin F, penicillin G, penicillin Z) produced by the growth of Penicillium notatum or Penicillium chrysogenum, and each of the same substances produced by any other means, is a kind of penicillin.

(b) Of each of the several antibiotic substances produced by the growth of Strep-
tomyces griseus, and of the same substances produced by any other means, is a kind of streptomycin.

(b) Each of the antibiotic substances produced by the growth of Streptomycyes aureofaciens, and each of the same substances produced by any other means is a kind of chloramphenicol.

d) Each of the several antibiotic substances produced by the growth of Streptomycyes aureofaciens, and each of the same substances produced by any other means is a kind of tetracycline.

(f) Each of the several antibiotic substances produced by the growth of Streptomycyes aureofaciens, and each of the same substances produced by any other means is a kind of tetracycline.

g) Each of the several antibiotic substances produced by the growth of Streptomycyes aureofaciens, and each of the same substances produced by any other means is a kind of tetracycline.

(h) Each of the several antibiotic substances produced by the growth of Streptomycyes aureofaciens, and each of the same substances produced by any other means is a kind of tetracycline.

(i) Each of the several antibiotic substances produced by the growth of Streptomycyes aureofaciens, and each of the same substances produced by any other means is a kind of tetracycline.
The initial request for certification of a batch of any drug submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of each batch, including a description of (1) the methods and apparatus used in the manufacture and test of the drug; (2) the tests and assays of the drug made during the manufacture of the batch and after it is packaged; and (3) any other auxiliary facilities used in such controls. Such initial request shall also be preceded or accompanied by the key of the batch marks used by such person and by speciments of all labeling (including specimen of all brochures and other printed matter except readily available medical publications, referred to in such labeling) to be used for such drug. When any change is made in any such facility or control, or in any such key or labeling, such person shall promptly submit to the Commissioner a full statement of such change or, in the case of a change in labeling, speciments showing all such changes.

Each sample submitted pursuant to the regulations in this part shall be addressed to the Commissioner. Its package or identity shall be set forth on its contents as well as the name and post-office address of the person submitting it.

In addition to the information and samples specifically required to be submitted to the Commissioner by the regulations in this part, the person who requests certification of a batch shall submit all information and samples as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements of §146.3 for the issuance of a certificate.

The request for any person, stating reasonable grounds therefor, the Commissioner shall furnish such person with a portion of the working standards.

§146.3 Certification. (a) If it appears to the Commissioner, after such investigation as he considers necessary, if the information (including results of tests and assays) and samples required by or pursuant to the regulations in this part have been submitted, and the request for certification contains no untrue statement of a material fact, and

(1) The batch complies with the regulations in this part; or

(2) The batch complies with the applicable standards of identity, strength, quality, and purity prescribed by the regulations in this part; the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of certificates as are prescribed by §146.4, and shall issue to the person who requested certification, stating his reasons for refusal.

(2) Compliance of a drug with the standards of identity, strength, quality, and purity prescribed by regulations in this part shall be determined by the tests and assays required for such drug by regulations in Parts 151 to 154 of this chapter.

§146.4 Conditions on the effectiveness of certificates. (a) A certificate shall not become effective:

(1) If it is obtained through fraud or misrepresentation or concealment of a material fact;

(2) With respect to any package unless it complies with the packaging requirements, if any, prescribed by the regulations in this part which were in effect on the date of the certificate;

(3) With respect to any package unless its label and labeling bear all words, statements, and other information required by the regulations in this part; or

(4) With respect to any package of penicillin, streptomycin, dihydrostreptomycin, chlorotetracycline, chloramphenicol, or bacitracin, when it is included in a packaged combination with another drug, unless such other drug complies with the requirements of the regulations in this part.

(b) A certificate shall cease to be effective:

(1) With respect to any immediate container after the expiration date, if any, prescribed by the regulations in this part;

(2) With respect to any immediate container when it or its seal (if the regulations in this part require it to be sealed) is broken, or when its label or labeling is altered, mutilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling requirement prescribed by the regulations in this part, except that:

(i) If the drug in such container is re-packaged or used as an ingredient in the manufacture and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch;

(ii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued by a practitioner licensed by law to administer such drug, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch;

(iii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued by a pharmacist licensed by law to administer such drug, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch; or

(iv) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested, as provided by §146.6.

(3) With respect to any immediate container of penicillin when it is included in the packaged combination penicillin with albusol, or penicillin with a vasoconstrictor, or to any immediate container of bacitracin when it is included in the packaged combination bacitracin with a vasoconstrictor, except that when certification of the batch or package is requested, such certificate shall continue to be effective for a reasonable time to permit certification of such batch which is part of such combination.

With respect to any package when the drug therein fails to meet the standards of identity, strength, quality, and purity which were in effect on the date of the certificate, except that those minor changes which occur before the expiration date and which are normal and unavoidable in good storage and distribution practice shall be disregarded.

(5) With respect to any package of penicillin, streptomycin, dihydrostreptomycin, chlorotetracycline, chloramphenicol, or bacitracin, included in a packaged combination with another drug, when such other drug fails to meet the requirements of the regulations in this part;

(6) With respect to any immediate container, if such regulations require its labeling to bear a caution against dispensing otherwise than on prescription, at the beginning of the act of dispensing or offering to dispense it otherwise than:

(i) By a practitioner licensed by law to administer such drug; or

(ii) On his prescription issued in his professional practice.

§146.5 Records of distribution. (a) The person who requests and shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person acting in his behalf.

(b) The certificate shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than three years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§146.6 Authority to refuse certification service. When the Secretary finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by §146.5, and such failure may materially impair the certification service;

the Secretary will immediately suspend the authority to refuse certification service to such person under the regulations in this part and will continue such suspension unless and until such person shall show cause why such service should be resumed.
§ 146.7 New antibiotic and antibiotic-containing products. Any request that the Secretary provide, for the certification of batches of a drug for which no provision for certification is made in the existing regulations in this part shall be in a form specified by the Commissioner and shall be accompanied by a statement of the conditions for which the person who makes such request intends such drug to be used, and adequate specifications for use in such conditions; (a) A statement of the conditions for which the person who makes such request intends such drug to be used, and adequate specifications for use in such conditions; (b) Full reports of investigations which have been made to show whether not such drug is safe and efficacious for use in such conditions; (c) A full list of the articles used as components of such drug; (d) A full statement of the composition of such drug; (e) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (f) Full descriptions of, or references to, publications containing practical and accurate tests and methods of assay to determine the identity, strength, quality, and purity of such drug; (g) Such samples of such drug and of the articles used as components thereof as the Commissioner may require; and (h) Specifications including all brochures and other printed matter, except readily available medical publications, referred to in such labeling proposed to be used for such drug.

§ 146.9 Antibiotics for agricultural use. An article that contains one or more of the antibiotic substances described in this part and intended solely for application to plants for the control of plant diseases caused by microorganisms and conspicuously so labeled is not subject to the requirements of sections 502 (i) and 507 of the Federal Food, Drug, and Cosmetic Act, if it contains one or more suitable denaturants that make it unfit for drug use; but no case shall be exempt from the requirements of sections 502 (i) and 507 of the act if it is represented or intended to be administered to man or other animals for the prevention or treatment of disease or as an animal feed supplement.

§ 146.10 Antibiotics for export. Drugs containing penicillin, streptomycin, dihydrostreptomycin, chlorotetracycline, chloramphenicol, or bacitracin, or bacitracin, which are certified for export under the regulations in this part, shall be exempt from the requirements of section 502 (i) and 507 of the act or § 146.23; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of providing the service during an elapsed period of time, us the light of all circumstances and contingencies, warrants of the performance of the service during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under § 146.18.

§ 146.11 Exemptions for labeling. An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such labeling is to be done.

(2) In case the applicant is the operator of such establishment, the application shall include a written agreement signed by him that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801 (d) of the act or § 146.33; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of providing the service during an elapsed period of time, us the light of all circumstances and contingencies, warrants of the performance of the service during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under § 146.18.

§ 146.12 Fees. (a) Fees for the services rendered under the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Treasurer of the United States, collectible at par at Washington, D. C. All such deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D. C., whereupon after making appropriate records thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Bureau of the Treasury Department, for deposit to the special account “Certification and Inspection Services, Food and Drug Administration.”

§ 146.13 Exemptions from the requirements of section 502 (i) or § 146.23. An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such labeling is to be done. (2) In case the applicant is the operator of such establishment, the application shall include a written agreement signed by him that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801 (d) of the act or § 146.33; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of providing the service during an elapsed period of time, us the light of all circumstances and contingencies, warrants of the performance of the service during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under § 146.18.

§ 146.14 Exemptions for labeling. (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be labeled at an establishment located elsewhere in the United States shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from the requirements of section 502 (i) of the act or § 146.23. An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such labeling is to be done.

(2) In case the applicant is the operator of such establishment, the application shall include a written agreement signed by him that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801 (d) of the act or § 146.33; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of providing the service during an elapsed period of time, us the light of all circumstances and contingencies, warrants of the performance of the service during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under § 146.18.
§ 146.19 Exemptions for storage. (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of any such drug to be stored at a warehouse located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such warehouse, from the requirements of section 502 (1) of the act if the labeling of each shipping container bears the batch mark of the drug, or if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for storage in such warehouse.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the warehouse in which such drug is to be stored. Such application shall be accompanied by:

(1) A written agreement closed by the applicant and the Commissioner that each batch thereof unless it is exempt under section 501 (d) of the act or §§ 146.18, 146.21, or 146.22, that he will not remove any of such drug from such warehouse unless it complies with section 502 (1) of the act or is exempt from its requirements, unless such drug is to be reprocessed and certification, destruction, or such exemption at the establishment where it was manufactured.

(2) A written statement signed by the operator of such warehouse in such form as he may require in advance of such storage that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery; and

§ 146.20 Exemptions for processing. (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of any such drug to be reprocessed and certification, destruction, or such exemption at the establishment where it was manufactured.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such processing is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and delivery of any such drug reprocessed and certification, destruction, or such exemption at the establishment where it was manufactured.

(2) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and delivery of any such drug to be reprocessed and certification, destruction, or such exemption at the establishment where it was manufactured.

(3) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and delivery of any such drug to be reprocessed and certification, destruction, or such exemption at the establishment where it was manufactured.
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cer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery, and that he will make complete, accurate, and legible records showing the date of receipt thereof, and the quantity and batch mark of each such shipment and delivery and the disposition thereof, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the processing is completed that he will request certification of each batch thereof unless it is exempt under the provisions of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (d) of the act. A written agreement signed by the applicant that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery, and the disposition thereof, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the operator of such establishment showing that he has adequate facilities for such repacking; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery, and the disposition thereof, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(2) A written statement signed by the person who introduced such shipment or delivery into interstate commerce showing that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery, or any part thereof, from or after processing, from such establishment unless it complies with section 502 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23 or, if certification is refused, unless such shipment or delivery is reprocessed and certified, or returned to permit reprocessing and certification, or such exemption at the establishment where it was manufactured.

§ 146.22 Exemptions for manufacturing use. (a) Except as provided by paragraphs (d) and (e) of this section, a shipment or other delivery of penicillin, streptomycin, dihydrostreptomycin, chloramphenicol, or bacitracin which is packed in containers of not less than 10,000,000 units of penicillin or 10 grams of streptomycin, dihydrostreptomycin, chlorotetracycline, chloramphenicol, or bacitracin each of which is intended for manufacturing use in such establishment shall be exempt, during the time of its introduction into and movement in interstate commerce and the time of holding in such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery, or any part thereof, from or after processing, from such establishment unless it complies with section 502 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, or such exemption at the establishment where it was manufactured.

§ 146.21 Exemptions for repacking. (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be repacked at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of such repacking and delivery, until the time of holding in such establishment from the requirements of section 502 (l) of the act and from the regulations in this part which is specifically applicable to such other drug, if the label of the container bears the batch mark of the drug and the number of units per package, and if the person who introduces such shipment or delivery into interstate commerce shall make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery, or any part thereof, from or after processing, from such establishment unless it complies with section 502 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, or such exemption at the establishment where it was manufactured.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery, or any part thereof, from or after processing, from such establishment unless it complies with section 502 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23 or, if certification is refused, unless such shipment or delivery is reprocessed and certified, or returned to such person for labeling or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, or such exemption at the establishment where it was manufactured.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery, or any part thereof, from or after processing, from such establishment unless it complies with section 502 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, or such exemption at the establishment where it was manufactured.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery, or any part thereof, from or after processing, from such establishment unless it complies with section 502 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, or such exemption at the establishment where it was manufactured.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.
years after the date of such shipments or delivery into interstate commerce, shall be exempt from the requirements of such paragraph to be kept and made available for inspection is not kept or made available as so required.

(d) An exemption under paragraph (a) or (b) of this section shall become void if any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery for such drug imported has caused an exemption to become void as provided by paragraph (c) or (d) of this section.

§ 146.24 Penicillin for diagnostic use; streptomycin for diagnostic use; dihydrostreptomycin for diagnostic use; chloramphenicol for diagnostic use; tetracycline for diagnostic use; chlortetracycline for diagnostic use; bacitracin for diagnostic use. (a) Penicillin, streptomycin, dihydrostreptomycin, chloramphenicol, tetracycline, chlortetracycline, bacitracin, and use in laboratory diagnosis for diagnostic use; for use in laboratory diagnosis only.
(2) It is intended for use solely in the control of coccidial outbreaks in poult-}


dier feed, not less than 0.015 or not more than 0.3 grams of chlortetracycline per ton of feed. When intended for such use it may also contain oxytetracycline in a quantity, by weight of feed, not less than 0.033 percent and not more than 0.1 percent.

(ii) Nitrobenzene: 0.05 percent.

(iii) Nitrofurazone: 0.0112 percent.

(iv) Sodium arsinite: Not less than 0.0025 or not more than 0.033 percent.

(a) It is intended for use solely as an ingredient in the manufacture of animal feed and conspicuously so labeled, and it contains not more than 0.05 percent of the act under the requirements of sections 502 (1) and 507 of the act if it complies with the following conditions:

(b)(i) It is intended for use solely in the prevention of outbreaks of histomoniasis ("blackhead") in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) 3-Amino-5-nitrothiazole: 0.05 percent.

(ii) 4-Nitrophenylarsenic acid: 0.05 percent.

(iii) Furazolidone: 0.011 percent.

(iv) Sulfaquinoxaline: Not less than 0.005 or not more than 0.0125 percent.

(v) Nicotine, not less than 0.3 percent and not more than 1.0 percent, and nicotine, not less than 0.005 percent and not more than 0.05 percent.

(vi) Sodium fluoride: 0.1 percent.

(vii) Cadmium oxide, 0.015 percent.

(viii) Sodium fluoride, not less than 0.5 percent and not more than 0.1 percent.

(v) It is intended for use solely as an antimetic for poultry or swine, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) Phenothiazine, not less than 0.05 percent.

(ii) Phenothiazine, 0.03 percent.

(iii) Phenothiazine, not less than 0.3 percent and not more than 1.0 percent, and nicotine, not less than 0.05 percent and not more than 0.5 percent.

(vi) Sodium fluoride, 0.3 percent and sodium sulfate 2.0 percent.

(vii) Cadmium anthranilate, 0.044 percent.

(viii) Cadmium oxide, 0.015 percent.

(ix) Sodium fluoride, not less than 0.5 percent and not more than 1.0 percent.

(6) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection) and hexamitiosis in poultry, infectious swine enteritis, and/or calf scours; its labeling bears adequate directions and warnings for such use; and it contains not less than 50 grams of chlortetracycline per ton of feed.

When intended for such use it may also contain oxytetracycline in a quantity, by weight of feed, not less than 0.033 percent and not more than 0.1 percent.

(ii) Nitrobenzene: 0.05 percent.

(iii) Nitrofurazone: 0.0112 percent.

(iv) Sulfaquinoxaline: Not less than 0.0025 or not more than 0.033 percent.

(a) It is intended for use solely as an ingredient in the manufacture of animal feed, not less than 0.015 or not more than 0.3 grams of chlortetracycline per ton of feed. When intended for such use it may also contain oxytetracycline in a quantity, by weight of feed, not less than 0.033 percent and not more than 0.1 percent.

(ii) Nitrobenzene: 0.05 percent.

(iii) Nitrofurazone: 0.0112 percent.

(iv) Sulfaquinoxaline: Not less than 0.0025 or not more than 0.033 percent.

(a) It is intended for use solely as an ingredient in the manufacture of animal feed, not less than 0.015 or not more than 0.3 grams of chlortetracycline per ton of feed. When intended for such use it may also contain oxytetracycline in a quantity, by weight of feed, not less than 0.033 percent and not more than 0.1 percent.

(ii) Nitrobenzene: 0.05 percent.

(iii) Nitrofurazone: 0.0112 percent.

(iv) Sulfaquinoxaline: Not less than 0.0025 or not more than 0.033 percent.

(a) It is intended for use solely as an ingredient in the manufacture of animal feed, not less than 0.015 or not more than 0.3 grams of chlortetracycline per ton of feed. When intended for such use it may also contain oxytetracycline in a quantity, by weight of feed, not less than 0.033 percent and not more than 0.1 percent.
plex with 2-hydroxy-4,6-dimethylpyrimidinicarbazin (4,4"-dinitrocarbanilde complex) and it contains the equivalent of not less than 25 grams of oxytetracycline per ton of feed if it also contains not less than 25 grams of oxytetracycline per ton of feed and it contains furazolidone in a quantity, by weight of feed, of 0.0075 percent, if intended for prevention of the diseases in birds older than 2 weeks, or 0.011 percent, if intended for prevention of the diseases in birds younger than 2 weeks, or for the treatment of the diseases in birds older than 2 weeks, or for the treatment of the diseases in birds younger than 2 weeks, or for the treatment of the diseases in birds older than 2 weeks, or for the treatment of the diseases in birds older than 2 weeks.

(16) It is intended for use solely in the prevention of chromosomal respiratory disease (air-sac infection) hematomatosis, fowl typhoid, pullorum, and the paratyphoids in poultry; its labeling bears adequate directions and warnings for such uses; it contains not less than 50 grams of chlortetracycline per ton of feed (except that it may contain not less than 25 grams of chlortetracycline per ton of feed if it also contains not less than 25 grams of oxytetracycline per ton of feed) and it contains furazolidone in a quantity, by weight of feed, of 0.0075 percent, if intended for prevention of the diseases in birds older than 2 weeks, or 0.011 percent, if intended for prevention of the diseases in birds younger than 2 weeks, or for the treatment of the diseases in birds older than 2 weeks, or for the treatment of the diseases in birds older than 2 weeks, or for the treatment of the diseases in birds older than 2 weeks, or for the treatment of the diseases in birds older than 2 weeks.

(17) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) nonspecific enteritis, blue comb, and infectious anemia, fowl typhoid, pullorum, and the paratyphoids in poultry; its labeling bears adequate directions and warnings for such uses; it contains not less than 50 grams of oxytetracycline per ton of feed (except that the quantity of oxytetracycline may be 50 grams per ton if it also contains 50 grams per ton of oxytetracycline) and it contains furazolidone in a quantity, by weight of feed, of 0.011 percent, if intended for use solely in the treatment of chronic respiratory disease (air-sac infection) nonspecific enteritis, infectious anemia, and blue comb in poultry; its labeling bears adequate directions and warnings for such uses; and it contains not less than 100 grams of bacitracin activity, if intended for treatment of the diseases.

(18) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) nonspecific enteritis, infectious anemia, and blue comb in poultry; its labeling bears adequate directions and warnings for such uses; and it contains not less than 100 grams of bacitracin G master standard per ton of feed.

(19) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) nonspecific enteritis, infectious anemia, and blue comb in poultry; its labeling bears adequate directions and warnings for such uses; and it contains not less than 100 grams of bacitracin G master standard per ton of feed.

(20) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) nonspecific enteritis, infectious anemia, and blue comb in poultry; its labeling bears adequate directions and warnings for such uses; and it contains not less than 100 grams of bacitracin G master standard per ton of feed.

(21) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) nonspecific enteritis, infectious anemia, and blue comb in poultry; its labeling bears adequate directions and warnings for such uses; and it contains not less than 100 grams of bacitracin activity, if intended for treatment of the diseases.

(22) It is intended for use solely in the prevention or treatment of outbreaks of histomoniasis ("blackhead") in turkeys and flocks, and it contains 2-acetylaminohexalimoozothiazole in a quantity, by weight of feed, of 0.015 percent if intended for the prevention of the disease, or 0.05 percent if intended for the control of the disease, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in subdivision (1) of this paragraph, and in the amounts specified in that paragraph.

(23) It is intended for use solely in the prevention or control of outbreaks of histomoniasis ("blackhead") in turkeys and flocks, and it contains 2-acetylaminohexalimoozothiazole in a quantity, by weight of feed, of 0.015 percent if intended for the prevention of the disease, or 0.05 percent if intended for the control of the disease, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in subdivision (1) of this paragraph, and in the amounts specified in that paragraph.

(24) It is intended for use solely in the prevention or control of outbreaks of histomoniasis ("blackhead") in turkeys and flocks, and it contains 2-acetylaminohexalimoozothiazole in a quantity, by weight of feed, of 0.015 percent if intended for the prevention of the disease, or 0.05 percent if intended for the control of the disease, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in subdivision (1) of this paragraph, and in the amounts specified in that paragraph.

(25) It is intended for use solely in the prevention or control of outbreaks of histomoniasis ("blackhead") in turkeys and flocks, and it contains 2-acetylaminohexalimoozothiazole in a quantity, by weight of feed, of 0.015 percent if intended for the prevention of the disease, or 0.05 percent if intended for the control of the disease, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in subdivision (1) of this paragraph, and in the amounts specified in that paragraph.

(26) It is intended for use solely in the prevention or control of outbreaks of histomoniasis ("blackhead") in turkeys and flocks, and it contains 2-acetylaminohexalimoozothiazole in a quantity, by weight of feed, of 0.015 percent if intended for the prevention of the disease, or 0.05 percent if intended for the control of the disease, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in subdivision (1) of this paragraph, and in the amounts specified in that paragraph.
referred to in §146.7, as well as any additional information necessary to establish the safety and efficacy of the article, and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in its manufacturing, processing, or repackaging, or the facilities and controls used for such manufacturing, processing, or repackaging, unless the person who obtains the exemption has submitted to the Commissioner, in triplicate, amended information describing such proposed changes and such amendment has been accepted by the Commissioner.

(ii) It is intended for use in the disease specified in subdivision (i) of this subparagraph, it contains the ingredients in the amounts and under the conditions specified in that subdivision, and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section and in the amounts specified in that paragraph.

§ 146.27 Antibiotics for fish diseases. Penicillin, streptomycin, dihydrostreptomycin, neomycin, oxytetracycline, tetracycline, chloramphenicol, or bacitracin intended for use solely in the treatment or prevention of disease in fish and conspicuously so labeled shall be exempt from the requirements of sections 502 (i) and 507 of the act.

§ 146.28 Antibiotics for bull semen. Penicillin, streptomycin, dihydrostreptomycin, chlorotetracycline, chloramphenicol, or bacitracin intended for use solely as a preservative for bull semen, and conspicuously so labeled, shall be exempt from the requirements of sections 502 (i) and 507 of the act.

§ 146.29 Biological drugs that contain antibiotics. Biological drugs that contain penicillin, streptomycin, dihydrostreptomycin, bacitracin, or chloramphenicol, and the purpose of the antibiotic is for use only as a preservative and the biological drug is conspicuously so labeled, shall be exempt from the requirements of sections 502 (i) and 507 of the act, if such drugs are licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 662; 42 U. S. C. 201 et seq.) or under the Virus-Toxin Act of March 4, 1913 (37 Stat. 832; 42 U. S. C. 210 et seq.) issued under sec. 701, 59 Stat. 1055; 21 U. S. C. 371, Interpret or apply sec. 607, 59 Stat. 463, as amended; 21 U. S. C. 357.

Part 146a—Certification of Penicillin-Containing Drugs

Sec. 146a.24 Sodium penicillin, calcium penicillin, calcium penicillin, and crystalline penicillin.

146a.25 Penicillin in oil and wax.

146a.26 Penicillin ointment.

146a.27 Penicillin tablets.

146a.28 Crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, potassium penicillin G, and penicillin G sodium.

146a.29 Penicillin with aluminum hydroxide gel.

146a.30 Penicillin troches.

146a.31 Penicillin dental cones.

146a.32 Penicillin with vasodilator; penicillin with vasodilator; penicillin with vasodilator.

146a.33 Penicillin for surface application.

146a.34 Tablets aluminum penicillin.

146a.35 Penicillin sulfonamide powder.

146a.36 Penicillin vaginal suppositories.

146a.37 Buffered crystalline penicillin.

146a.38 Capsules containing potassium penicillin with pectin hydrolysate.

146a.39 Capsules potassium penicillin in oil.

146a.40 Potassium penicillin.

146a.41 Crystalline penicillin and epinephrine in oil.

146a.42 Aluminum penicillin.

146a.43 Neomycin in oil.

146a.44 Procaine penicillin, procaine penicillin G.

146a.45 Procaine penicillin in oil.

146a.46 Crystalline penicillin for inhalation therapy.

146a.47 Procaine penicillin for aqueous injection.

146a.48 Ephedrine penicillin, ephedrine penicillin.

146a.49 Ephedrine penicillin tablets.

146a.50 Procaine penicillin and buffered crystalline penicillin for aqueous injection.

146a.51 Buffered penicillin powder, penicillin powder with buffered aqueous detergent.

146a.52 Procaine penicillin and crystalline penicillin in oil.

146a.53 Penicillin — streptomycin ointment; penicillin — dihydrostreptomycin ointment.

146a.54 Penicillin — streptomycin bougie; penicillin — dihydrostreptomycin bougie.

146a.55 Penicillin — streptomycin ointment.

146a.56 Penicillin with dihydrostreptomycin.

146a.57 Ephedrine penicillin, ephedrine penicillin.

146a.58 Procaine penicillin and streptomycin, penicillin and dihydrostreptomycin.

146a.59 Penicillin tooth powder.

146a.60 Penicillin H.L. troches.

146a.61 Crystalline penicillin and bacitracin.

146a.62 I-Ephedrine penicillin G.

146a.63 I-Ephedrine penicillin G in oil.

146a.64 I-Ephedrine penicillin G for aqueous injection.

146a.65 Procaine penicillin in streptomycin sulfate solution; procaine penicillin in dihydrostreptomycin sulfate solution.

146a.66 Benzathine penicillin G.

146a.67 Benzathine penicillin G oral suspension; benzathine penicillin G for oral suspension.

146a.68 Penicillin — streptomycin — bacitracin ointment; penicillin — dihydrostreptomycin — bacitracin ointment.

146a.69 Penicillin-streptomycin dental cones; penicillin-dihydrostreptomycin dental cones.

146a.70 Diethylaminoethyl ester penicillin G hydroiodide.

146a.71 Diethylaminoethyl ester penicillin G hydroiodide for aqueous injection.

146a.72 Penicillin-streptomycin implantation pellets; penicillin-dihydrostreptomycin implantation pellets.

146a.73 Benzathine penicillin G for aqueous injection.

146a.74 Benzathine penicillin G and buffered crystalline penicillin for aqueous injection.

146a.75 Chloroprocaine penicillin O.

146a.76 Chloroprocaine penicillin O for aqueous injection.

146a.77 Penicillin-streptomycin vaginal suppositories; penicillin-dihydrostreptomycin vaginal suppositories.

146a.78 Penicillin-streptomycin — bacitracin dental paste; penicillin-dihydrostreptomycin — bacitracin dental paste.

146a.79 Procaine penicillin and dihydrostreptomycin — bacitracin dental paste.

146a.80 Procaine penicillin and streptomycin — bacitracin dental paste.

146a.81 Procaine penicillin and dihydrostreptomycin — bacitracin dental paste.

146a.82 Penicillin-streptomycin sulfates, procaine penicillin-streptomycin sulfates, procaine penicillin-streptomycin sulfates.
line penicillin is the heat-stable crystalline sodium or potassium salt of one or more kinds of penicillin, but the quantity of any salt of penicillin therein is not more than 30 percent; crystalline penicillin G is crystalline penicillin which contains not less than 65 percent by weight of the sodium salt or potassium salt of penicillin G; crystalline penicillin O is crystalline penicillin which contains not less than 85 percent by weight of the sodium salt or potassium salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 500 units per milligram, except that if it contains not less than 50 percent of a salt of penicillin X its potency is not less than 350 units per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) Its moisture content is not more than 2.5 percent, unless it is crystalline penicillin in which case its moisture content is not more than 1.5 percent;

(6) Its pH in aqueous solution of from 3,000 to 10,000 units per milliliter is not less than 5.0 or more than 7.5.

(b) Packaging. In all cases the immediate containers shall be tight containers as defined by the U.S. P., shall be sterile at the time of filling and closing, shall contain such quantities and purities of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle is introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain 100,000 units, 200,000 units, 400,000 units, 1,000,000 units, 2,000,000 units, 3,000,000 units, 4,000,000 units, or 5,000,000 units, except that when packaged and labeled solely for dental use each such container may contain not less than 10,000 units, and each may be packaged in combination with a container of the solvent, water for injection U.S.P., destilled injection water, or an aqueous solution of a suitable local anesthetic.

(c) Labeling. Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date ___/___/___", the blank being filled in with the date which is 36 months after the batch was certified: Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statement "For Manufacturing Use," "For Repacking," or "For Manufacturing Use or Repacking" when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the immediate container, the statement "Sterile solution may be kept refrigerated but not in a freezer without significant loss of potency," the blank being filled in with the figure 3" if it is crystalline penicillin or with the figure 1" if it is not crystalline penicillin, unless such information is contained in the labeling within the package from which it is dispensed.

(3) On the outside wrapper or container:

(i) If it is not crystalline penicillin, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)

(ii) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(iii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily understandable result of testing and assay or containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it, or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(iv) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions for repacking or repacking and assay made required by § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a sample consisting of 10 immediate containers for sterility testing and, for all tests except sterility, one immediate container for each 5,000 immediate containers in the batch but in no case less than or more than the following quantities (excluding the 10 containers submitted for sterility):

(1) If it is not crystalline penicillin, not less than 5 or more than 15 immediate containers;

(2) If it is crystalline penicillin, not less than 10 or more than 17 immediate containers;

(3) If it is packaged in containers of less than 100,000 units each for dental use, not less than 20 or more than 100 immediate containers if it is not crystalline penicillin, not more than 2 or more than 15 immediate containers;

(4) If it is packaged in containers of 100,000 units or more each, not less than 100 immediate containers if it is crystalline penicillin or with the figure 10,000 units.

Such sample shall be collected by taking single immediate containers before or after labeling, at such intervals throughout the entire time of packaging a batch that the quantities packaged during the intervals are approximately equal.

(5) If such batch is packaged for repacking or for use in the manufacture of another drug, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility: 6 packages, or in the case of crystalline penicillin 10 packages, containing approximately equal portions of not less than 69 milligrams each.

(ii) For sterility testing: 10 packages, each containing approximately 300 milligrams.

Each such portion shall be taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(6) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make such tests and assays on a sample of such batch taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph, tests and assays not required by the batch when used in such other drug. The Commissioner shall report to such
dered with respect to each batch under manufacturer results of such check tests and assays as are so requested.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in a batch under §146.3 of this chapter; and

(2) (i) $3.00 for each immediate container in a batch under §146.3 of this chapter; and

(ii) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (1) (i) and (ii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

(b) Packaging. The immediate container of penicillin in oil and wax shall be of colorless transparent glass (if packaged and labeled solely for udder instillations of cattle, it shall be of transparent glass) so chosen as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes such as are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.3 (d) (i) of this section.

(f) Exemption of crystalline penicillin G from certification. Crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, penicillin G potassium salt, and crystalline penicillin G potassium salt, shall be exempt from the requirements of sections 502 (d) and 507 of the act. No provision of any regulation in this part shall apply to such drug except for fillers, coloring material, and other ingredients.

(g) Standards of identity, strength, quality, and purity. Penicillin in oil and wax is a suspension of calcium penicillin or crystalline penicillin in a menstruum of refined peanut oil or sesame oil in which white wax is dispersed. If it is represented to be free-flowing, not less than 50 percent of the total weight of the drug shall be in the form of discrete units having a particle size of not less than 50 microns in length. Its potency is 100,000 units, 200,000 units, or 300,000 units per milliliter except if it is packaged and labeled solely for udder instillations of cattle its potency is 2,000 units per milliliter. The content of white wax in the menstruum before the addition of the penicillin is not less than 3.0 percent (w/v) if the potency is to be not more than 200,000 units per milliliter, and not less than 4.7 or more than 4.9 percent (w/v) if the potency is to be 300,000 units per milliliter. The moisture content is not more than 1.0 percent. It is sterile. The calcium penicillin or crystalline penicillin used conforms to the requirements of §146.26 (a) but its potency is not less than 750 units per milligram if it is used in making a product of not more than 200,000 units per milliliter, and not less than 800 units per milliliter if it is used in making a product containing 300,000 units per milliliter.

(h) Testing. The immediate container of penicillin in oil and wax shall be of colorless transparent glass (if packaged and labeled solely for udder instillations of cattle, it shall be of transparent glass) so chosen as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes such as are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The quantity of penicillin in oil and wax in each such container shall be not less than one milliliter and not more than 20 milliliters, unless it is packaged for repackaging or is packaged and labeled solely for udder instillations of cattle. Unless it is packaged and labeled solely for udder instillations of cattle, it shall be filled with a volume of penicillin in oil and wax in excess of that designated, which excess shall be sufficient to permit the addition, with the administration of the volume indicated whether administered in either single or multiple doses.

(i) Labeling. Each package of penicillin in oil and wax shall bear, on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container of the drug:

(ii) the batch mark;

(iii) the number of units per milliliter of the batch;

(iv) the statement “Expiration date ———” the blank being filled in, if crystalline penicillin is used, with the date which is 18 months, or if crystalline penicillin is not used, with the date which is 12 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container of such immediate container if such immediate container is packaged in an individual wrapper or container;

(v) the statement “For intramuscular use only”; (vi) if it is represented to be free-flowing, the statements “Do not heat” and “Shake well”;

(vi) if it is represented to be free-flowing, it is stated “For udder instillations of cattle only”;

and

(vii) The name of each oil used in making the batch.

(2) On the outside wrapper or container:

(i) The statement “Caution: Federal law prohibits dispensing without prescription,” unless it is packaged for dispensing and is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by practitioners licensed by law to administer it or persons who request certification of a batch of penicillin in oil and wax shall submit with his request a statement to the effect that the batch meets the standards of identity, strength, quality, and purity prescribed therefor in applicable standards, except for fillers, coloring material, and other ingredients.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: potency, sterility, moisture, and if it is represented to be free-flowing, the particle size of the drug.

(ii) The penicillin used in making the batch: potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content (unless it is crystalline penicillin), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(a) For all tests except sterility: one package for each 500 packages in the batch, but in no case less than 3 packages, except if it is represented to be free-flowing, in which case not less than 4 packages or more than 12 packages.

(b) For sterility testing: 10 packages. Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.
(ii) The penicillin used in making the batch:
(a) For all tests except sterility: 6 packages if it is calcium penicillin or 10 packages if it is crystalline penicillin, containing approximately equal portions of not less than 300 milligrams. Such samples shall be packaged in accordance with the requirements of § 146a.24 (b).
(b) For sterility testing: 10 packages, each containing approximately equal portions of not less than 300 milligrams.

(3) In case of an initial request for certification, the peanut oil or sesame oil and white wax used in making the batch; one package of each containing, respectively, approximately 230 grams and 25 grams.

(4) No result referred to in subparagraph (3) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(a) The fees for the services rendered with respect to each batch of penicillin in oil and wax under the regulations in this part shall be:

(1) $4.00 for each package in the samples of the following: 60 packages if it is calcium penicillin, or 20 packages if it is crystalline penicillin, or 1-ephenamine penicillin, or Z-ephenamine, or I-ephenamine, or Z-aminicillin, or I-aminicillin, or Z-ephenamine penicillin G, or I-ephenamine penicillin G.

(2) In addition to complying with the requirements of § 146a.24 (a) except § 146a.24 (a) (2) and (4) of that paragraph, it is intended solely for veterinary use, penicillin ointment shall be packaged in collapsible tubes, which shall be well-closed containers, as will not cause any change in the strength, quality, or purity of the content beyond any limit therefor in applicable standards, except that minor changes so used that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(b) Each package of penicillin ointment shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container: the batch mark, the number of units per gram of the batch;

(2) On the outside wrapper or container:

(i) The statement "Expiration date of the batch given in the date, which is not more than 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 or 24 or 30 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that for each of the following time periods after having been stored for such period, the batch contains in addition to penicillin one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient per gram of the batch;

(ii) The statement "Expiration date of the batch given in the date which is not more than 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 or 24 or 30 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that for each of the following time periods after having been stored for such period, the batch contains in addition to penicillin one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient per gram of the batch;

(v) The statement "Expiration date of the batch given in the date which is not more than 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 or 24 or 30 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that for each of the following time periods after having been stored for such period, the batch contains in addition to penicillin one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient per gram of the batch;

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, and except otherwise provided by subparagraph (4) of this paragraph, each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest batch of the penicillin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest batch of the drug comprising such batch was completed, and each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit, with his request for certification, in the quantities hereinafter indicated, inaccurately representative samples of:

(i) The batch; potency and moisture.

(ii) The penicillin used in making the batch; potency, occult, moisture, pH, crystallinity if it is a crystalline salt of penicillin, heat stability if it is crystalline penicillin or l-ephenamine penicillin G, the penicillin G content if it is penicillin G, and the specific rotation if it is l-ephenamine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest batch of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest batch of the drug comprising such batch was completed, and each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(4) Except as otherwise provided by subparagraph (4) of this paragraph, each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest batch of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest batch of the drug comprising such batch was completed, and each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(5) Except as otherwise provided by subparagraph (4) of this paragraph, each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest batch of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest batch of the drug comprising such batch was completed, and each component of the ointment base used conforms to the requirements prescribed therefor by this section.
The penicillin used in making the batch; 5 packages, or in the case of crystalline penicillin, packaged in individual wrappers; and not less than 100,000 units if it is sodium penicillin, or procaine penicillin, or crystalline penicillin V benzathine penicillin G, or crystalline penicillin O, or crystalline penicillin V benzathine penicillin G, or procaine penicillin, or with or without one or more suitable analgesic substances, and one or more suitable analgesic substances, buffer substances, dyes, binders, lubricants, colors, and flavors. They may also contain probenecid or one or more suitable analgesic substances, and it does not contain a vitamin substance, 24 months.

(d) If a crystalline penicillin other than a penicillin V is used and it does not contain a vitamin substance, 24 months.

(e) If a penicillin V is used, and it does not contain a vitamin substance, 24 months.

(f) If a crystalline penicillin other than a penicillin V is used and it does not contain a vitamin substance, 36 months.

(g) In lieu of the expiration date prescribed above for a drug, if the person who requests certification has submitted to the Commissioner results of tests and assays that show such drug as prepared by him and his batch number, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed, the number of units in each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (e) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, or other printed matter containing such information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by the law to administer it:

(i) The statement "Expiration date

(ii) The statement "Expiration date

(iii) A statement that the drug is used in the manner prescribed for the drug by the regulations in this chapter, except the standards for stability and pyrogens. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Unless each penicillin tablet is encased in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except that it shall be capable of being solution of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. If the penicillin tablets are freely soluble, each immediate container may be packaged in combination with one immediate container of a suitable and harmless aqueous vehicle with or without one or more suitable sulfonamides.

(c) Labeling. Each package of penicillin tablets shall bear, on the label or labeling as hereinafter indicated, the following:

(i) The name of each batch, the name of each ingredient used in making the batch; and

(ii) The number of units in each tablet of the batch;

(iii) If the batch contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient in each tablet.

(iv) If the batch contains buffer substances, the name of each such substance used in making the batch;

(v) If it is a packaged combination of penicillin tablets and a vehicle with or without sulfonamides, a statement giving the method of dissolving the penicillin; and

(vi) The statement "Expiration date ________"," the blank being filled with the name of the drug, the batch number, the number of packages of each size in such batch, the batch mark and, if the expiration date prescribed above for a drug, if the person who requests certification has submitted to the Commissioner results of tests and assays that show such drug as prepared by him and his batch number, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed, the number of units in each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.
it is a penicillin G or crystalline peni- cillin O- the penicillin V content if it is a penicillin V- and the penicillin O content if it is O-

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities herein- after indicated, accurately representa- tive samples of the following:

(i) The batch; one for each 5,000 tablets in the batch, but in no case less than one for each 50 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tabled during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 6 packages, or in the case of crys- talline penicillin 10 packages, each con- taining approximately equal portions of not less than 60 milligrams, except that if it is procaine penicillin, benzathine penicillin G, or penicillin V each package shall contain 10 such sub- grams, packaged in accordance with the requirements of § 146a.24 (b) 146a.44 (b) 146a.68 (b) or 146a.103 (b)

(iii) In case of an initial request, each other than examination render with respect to each batch of submitted.

result or sample has been previously

g (2) The outside wrapper or container and the immediate container bear an expiration date that is not more than 36 months after the month during which the batch was last assayed and released by the manufacturer.

(3) They are intended to be admin- istered by an accurately represent- ative sample of:

then applied to a label or labeling, as herein- described. Provided, however, That such notation may be omitted if the information is contained in a cir- cular or other label within or at- tached to the package.

(3) On the label and labeling, if it contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this sec- tion, after the name "crystalline penicil- lin G oral suspension," wherever it ap- pears, the words "with- (the blank being filled in with the common or usual name of such other ingredient)" in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it in- cludes the following statement: "The use of this drug is subject to minor changes so caused that are not more than 1.0 percent. The crystalline peni- cillin used conforms to § 146a.24 (a), except § 146a.24 (a) (2) and (4). Each other substance used, if its name is rec- ognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium."

(b) Packaging. The immediate con- tainer shall be a tight container as de- fined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are not less than 20,000 units per milli- liter. Its moisture content is not more than 1.0 percent. The crystalline peni- cillin used conforms to § 146a.24 (a), except § 146a.24 (a) (2) and (4).

(i) On the outside wrapper or con- tainer and the immediate contain-

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

Exemption of penicillin tablets from certification. Penicillin tablets, with or without added vitamin sub- stances and residues from streptomycines fermentation, shall be exempt from the requirements of sections 502 (1) and 507 of the act, if they comply with the fol- lowing conditions:

(1) They contain not more than 1,000 units per tablet.

(2) The number of units in each milli- liter of the batch.

(3) The name of each bulk sub- stance, the quantity of proheneed, and the name and quantity of each sulfona- mide and preservative used in making the batch.

(a) The statement "Shake well."

(b) The statement "Expiration date-__," the blank being filled in with the date on which the batch was last assayed and released by the manufacturer.

(c) The batch; average potency per milliliter and moisture.

(d) The penicillin G used in making the batch; potency, toxicity, pH, mois- ture, crystallinity, and the penicillin G content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities here- inafter indicated, accurately representa- tive samples of the following:

(i) The batch; 1 immediate container for each 5,000 immediate containers in

(ii) If it is packaged for dispensing and it is intended for use by man, a reference to a brochure or other printed matter containing information (including con- traindications and possible sensitization) adequate for the use of such drug by laymen. Provided, however, That such notation may be omitted if the information is contained in a cir- cular or other label within or at- tached to the package.

(3) On the label and labeling, if it contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this sec- tion, after the name "crystalline penicil- lin G oral suspension," wherever it ap- pears, the words "with- (the blank being filled in with the common or usual name of such other ingredient)" in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it in- cludes the following statement: "The use of this drug is subject to minor changes so caused that are not less than 20,000 units per milli- liter. Its moisture content is not more than 1.0 percent. The crystalline peni- cillin used conforms to § 146a.24 (a), except § 146a.24 (a) (2) and (4). Each other substance used, if its name is rec- ognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium."

(b) Packaging. The immediate con- tainer shall be a tight container as de- defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are not less than 20,000 units per milli- liter. Its moisture content is not more than 1.0 percent. The crystalline peni- cillin used conforms to § 146a.24 (a), except § 146a.24 (a) (2) and (4).

(i) On the outside wrapper or con- tainer and the immediate contain-

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

Exemption of penicillin tablets from certification. Penicillin tablets, with or without added vitamin sub- stances and residues from streptomycines fermentation, shall be exempt from the requirements of sections 502 (1) and 507 of the act, if they comply with the fol- lowing conditions:

(1) They contain not more than 1,000 units per tablet.

(2) The outside wrapper or container and the immediate container bear an expiration date that is not more than 36 months after the month during which the batch was last assayed and released by the manufacturer.

(3) They are intended to be admin- istered by an accurately represent- ative sample of:

then applied to a label or labeling, as herein- described. Provided, however, That such notation may be omitted if the information is contained in a cir- cular or other label within or at- tached to the package.

(3) On the label and labeling, if it contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this sec- tion, after the name "crystalline penicil- lin G oral suspension," wherever it ap- pears, the words "with- (the blank being filled in with the common or usual name of such other ingredient)" in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it in- cludes the following statement: "The use of this drug is subject to minor changes so caused that are not less than 20,000 units per milli- liter. Its moisture content is not more than 1.0 percent. The crystalline peni- cillin used conforms to § 146a.24 (a), except § 146a.24 (a) (2) and (4).

(i) On the outside wrapper or con- tainer and the immediate contain-

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

Exemption of penicillin tablets from certification. Penicillin tablets, with or without added vitamin sub- stances and residues from streptomycines fermentation, shall be exempt from the requirements of sections 502 (1) and 507 of the act, if they comply with the fol- lowing conditions:

(1) They contain not more than 1,000 units per tablet.
the batch, but in no case less than 5 or more than 12 immediate containers, collected by taking single immediate containers at such time intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin G used in making the batch; 1 package of each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146a.24 (b), may be introduced into the immediate container if such immediate container is packaged in an individual wrapper or container.

(iii) In case of an initial request for certification, each other ingredient used in making the batch; 1 package of each containing approximately 5.0 grams.

(iv) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraphs (3) (i) and (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be: $1.00 for each 100 packages, and (4) of § 146a.24, except that the immediate container of the aluminum hydroxide gel, the number of packages thereof in such combination shall be determined as previously submitted the date on which the latest assay of the penicillin included in such combination was completed, and a statement that the aluminum hydroxide gel shall conform to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays made by him on an accurately representative sample of the penicillin for potency, sterility, toxicity, moisture, heat stability, and crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) If the penicillin has not been certified previously, such person shall submit in connection with his request a sample of the batch consisting of one package for each 5,000 packages in the batch, but in no case less than 6 or more than 13 packages except that in the case of crystalline penicillin other than crystalline penicillin G such sample shall consist of not less than 8 and not more than 15 packages, and in the case of crystalline penicillin G not less than 10 and not more than 17 packages. Such sample shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(d) No result referred to in subparagraph (2) of this paragraph is required if such result has been previously submitted.

(e) Fees. The fees for the services rendered with respect to each batch of penicillin for inclusion in combination with aluminum hydroxide gel under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) of this section, or $2.00 if no such sample is submitted, and

(2) If the Commissioner considers that investigations, other than examination of such containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, or $2.00.

§ 146a.29 Penicillin with aluminum hydroxide gel—(a) Standards of identity, strength, quality, and purity

Penicillin with aluminum hydroxide gel as a packaged combination of one immediate container of penicillin and one immediate container of aluminum hydroxide gel. Such penicillin conforms to the standards prescribed therefor by § 146a.24 (a) except subparagraphs (1) and (4) of § 146a.24 (a) but its potency is not less than 300,000 units per milligram.

Such aluminum hydroxide gel conforms to the standards prescribed therefor by the U. S. P., but contains not more than 50 viable microorganisms per milliliter.

(b) Packaging. The immediate container of the penicillin shall conform to the packaging requirements set forth in § 146a.24 (b) except that it shall contain not less than 100 units and its closure may be one through which a hypodermic needle cannot be introduced. The immediate container of the aluminum hydroxide gel shall be a tight container as defined by the U. S. P., the quantity therein shall be 30 milliliters for each 100,000 units in the immediate container of penicillin.

(c) Stating. Each package of penicillin with aluminum hydroxide gel shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outer wrapper or container and on the immediate container of the penicillin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) A statement "Expiration date ________" the blank being filled in with the date which is 18 months after the month during which the batch was certified, unless it is crystalline penicillin, in which case the date is 36 months after the month during which the batch was certified: Provided, however That such expiration date may be filled in with the date which is 36 months after the month during which the batch was certified.

(2) On the immediate container of the penicillin the statement "Warning—Not for injection," unless it conforms to the standards and packaging requirements prescribed therefor by § 146a.24 (a) and (b) except that the immediate container may contain 300,000 units.

(3) On the immediate container of the aluminum hydroxide gel, the conditions under which the mixture should be stored, and its instability when stored under other conditions, and the statement "The mixture may be kept in refrigerator for 1 week maximum. After that time it may not be used" unless such information is contained in the circular or other labeling within or attached to the package.

(4) On the outer wrapper or container and the immediate container of the aluminum hydroxide gel:

(i) A statement giving the method for dissolving the penicillin in the aluminum hydroxide gel.

(ii) The potency per milliliter after the penicillin has been dissolved therein.

(5) On the outer wrapper or container of the batch:

(i) The statement "Caution: Federal law prohibits dispensing without prescription;" unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is not crystalline penicillin the statement "Store in refrigerator not above 15°C. (59°F.)" or "Store below 15°C."

(iii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request.

(2) On the circular or other labeling within or attached to the package, if it contains 100,000 units, packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the label or the unopened circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Requests for certification, samples.

(1) In addition to the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin for inclusion in such combination shall submit with his request a complete blank of the mark of the penicillin, the number of packages thereof in such batch, the number of units in the immediate container thereof, and (unless it was previously submitted) the date on which the latest assay of the penicillin included in such combination was completed, and a statement that the aluminum hydroxide gel shall conform to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays made by him on an accurately representative sample of the penicillin for potency, sterility, toxicity, moisture, heat stability, and crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) If the penicillin has not been certified previously, such person shall submit in connection with his request a sample of the batch consisting of one package for each 5,000 packages in the batch, but in no case less than 6 or more than 13 packages except that in the case of crystalline penicillin other than crystalline penicillin G such sample shall consist of not less than 8 and not more than 15 packages, and in the case of crystalline penicillin G not less than 10 and not more than 17 packages. Such sample shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(4) No result referred to in subparagraph (2) of this paragraph is required if such result has been previously submitted.

(e) Fees. The fees for the services rendered with respect to each batch of penicillin for inclusion in combination with aluminum hydroxide gel under the regulations in this part shall be:

(1) §4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) of this section, or $2.00 if no such sample is submitted, and

(2) If the Commissioner considers that investigations, other than examination of such containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, or $2.00.

§ 146a.30 Penicillin troches—(a) Standards of identity, strength, quality, and purity

Penicillin troches are
troches composed of sodium penicillin, calcium penicillin, potassium penicillin, procaine penicillin, L-ephenamine penicillin G, or crystalline penicillin O and one or more suitable or harmless diluents, binders, and lubricants, with or without one or more suitable or harmless diluents, binders, and lubricants, with or without ones are certified in accordance with the applicable standards; except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practices shall be disregarded.

(c) Labeling: Each package of penicillin troches shall bear, on its label or labeling as hereinbefore indicated, the following:

(i) The batch; average potency per troche, average moisture content.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH; crystallinity if it is crystalline penicillin; specific rotation if it is L-ephenamine penicillin G; base name and salt name; it is sodium penicillin, potassium penicillin, l-ephenamine penicillin G, or crystalline penicillin O; the penicillin G content if it is crystalline penicillin G, potassium penicillin G, or crystalline penicillin O; the procaine penicillin G content if it is crystalline procaine penicillin G; the L-ephenamine penicillin G, the L-ephenamine penicillin G, or the penicillin O content if it is crystalline penicillin O.

(iii) The expiration date, "Expiration date___________", the blank being filled in, if it is crystalline penicillin, procaine penicillin, L-ephenamine penicillin G, or crystalline penicillin O is used, with the date which is 12 months after the month during which the batch was certified, except that the batch may be filled in with the date which is 18 months or 24 months or 36 months or 48 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section; Provided, however, that no expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The expiration date, "Expiration date___________", the blank being filled in, if crystalline penicillin, procaine penicillin, L-ephenamine penicillin G, or crystalline penicillin O is not used, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)."

(v) The statement "Caution: Federal law prohibits dispensing without prescription".

(vi) If it is packaged for dispensing, a reference specifically identifying a readily available medical publication containing complete information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(vii) The label and labeling, wherever the name penicillin troches appears:

(i) Immediately preceding such name, if a masticatory substance is present, the word "chewing" or "masticatory";

(ii) Immediately following such name, if a local anesthetic and/or a chemical antimicrobial agent is present, the words "with ________", the blank being filled in with the common or usual name of each such other ingredient present.

(d) Requests for certification; samples.

(1) In addition to complying with the requirements of § 156.2 of this chapter, a person who requests certification of a batch of penicillin troches shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of each package of each size in such batch was completed, the number of units in each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of such batch was completed, the number of units in each troche, the quantity of each ingredient used in making such batch was completed, and a statement that each ingredient used in making such batch conforms to the requirements prescribed with respect to each batch of penicillin troches under the regulations in this part shall be:

(i) $1.00 for each troche without masticatory substance in the sample submitted in accordance with paragraph (d) (1) (i) of this section, $2.00 for each troche with masticatory substance in such sample, $4.00 for each package in the samples submitted in accordance with paragraph (d) (2) (i) and (iii) of this section; and

(ii) If the Commissioner considers the investigations, other than examination of such troches, is necessary to determine whether or not such batches of samples with the requirements of § 156.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 156.3 of this chapter.
§ 146a.31. Penicillin dental cones (calcium penicillin dental cones, penicillin dental cones calcium salt, crystalline penicillin dental cones)—(a) Standards of identity, strength, quality, and purity. Penicillin cones conform to the requirements of U. S. P. or the Food and Drug Administration, if used as a local treatment for Vincent's infection (Vincent's angina) and as an adjunct in penicillin-sensitive syphilis and other superficial dental infections due to penicillin-sensitive organisms; and, further, that such brochures, printed matter, and circular bear directions and warnings adequate for such use by practitioners licensed by law to administer such drug.

(b) Packaging. Unless each penicillin dental cone is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P. or F. F. conforms to the standards prescribed therefor by such official compendium.

(c) Laboratory. A package of penicillin dental cones shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each cone of the batch;

(iii) If the batch contains, in addition to penicillin, one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient in each cone;

(iv) The statement “Expiration date ________”--the blank being filled in, if crystalline penicillin is used, with the date which is 12 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement “Caution: Federal law prohibits dispensing without prescription,” unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for “dispensing and it is intended for use by man, a reference specification indicating the readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it, or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(iii) On the label and labeling, if it contains, in addition to penicillin, one or more other active ingredients specified in paragraph (a) of this section, after the name “penicillin dental cones,” wherever it appears, the words “with ________” in juxtaposition with such name, the blank being filled in with the common or usual name of each such other ingredient used.

(iv) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) Requests for certification; samples. (1) In certifying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin dental cones shall submit with his request a statement showing the batch mark, adequate directions and warnings for the veterinary use of such drug by the laity.

(2) Requests for certification; samples. (1) In certifying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin dental cones shall submit with his request a statement showing the batch mark, adequate directions and warnings for the veterinary use of such drug by the laity.

(3) Certification. Each other substance used in making the batch; one package of each containing approximately equal parts of not less than 50 milligrams each, packaged in accordance with the requirements of § 146a.24 (b).

(4) No result referred to in subparagraph (2) (i) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch of penicillin dental cones under the regulations in this part shall be:

(1) $1.00 for each cone in the sample submitted in accordance with paragraph (b) of this section; $2.00 for each package in the samples submitted in accordance with paragraph (c) of this section.

(2) In addition to the fees prescribed, each other substance used in making the batch; one package of each containing approximately 5 grams.

(f) If the Commissioner considers that investigations, other than examination of such cones and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (f) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 140.8 (d) of this chapter.

§ 146a.32. Penicillin with vasoconstrictor for penicillin with vasoconstrictor—(f) The blank being filled in with the common or usual name of the vasoconstrictor)—(a) Standards of identity, strength, quality, and purity. Penicillin with vasoconstrictor contains not less than 100,000 units of penicillin containing approximately equal parts of not less than 50 milligrams each, packaged in accordance with the requirements of § 146a.24 (b).
without suitable buffer substances and preservatives, or it is a packaged combination of one immediate container of penicillin and one immediate container of an aqueous solution of a suitable vasoconstrictor. The penicillin is of such quantity that when dissolved as directed the potency is not less than 500 units per milliliter after it has been kept for 7 days at a temperature of 15° C. (59° F.). Such solution is isotonic and has a pH of 5-8.2. The content of the dry mixture of penicillin with vasoconstrictor is not more than 1.5 percent. The penicillin used conforms to the requirements of § 146a-24 (a) except the limit on penicillin K content and except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or NF, conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Each immediate container shall be a tight container as defined by the blank being filled with the date which is 12 months and 1 week after the month during which the batch was certified. If it is the dry mixture of penicillin with vasoconstrictor, the statement "Expiration date -", the blank being filled in with the date which is 24 months after the month during which the batch was certified. Such expiration dates may be omitted from the immediate container if such container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container and on the immediate container of the penicillin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) If it is a packaged combination of one immediate container of penicillin and one immediate container of a vasoconstrictor, the statement "Expiration date --", the blank being filled in with the date which is 24 months after the month during which the batch was certified.

(c) Labeling. Each package of penicillin with vasoconstrictor shall be labeled by the owner or operator and shall bear on the outside wrapper or container and on the immediate container of the penicillin:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously labeled.

(ii) If it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously labeled.

(4) No result referred to in subparagraph (4) of this paragraph, and no sample referred to in subparagraph (3) of this paragraph, is required if such result or sample has been previously submitted, or if it contains penicillin and other ingredients; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, unless it is in tablet form in which case such sample shall consist of not less than 250 tablets.

(b) It contains only penicillin and the penicillin used has been previously submitted, or it contains penicillin and other ingredients; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, unless it is in tablet form in which case such sample shall consist of not less than 250 tablets.

(c) If it contains only penicillin and the penicillin used has been previously submitted, or it contains penicillin and other ingredients; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, unless it is in tablet form in which case such sample shall consist of not less than 250 tablets.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously labeled, the following:

(i) The number of packages of not less than 60 milligrams each, packaged in accordance with the requirements of § 146a-24 (b)

(ii) In case of a batch of a dry mixture of penicillin with vasoconstrictor, five packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 50 milligrams each, packaged in accordance with the requirements of § 146a-24 (b)

(iii) In case of an initial request for certification of a batch of a dry mixture of penicillin with vasoconstrictor; and each other substance used in making the batch; one package of each containing approximately 5 grams.

(iv) In case of an initial request for certification of a packaged combination of penicillin with vasoconstrictor, or when any change is made in the composition of such solution; five packages of the solution included in the combination.

(d) Request for certification; samples.

(1) In addition to complying with the requirements of § 146a-24 of this chapter a person who requests certification of a batch of penicillin with vasoconstrictor shall submit with his request a statement showing the amount of drug and of each immediate container thereof, and (unless it was previously submitted) the date on which the latest assay of the penicillin included in such batch was completed, the quantity of each ingredient used in making the batch of the dry mixture of penicillin with vasoconstrictor, the quantity of each ingredient used in making the solution included in the packaged combination, and a statement conforming to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample:

(i) The penicillin included in the packaged combination and the penicillin used in making the batch of the dry mixture of penicillin with vasoconstrictor; potency, toxicity, moisture, pH, crystallinity and heat stability, if it is crystalline penicillin G; and

(ii) The solution after the penicillin has been dissolved therein; potency.

(iii) The following statement of penicillin with vasoconstrictor; potency, moisture content.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, an owner or operator shall submit, in connection with his request in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The batch.

(ii) It contains only penicillin and the penicillin used has been previously submitted, or it contains penicillin and other ingredients; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, unless it is in tablet form in which case such sample shall consist of not less than 250 tablets.

(iv) The statement "Warning: Not for injection".

(c) The conditions under which the solution should be stored, including a reference to the instability when stored under other conditions, and a statement "The solution may be kept in a refrigerator for one week without significant loss of potency.

(3) In the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously labeled.

(ii) If it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously labeled.

The fee for the services rendered with respect to each batch of penicillin with vasoconstrictor under the regulations in this part shall be:

(1) $1.00 for each tablet submitted in accordance with paragraph (d) (3) (1) and (b) of this section; $1.00 for each immediate container submitted in accordance with paragraph (d) (3) (1) of this section; and $4.00 for each immediate container submitted in accordance with paragraph (d) (3) (1), (ii), (iii), and (iv) of this section.
The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8(d) of this chapter.

§ 146a.33 Penicillin for surface application—(a) Standards of identity, strength, purity, and quality. Penicillin for surface application is calcium penicillin and one or more of the diluents sodium chloride, milk sugar, sodium citrate, and dextrose. Its moisture content is not more than 1.0 percent. The penicillin used conforms to the requirements of § 146a.34(a), except the limitation of penicillin B except subgroups (1) and (2) of § 146a.34(a) but its potency is not less than 200 units per milligram. Each diluent conforms to the standards prescribed therefor by the U.S.P.

(b) Packaging. Unless the penicillin for surface application is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U.S.P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The composition of the immediate container, the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each immediate container (except when its content is two or more foil or film enclosures) and each foil or film enclosure shall contain not less than 10,000 units or more than 30,000 units and shall be so sealed that the contents cannot be used without destroying such seal.

(c) Labeling. Each package of penicillin for surface application shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:
   (i) The batch mark;
   (ii) The number of units in the immediate container or in each foil or film enclosure therein, and the number of such foil or film enclosures;
   (iii) The expiration date, and "---", the blank being filled in with the date which is 12 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) In case the drug is not sterile, the statement "Not sterile—not for injection—not to be used in deep wounds or body cavities.

(2) On the immediate container, the conditions under which solutions of penicillin for surface application should be stored, including a reference to its number of units, the number of such conditions, and the statement: "The mixture may be kept in refrigerator for 1 week without significant loss of potency," unless such information is contained in the circular or other labeling within or attached to the package.

(3) On the outside wrapper or container:
   (i) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)"
   (ii) If two or more immediate containers or foil or film enclosures are in such packages, the number of such containers or foil or film enclosures therein and the number of units in each.

(iii) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(iv) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information concerning contraindications and possible sensitization adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained within or attached to the packaging or labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear the statement that the drug is a printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Requests for certification; samples. (1) In addition to complying with the requirements of § 146.3 of this chapter, a person who requests certification of a batch of penicillin for surface application shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each immediate container or foil or film enclosure, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug composing such batch was completed, and that the sodium chloride, milk sugar, sodium citrate, and dextrose used in making such batch conformed to the standards prescribed therefor by the U.S.P., except the provision, that it shall be a tight container as defined P.,.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request the results of the tests and assays listed after each of the following, made by him on an accurately reproducible sample of such batch:
   (i) The batch; average potency per immediate container or foil or film enclosure, moisture.
   (ii) The penicillin used in making the batch; potency, toxicity, moisture, pH.
   (iii) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, a representative sample of the following:

   (i) The batch; one immediate container or, if the drug is packed in foil or film enclosures, one foil or film enclosure for each 5,000 such containers or enclosures in the batch, but in no case less than 20 such containers or enclosures or more than 100, collected by taking single containers or enclosures at such intervals throughout the entire time of packaging the batch, that the quantities packed during the intervals are approximately equal.

   (ii) The penicillin used in making the batch; five packages containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146a.34(b).

   (iii) In case of an initial request for certification, each other substance used in making the batch, one package of each containing approximately grams.

   (4) No result referred to in subparagraph (2) or (ii) of this paragraph, and no sample referred to in subparagraph (3) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch of penicillin for surface application under the regulations in this part shall be:

(1) $1.00 for each immediate container or foil or film enclosure, whichever is the greater number, in the samples submitted in accordance with paragraphs (d)(1) and (ii) of this section; $4.00 for each package submitted in accordance with paragraph (d)(3)(i) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such containers or enclosures, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1)(i) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8(d) of this chapter.

§ 146a.34 Tablets aluminum penicillin—(a) Standards of identity, strength, purity, and quality. Tablets aluminum penicillin are tablets composed of aluminum penicillin and sodium benzoate, with or without one or more suitable and harmless diluents, binders, lubricants, colored dyes, and other excipients. The potency of each tablet is not less than 50,000 units, and if it is less than 100,000 units it is "unscored." Each tablet contains 0.5 gram of sodium benzoate. Its
moisture content is not more than 2 percent. The aluminum penicillin used conforms to the standards of § 166a-32 (a) for aluminum penicillin except subparagraphs (2) and (3) thereof. Each other substance used in the preparation of aluminum penicillin tablets, if its name is not regulated by the U. S. P., conforms to the standards prescribed therefor by such official compendium.

(5) Packaging. Unless each tablet aluminum penicillin is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except that the provision that it shall be capable of tight closure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, and purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution shall be regarded. The number of tablets in the immediate container is such that the total number of units therein is not less than $300,000.

(c) Labeling. Each package of tablets aluminum penicillin shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:
  (i) The batch mark;
  (ii) The number of units in each tablet;
  (iii) The quantity of sodium benzoate in each tablet;
  (iv) The statement "Expiration date ____________", the blank being filled in with the date which is 24 months after the month during which the batch was compounded, the following:
    (b) After the expiration date shall be indicated, accurately representing the number of tablets in the sample used in making such batch was completed, the number of units in each tablet; the quantity of each ingredient used in making the tablets, collected during the entire time of tableting that the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request the tests and assays listed in each of the followings, made by him on an accurately representative sample of:
  (i) The batch; average potency per tablet, average moisture;
  (ii) The sodium benzoate used in making the batch; potency, moisture, pH, toxicity, and penicillin K content.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, the immediate container shall be of such a nature that each tablet shall bear with his request, in the quantities hereinafter indicated, accurately representative samples of the following:
  (i) The batch; one tablet for each 5,000 tablets, but not more than 20 tablets or more than 100 tablets, collected by taking simple tablets at such intervals throughout the entire time of tableting that the quantity sampled during the intervals are approximately equal.

(4) The aluminum penicillin used in making the batch; 6 packages, each containing approximately equal portions of not less than 300 milligrams each, packaged in accordance with the requirements of § 166a-42 (b).

(5) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately five grams.

(6) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(c) Fees. The fee for the services rendered with respect to each batch of aluminum penicillin under this part shall be

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (1) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) and (ii) of this section; and

(2) If the Commissioner considers the samples submitted other than examination of such tablets and packages necessary to determine whether or not such batch complies with the requirements of § 166a.3 of this chapter, for the issuance of a certificate, the costs of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 166a.8 (d) of this chapter.

§ 166a.33 Penicillin sulfonamide powder. See note.

(a) Standards of identity, strength, quality, and purity. Penicillin sulfonamide powder shall conform to the standards of § 166a.33.

(b) Xamarin. The aluminum penicillin used conforms to the standards prescribed by the U. S. P. 150 is covered by an advance deposit in accordance with § 166a.8 (a) except subparagraph (4) of this section.

(c) Packaging. The immediate container shall be such that the container shall conform to the standards prescribed by the U. S. P. 150 is covered by an advance deposit in accordance with § 166a.8 (a) except subparagraph (4) of this section.

(d) Labeling. Each package of tablets aluminum penicillin under this part shall bear, on its label or labeling as hereinafter indicated, the following:

(1) The batch mark; the number of units in each tablet; the quantity of each ingredient used in making the tablets, collected during the entire time of tableting that the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request the tests and assays listed in each of the followings, made by him on an accurately representative sample of:
  (i) The batch; average potency per tablet, average moisture;
  (ii) The sodium benzoate used in making the batch; potency, moisture, pH, toxicity, and penicillin K content.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, the immediate container shall be of such a nature that each tablet shall bear with his request, in the quantities hereinafter indicated, accurately representative samples of the following:
  (i) The batch; one tablet for each 5,000 tablets, but not more than 20 tablets or more than 100 tablets, collected by taking simple tablets at such intervals throughout the entire time of tableting that the quantity sampled during the intervals are approximately equal.

(4) The aluminum penicillin used in making the batch; 6 packages, each containing approximately equal portions of not less than 300 milligrams each, packaged in accordance with the requirements of § 166a-42 (b).

(5) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately five grams.

(6) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(c) Fees. The fee for the services rendered with respect to each batch of aluminum penicillin under this part shall be

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (1) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) and (ii) of this section; and

(2) If the Commissioner considers the samples submitted other than examination of such tablets and packages necessary to determine whether or not such batch complies with the requirements of § 166a.3 of this chapter, for the issuance of a certificate, the costs of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 166a.8 (d) of this chapter.

§ 166a.33 Penicillin sulfonamide powder. See note.

(a) Standards of identity, strength, quality, and purity. Penicillin sulfonamide powder shall conform to the standards prescribed by the U. S. P. 150 is covered by an advance deposit in accordance with § 166a.8 (a) except subparagraph (4) of this section.

(b) Xamarin. The aluminum penicillin used conforms to the standards prescribed by the U. S. P. 150 is covered by an advance deposit in accordance with § 166a.8 (a) except subparagraph (4) of this section.

(c) Packaging. Each package of tablets aluminum penicillin shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:
  (i) The batch mark;
  (ii) The number of units in each tablet;
  (iii) The quantity of sodium benzoate in each tablet;

(b) The statement "Expiration date ____________", the blank being filled in with the date which is 24 months after the month during which the batch was compounded, the following:

(1) On the outside wrapper or container and the immediate container:
  (i) The batch mark;
  (ii) The number of units in each tablet;
  (iii) The quantity of sodium benzoate in each tablet;

(b) The statement "Expiration date ____________", the blank being filled in with the date which is 24 months after the month during which the batch was compounded, the following:

(1) On the outside wrapper or container and the immediate container:
  (i) The batch mark;
  (ii) The number of units in each tablet;
  (iii) The quantity of sodium benzoate in each tablet;

(b) The statement "Expiration date ____________", the blank being filled in with the date which is 24 months after the month during which the batch was compounded, the following:

(1) On the outside wrapper or container and the immediate container:
  (i) The batch mark;
  (ii) The number of units in each tablet;
  (iii) The quantity of sodium benzoate in each tablet;

(b) The statement "Expiration date ____________", the blank being filled in with the date which is 24 months after the month during which the batch was compounded, the following:

(1) On the outside wrapper or container and the immediate container:
  (i) The batch mark;
  (ii) The number of units in each tablet;
  (iii) The quantity of sodium benzoate in each tablet;

(b) The statement "Expiration date ____________", the blank being filled in with the date which is 24 months after the month during which the batch was compounded, the following:

(1) On the outside wrapper or container and the immediate container:
  (i) The batch mark;
  (ii) The number of units in each tablet;
  (iii) The quantity of sodium benzoate in each tablet;
(c) Labeling. Each package of penicillin sulfonamide powder shall bear, on its label or label as hereinafter indicated, the following:

(1) On the outside wrapper or container and immediate container:

(i) The batch mark;

(ii) The number of units in each immediate container.

(iii) The statement "Expiration date ________," the blank being filled in, if crystalline penicillin is used, with the date which is 12 months after the month during which the batch was certified; provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) If crystalline penicillin is not used, the statement "Store in refrigerator not above 15°C (59°F)." or "Store below 15°C (59°F)."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it, and a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request:

Provided, however, that such reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(ii) On the label and the labeling, after the penicillin sulfonamide powder, wherever it appears, the words "with __________" in juxtaposition with such name, the blank being filled in with the name of the sulfonamide used.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it, shall be sent to such veterinarian on request.

(d) Requests for certification; samples. (1) In addition to complying with the requirements of § 146a.3 of this chapter, a person requesting certification shall: (i) A batch of penicillin sulfonamide powder shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark (where it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each container of penicillin sulfonamide powder, the quantity of each immediate container of penicillin, the batch mark (where it was previously submitted) the date on which the latest assay of the penicillin sulfonamide powder comprising such batch was completed, and that such sulfonamide used in making the batch conform to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, the statement "Expiration date ________", the blank being filled in, with the date which is 12 months after the month during which the batch was certified; provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) If the batch mark, average potency per container, average moisture, sterility.

(ii) The penicillin used in making the batch; potency, sterility, toxicity, moisture, pH, crystallinity and heat stability. Provided, however, that such reference may be omitted if the information is contained in a circular or other labeling conforming to the requirements of § 146a.24 (a) except subparagraphs (1), (2), and (4) of that paragraph, but its potency is not less than 300 units per milligram. The contents beyond any limit therefor in paragraph (i) of § 146a.24 (a) except subparagraphs (2) and (4) of that paragraph. The spermaceti and cocoa butter used conform to the standards prescribed therefor by the U.S. P. except that the base of spermaceti contains no more than 1.0 percent. The sodium sulfonamide, calcium penicillin, and potassium penicillin used conform to the requirements of § 146a.24 (a) except subparagraphs (2) and (3) of paragraph. The casein, the immediate container of penicillin vaginal suppositories shall be a tight container as defined by the U.S. P., except the provision that it shall be capable of tight reclosure, and shall conform to such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in subparagraphs (1) and (3) of § 146a.24 (a) except subparagraphs (2) and (3) of paragraph. (1) If the immediately preceding paragraph of the requirements of § 146a.35 (a) and (b) of this chapter.

(3) If the immediate container of penicillin vaginal suppositories shall be a tight container as defined by the U.S. P., except the provision that it shall be capable of tight reclosure, and shall conform to such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in subparagraphs (1) and (3) of § 146a.24 (a) except subparagraphs (2) and (3) of paragraph. The spermaceti and cocoa butter used conform to the standards prescribed therefor by the U.S. P.

(2) The statement "Expiration date ________," the blank being filled in, with the date which is 12 months after the month during which the batch was certified; provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.
The immediate container, if it is packaged for dispensing, shall bear, in lieu of the statement prescribed for crystalline penicillin by § 146a.21 (c) (2), the statement "Sterile solution may be kept in refrigerator for 1 week; without significant loss of potency," unless such information is contained in the circular or other labeling within or attached to the package from which it is dispensed;

(d) A person who requests certification of a batch shall submit with his request a statement showing the quantity of sodium citrate used in making the batch, that such sodium citrate conforms to the requirements prescribed therefor by this section, and in case of an initial request for certification he shall submit an accurately representative sample of such sodium citrate consisting of approximately 5 grams; and

(e) The fee for the services required in connection with the sample referred to in subparagraph (3) of this paragraph, as required if such result or sample has been previously submitted.

(2) It is intended for use only in the treatment of the following conditions:

(i) Pulmonary suppuration due to Bacterial endocarditis due to Staphylococcic infections with and without bacteremia.

(ii) Anaerobic streptococcus infections including bacteremia.

(iii) Pneumococcic infections.

(iv) Gonococcal infections.

(v) Syphilis.

(vi) Anthrax.

(vii) As an adjunct to specific antitoxin therapy for diphtheria.

(viii) For the prevention of possible secondary infection following tonsillectomy and pharyngectomy in patients with a history of rheumatic fever or rheumatic heart disease, in congenital heart disease, and in other conditions in which secondary infection may occur; or the removal of a significant loss of potency, unless such information is contained in the circular or other labeling within or attached to the package from which it is dispensed;
drug is for use only in the treatment of one or more of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Bovine mastitis caused by Strep-tococcus agalactiae.
(ii) Leptospirosis in dogs.
(iii) Osteomyelitis.
(iv) Peritonitis.
(v) Strangles of horses.
(vi) Equine pneumonia.
(vii) Early tetanus, with antitoxin therapy.
(viii) Calf pneumonia.
(ix) Calf diphtheria.
(x) Phlegmon or chronic in cattle.
(xi) Blackleg.
(xii) Malignant edema.
(xiii) Early anthrax.
(xiv) Strangles of horses.
(xv) Bovine actinomycosis.
(xvi) Swine erysipelas in turkeys.

If such drug is represented for use as a treatment for mastitis, its labeling shall bear the statement, "Important: Milk from treated segments of udders should be discarded or used for purposes other than human consumption for at least 72 hours after the last treatment."

§ 146a.38 Capsules buffered penicillin with pectin hydrolysate (capsules buffered potassium penicillin with pectin hydrolysate) — (a) Standards of identity, strength, quality and purity. Capsules buffered penicillin with pectin hydrolysate are capsules composed of potassium penicillin with pectin hydrolysate and sodium citrate enclosed in a hard gelatin capsule. The potassium penicillin with pectin hydrolysate is prepared by lyophilizing a solution containing one part potassium penicillin and three parts of pectin hydrolysate by weight. The potency of each capsule is not less than 50,000 units. Its moisture content is not more than 4.0 percent. The penicillin used conforms to the requirements prescribed by § 146a.24 (a) and (b), and to the requirements of § 146a.24 (a) and (b), except the provision that it shall be capable of tight reclusion. The immediate container shall be a tight container as prescribed by the U. S. P., except the provision that it shall be capable of tight reclusion, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the capsules by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are not more than 2 percent in weight or strength of the contents shall be disregarded in checking the weight or strength of the contents. The number of capsules in the immediate container is such that the total number of units therein is not less than 300,000.

(b) Labeling. Each package of capsules buffered penicillin with pectin hydrolysate shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:
   (i) The batch mark;
   (ii) The number of units in each capsule of the batch;
   (iii) The quantity of the sodium citrate in each capsule of the batch; and
   (iv) The statement "Expiration date __________, the drug is in its full strength if the date which is twelve months after the month during which the batch was prepared: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:
   (i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.
   (ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request. Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled:
   (i) The statement that each ingredient used in making the batch; ten packages containing approximately equal portions of not less than 50 milligrams each, packaged in accordance with the requirements of § 146a.24 (b) (ii) and (iii).

(4) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The batch of capsules for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities contained in the intervals are approximately equal.
(2) The penicillin used in making the batch; ten packages containing approximately 250 cc. of the penicillin hydrolysate and one package of approximately five grams of the sodium citrate used in making the batch, one package of approximately 500 cc. of the penicillin hydrolysate and one package of approximately five grams of the sodium hydroxide used in preparing the penicillin hydrolysate.
(3) No result referred to in subparagraph (d) (3) (i) of this paragraph, is required if such result or such sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch of capsules buffered penicillin with pectin hydrolysate under the regulations in this part shall be

(1) $1.50 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (ii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsules and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The statement that each ingredient used in making such batch was completed, the number of units in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request the results of the tests and assays listed after each of the following, made by him on an accurately representative sample:

(1) The batch; average potency per capsule, average moisture.
(2) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G, penicillin G content.
(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The batch of capsules for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities contained in the intervals are approximately equal.
(2) The penicillin used in making the batch; ten packages containing approximately equal portions of not less than 50 milligrams each, packaged in accordance with the requirements of § 146a.24 (b) (ii) and (iii).

(2) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The batch of capsules for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities contained in the intervals are approximately equal.
(2) The penicillin used in making the batch; ten packages containing approximately 250 cc. of the penicillin hydrolysate and one package of approximately five grams of the sodium citrate used in making the batch, one package of approximately 500 cc. of the penicillin hydrolysate and one package of approximately five grams of the sodium hydroxide used in preparing the penicillin hydrolysate.
(3) No result referred to in subparagraph (d) (3) (i) of this paragraph, is required if such result or such sample has been previously submitted.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The batch of capsules for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities contained in the intervals are approximately equal.
(2) The penicillin used in making the batch; ten packages containing approximately equal portions of not less than 50 milligrams each, packaged in accordance with the requirements of § 146a.24 (b) (ii) and (iii).

(2) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The batch of capsules for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities contained in the intervals are approximately equal.
(2) The penicillin used in making the batch; ten packages containing approximately equal portions of not less than 50 milligrams each, packaged in accordance with the requirements of § 146a.24 (b) (ii) and (iii).

(2) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The batch of capsules for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities contained in the intervals are approximately equal.
(2) The penicillin used in making the batch; ten packages containing approximately equal portions of not less than 50 milligrams each, packaged in accordance with the requirements of § 146a.24 (b) (ii) and (iii).

(2) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The batch of capsules for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities contained in the intervals are approximately equal.
(2) The penicillin used in making the batch; ten packages containing approximately equal portions of not less than 50 milligrams each, packaged in accordance with the requirements of § 146a.24 (b) (ii) and (iii).
The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.39 Capsules procaine penicillin in oil—(i.e.) of identity, strength, quality, and purity. Capsules procaine penicillin in oil are capsules composed of procaine penicillin, aluminum monostearate, and sesame oil or peanut oil, blended in a suitable and harmless soft gelatin capsule. The potency of each capsule is not less than 200,000 units. Its moisture content is not more than 2.5 percent. The procaine penicillin used conforms to the standards prescribed by § 146a.44 (a) except § 146a.44 (a) (2) and (3). Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therein set forth. Standards of identity, strength, quality, and purity for capsules procaine penicillin in oil is such that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:
   (i) The batch mark.
   (ii) The number of units in each capsule of the batch.
   (iii) The name of the vegetable oil and the quantity of aluminum monostearate used in making the batch.
   (iv) The statement “Expiration date ________” the blank being filled in with the date which is 36 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container was made in an individual wrapper or container.

(2) On the outside wrapper or container:
   (i) The statement “Caution: Federal law prohibits dispensing without prescription,” unless it is packaged for dispensing and it is intended solely for veterinary use and is consecutively so labeled.
   (ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it, or a reference to a brochure or other printed matter containing similar information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That such references and statements shall be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is consecutively so labeled, adequate directions and warnings for the veterinary use of the contents shall be enclosed. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information (including contraindications and possible sensitization) adequate for the use of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Request for certification. Samples.

(1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each capsule, the quantity of each ingredient used in making the batch, the date on which the label and any other printed matter accompanying such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, if made by an accurately representative sample of:
   (i) The batch; average potency per capsule and average moisture.
   (ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is procaine penicillin) crystallinity, and the procaine penicillin K content.
   (iii) Except as otherwise provided by subparagraph (4) of this paragraph, the penicillin used conforms to the requirements of § 146a.44 (a) except the limitation on penicillin K content and except § 146a.44 (a) (2) and (3). Each other substance used, if its name is recognized in the U. S. P. or N. P., conforms to the standards prescribed therefor by such official compendium.

(4) In case of an initial request for certification, the sesame oil or peanut oil, and each other ingredient used in making the batch; 1 package of each containing, respectively, approximately 250 grams and approximately 5 grams.

(5) No result referred to in subparagraph (4) of this paragraph, and no sample referred to in subparagraph (3) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $3.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such capsules and packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations may be included in the fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.40 Penicillin bougies (sodium penicillin bougies, calcium penicillin bougies, potassium penicillin bougies, procaine penicillin bougies, penicillin bougies sodium salt, penicillin bougies calcium salt, penicillin bougies potassium salt, penicillin bougies protamine salt) (a) Standards of identity, strength, quality, and purity. Penicillin bougies are bougies composed of sodium penicillin, calcium penicillin, potassium penicillin, or procaine penicillin in an equivalent of polyethylene glycol or of one or more other suitable and harmless diluents, binders, and lubricants. The potency of each bougie is not less than 100 units per milligram. The sodium penicillin, calcium penicillin, or potassium penicillin used conforms to the requirements of § 146.24 (a) except the limitation on penicillin K content and except § 146.24 (a) (1) (2) and (4). But its potency is not less than 300 units per milligram. The sodium penicillin used conforms to the requirements of § 146a.44 (a) except the limitation on penicillin K content except § 146a.44 (a) (2) and (3). Each other substance used, if its name is recognized in the U. S. P. or N. P., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Unless each penicillin bougie is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight closure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the bougies by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therein set forth in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of penicillin bougies shall bear, on its label or
the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If the excipient is polyethylene glycol, the excipient shall be not above 15° C. (59° F.) unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug is stable at such intervals throughout the entire time the bougies are being made, that the quantities made during the intervals are approximately equal.

The statement “Expiration date __________” shall be not less than one milliliter and not more than 20 milliliters unless it is packaged for repacking. Unless it is packaged for repacking the container shall be filled with a volume of crystalline penicillin and epinephrine in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated whether administered in either single or multiple doses.

(c) Labelling. Each package of crystalline penicillin and epinephrine in oil shall bear, on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and the immediate container of the batch;

(2) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) Requests for certification, samples, (1) The person applying for a certificate of a batch of penicillin bougies shall file with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(2) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample:

(i) The batch; average potency per bougie, and moisture.

(iii) The statement “Expiration date __________” shall be not less than one milliliter and not more than 20 milliliters unless it is packaged for repacking. Unless it is packaged for repacking the container shall be filled with a volume of crystalline penicillin and epinephrine in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated whether administered in either single or multiple doses.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one bougie for each 5,000 bougies in the batch; in no case less than 20 bougies or more than 100 bougies, collected by taking single bougies at such intervals throughout the entire time the bougies are being made, that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 5 packages, or in the case of crystalline penicillin 10 packages, each containing not less than 600 milligrams of not less than 50 milligrams if it is not procaine penicillin and not less than 300 milligrams if it is procaine penicillin, packaged in accordance with the requirements of §§ 146a.24 (b) or § 146a.44 (b)

(iii) In case of an initial request for certification, each polyethylene glycol and each carrier ingredient used in making the batch; one package of each containing approximately 25 grams.

(4) No result referred to in subparagraph (d) (i) of this paragraph, and no sample referred to in subparagraph (d) (ii) of this paragraph, is required if such result or sample has been previously submitted:

(c) Fees. The fee for the services rendered with respect to each batch of penicillin bougies under the regulations in this part shall be:

(1) $1.00 for each bougie in the sample submitted in accordance with paragraph (d) (1) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (2) (i) or (ii) and (3) (i) or (ii)

(2) If the Commissioner considers that investigations other than examination of such bougies and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations shall be covered by such fee.

The fee prescribed by subparagraph (d) (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 156.5 (d) of this chapter.

§ 146a.41 Crystalline penicillin and epinephrine in oil -- Standards of identity, strength, quality, and purity.

Crystalline penicillin and epinephrine in oil is a suspension of crystalline penicillin and epinephrine in a menstrum of refined peanut oil or sesame oil. Each milliliter has a potency of 500,000 units and contains 0.3 milligram of epinephrine. Its moisture content is not more than 0.2 percent. It is sterile. The penicillin used conforms to the requirements of § 146a.24 (a) for crystalline penicillin. The epinephrine, peanut oil, and sesame oil used conform to the standards prescribed therefor.

(b) Packaging. The immediate container of crystalline penicillin and epinephrine in oil shall be of colorless transparent glass so closed as to be a tight closure against passage of air and light. Each ampuls shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that the changes occasioned which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

The quantity of crystalline penicillin and epinephrine in oil shall not be less than one milliliter and not more than 20 milliliters unless it is packaged for repacking. Unless it is packaged for repacking the container shall be filled with a volume of crystalline penicillin and epinephrine in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated whether administered in either single or multiple doses.

(v) The statement “For intramuscular use only” and “Shake well”;

(vi) The name of the oil used in making the batch.

(2) On the outside wrapper or container, the statement “Caution: Federal law prohibits dispensing without prescription,” unless it is packaged for dispensing;

(3) The quantity of epinephrine per milliliter of the batch;

(iv) The statement “Expiration date __________” shall be not less than one milliliter and not more than 20 milliliters unless it is packaged for repacking. Unless it is packaged for repacking the container shall be filled with a volume of crystalline penicillin and epinephrine in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated whether administered in either single or multiple doses.

(2) Except as otherwise provided by subparagraph (d) (i) of this paragraph, the person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request adequate directions and warnings for its veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer such drug.

(2) Except as otherwise provided by subparagraph (d) (i) of this paragraph, the person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request adequate directions and warnings for the veterinary use of such drug by a veterinarian licensed by law to administer it.

(2) Except as otherwise provided by subparagraph (d) (i) of this paragraph, the person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request adequate directions and warnings for its veterinary use and is conspicuously so labeled.

(2) Except as otherwise provided by subparagraph (d) (i) of this paragraph, the person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request adequate directions and warnings for the veterinary use of such drug by the laity.

Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer such drug.

(2) Except as otherwise provided by subparagraph (d) (i) of this paragraph, the person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request adequate directions and warnings for the veterinary use of such drug by a veterinarian licensed by law to administer it.

(2) Except as otherwise provided by subparagraph (d) (i) of this paragraph, the person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request adequate directions and warnings for the veterinary use of such drug by the laity.

Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer such drug.

(2) Except as otherwise provided by subparagraph (d) (i) of this paragraph, the person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request adequate directions and warnings for the veterinary use of such drug by the laity.

Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer such drug.

(2) Except as otherwise provided by subparagraph (d) (i) of this paragraph, the person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request adequate directions and warnings for the veterinary use of such drug by the laity.

Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer such drug.
penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the epinephrine, peanut oil or sesame oil used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (a) of this paragraph, such person shall submit to the Commissioner with his request results of the tests and assays listed in the following:

(a) The quantities packaged in each batch.
(b)Such samples shall be collected at such intervals during the batch as indicated, and not less than 2 grams and 250 packages, each containing approximately 2 grams and 250 peanut oil or sesame oil used in making the batch. The quantities hereinafter indicated, accurate representative samples of the following:

(i) The batch; potency, sterility, moisture, and epinephrine content.
(ii) The penicillin used in making the batch; potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content (unless it is crystalline penicillin G); crystallinity, heat stability and the penicillin G content if it is crystalline penicillin G.
(iii) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as to be closed in such a manner as to prevent any loss of strength or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (1) and (3) of this section; and
(2) If the Commissioner considers that investigations, other than the examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fees prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.42 Aluminum penicillin (aluminum potassium salt)—(a) Standards of identity, strength, purity, and quality.
Aluminum potassium penicillin is a suspension of aluminum penicillin in a menstruum of refined peanut oil or sesame oil. Its potency is not less than 500 units per milliliter. Its moisture content is not more than 3 percent; and its pH in saturated aqueous solution is not less than 3.5 and not more than 4.5.

(b) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as to be closed in such a manner as to prevent any loss of strength or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of aluminum potassium penicillin shall bear on its outside wrapper or container the immediate container as hereinafter indicated, the following:

(1) The batch mark;
(2) The weight of the drug and the number of units in the immediate container;
(3) The statement "Expiration date ___" and the blank being filled in with the date which is 12 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container; and
(4) The statement "Store in refrigerator not above 15° C. (59° F.)." or "Store below 15° C. (59° F.)."
(5) The statement "For manufacturing use only;"
(6) The statement "Caution: Federal law prohibits dispensing without prescription;"

(d) Request for certification, checks tests and assays; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who makes the certification of a batch of aluminum penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed with results of the tests and assays made by him on the penicillin, potency, sterility, pyrogens, toxicity, moisture, pH, and the penicillin K content.

(2) Such person shall submit in connection with his request an accurately representative sample of the batch, consisting of the following:

(1) For all tests except sterility- 6 packages.
(2) For sterility testing- 10 packages.

Each such package shall contain approximately 300 milligrams taken from different parts of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manner in which aluminum penicillin is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make such tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not necessary to show when used in such other drug. The Commissioner shall report to such manufacturer results of each check test and assay as are so requested.

(e) Fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.43 Aluminum penicillin in oil—(a) Standards of identity, strength, quality, and purity.
Aluminum penicillin in oil is a suspension of aluminum potassium penicillin in a menstruum of refined peanut oil or sesame oil. Its potency is 300,000 units per milliliter. Its moisture content is not more than 1.5 percent. It is sterile. The aluminum penicillin used conforms to the requirements of § 146a.42 (a) (d). The peanut oil or sesame oil used conforms to the standards prescribed therefor by the U. S. P.

(b) Packaging. The immediate container of aluminum penicillin in oil shall be of colorless, transparent glass, closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed...
that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents during the intervals at which it is maintained in accordance with regulations in this part. Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The aluminum penicillin used in making the batch:
   (a) For all tests except sterility: one package for each 500 packages in the batch, but in no case less than 3 packages or more than 12 packages.
   (b) For sterility testing: 10 packages.

Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The aluminum penicillin used in making the batch:
   (a) For all tests except sterility: one package for each 500 packages in the batch, but in no case less than 3 packages or more than 12 packages.
   (b) For sterility testing: 10 packages.

Each such drug is so purified and dried that:

(1) Its potency is not less than 900 units per milligram;
(2) It is sterile;
(3) It is nonpyrogenic;
(4) It is nontoxic;
(5) Its moisture content is not more than 7.5.

(b) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labelling. Each package of procaine penicillin shall bear on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark;
(2) The weight of the drug and the number of units in the immediate container;
(3) The statement "Expiration date..." the blank being filled in with the date which is 36 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 6 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared in them complies with the standards prescribed by paragraph (a) of this section: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container if such immediate container is packaged during the intervals are approximately equal.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(d) Fee. The fee for the services rendered with respect to each batch of aluminum penicillin in oil under the regulations in this part shall be:

$4.00 for each package in the samples referred to in subparagraph (3) (ii) of this section:

§ 146a.44 Procaine penicillin (penicillin G procaine salt)—(a) Standards of identity, strength, quality, and purity. Procaine penicillin is the crystalline procaine salt of a kind of penicillin, or a mixture of two or more such salts prepared from procaine hydrochloride that complies with all the standards prescribed by the U. S. P., except for the color of the crystals and penicillin, but the quantity of any salt of penicillin K therein is not more than 30 percent; procaine penicillin G is procaine penicillin which contains not less than 85 percent by weight of the procaine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 900 units per milligram;
(2) It is sterile;
(3) It is nonpyrogenic;
(4) It is nontoxic;
(5) Its moisture content is not more than 4.2 percent; and
(6) Its pH In saturated aqueous solution is not less than 5 and not more than 7.5.

(b) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labelling. Each package of procaine penicillin shall bear on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark;
(2) The weight of the drug and the number of units in the immediate container;
(3) The statement "Expiration date..." the blank being filled in with the date which is 36 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 6 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared in them complies with the standards prescribed by paragraph (a) of this section: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container

was previously submitted) the date on which the latest assay of the aluminum penicillin used in making such batch was completed, the number of units in each package referred to in subparagraph (3) (ii) of this section showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it
container is packaged in an individual wrapper or container, except that such drug be so labeled, it may contain nitrofurazone or adrenocorticosterone hormone (ACTH). Its potency is 300,000 units per milliliter, except if it is packaged in a single dose, its potency is not less than 10,000 units per milliliter. Its moisture content is not more than 1.4 percent. It is sterile, unless it is packaged and labeled solely for use in subcutaneous injection in fowl. The procaine penicillin used conforms to the requirements of § 146a.44 (a), except if the batch of procaine penicillin in oil is packaged and labeled solely for use in subcutaneous injection in fowl, the procaine penicillin used is exempt from the requirements of subparagraph (2) of this section. The sesame oil and peanut oil used conform to the standards prescribed thereunder.

§ 146a.45 Procaine penicillin in oil—
(a) Standards of identity, strength, quality and purity. Procaine penicillin in oil is a suspension of procaine penicillin in refined peanut oil or sesame oil, except if it is packaged in a single dose, it shall contain no more suitable and harmless dispersing agents and with or without the addition of a hardening agent. If it is intended solely for veterinary use and contains adrenocorticosterone hormone, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and is intended solely for veterinary use and is conspicuously so labeled.

(b) Packaging. The immediate container of procaine penicillin in oil shall be of colorless transparent glass (unless it is packaged to contain a single dose), or closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, and shall be so sealed that its contents cannot be used without destroying such seal, except if it is labeled solely for use in subcutaneous injection in fowl. It may be packaged in plastic or collapsible tubes which shall be well-closed by means of a preservative and convenient to use.

The immediate container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit thereunder in applicable standards, except that minor changes so caused which are normal and unavoidable in good marketing, storage, and distribution practice shall be disregarded. The quantity of procaine penicillin in oil in each such container shall not be less than 1 milliliter and not more than 20 milliliters, unless it is packaged for repackaging or is packaged in a container of a size in the batch and, if aluminum monostearate is used as the dispersing agent or if nitrofurazone or adrenocorticosterone hormone is used, the quantity used.

(2) If it is intended solely for veterinary use and contains adrenocorticosterone hormone, the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian.

(3) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it, or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled:

(a) The date on which the batch was certified, except if it is packaged in a single dose, it shall contain no more suitable and harmless dispersing agents and with or without the addition of a hardening agent. If it is intended solely for veterinary use and contains adrenocorticosterone hormone, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and is intended solely for veterinary use and is conspicuously so labeled.

(b) The batch mark; and

(iii) The statement "Expiration date:____" on the label, the blank being filled in, if it is packaged in a single dose, if it is intended solely for veterinary use and contains adrenocorticosterone hormone, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and is intended solely for veterinary use and is conspicuously so labeled.

(c) Label and labeling of package of procaine penicillin in oil shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container of the package:
ment, if it is intended for subcutaneous injection in fowl, that it should be injected in the neck immediately behind the head.

Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug be available at no charge by written request to such veterinarian as hereafter indicated, the number of units in each such package, the quantity of each ingredient used in making such load, and the date on which this assay of the drug was performed, and that each ingredient used in making such batch conforms to the requirements prescribed therefor by this section.

(d) Requests for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of procaine penicillin in oil shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed, and that each ingredient used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by a person accurately representative of samples of:

(i) The batch; potency, sterility (unless it is intended solely for udder instillations of cattle or subcutaneous injection in fowl) and moisture.

(ii) The procaine penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, penicillin K content (unless it is crystalline penicillin) (2) procaine penicillin G content if it is the procaine penicillin G, and, unless the batch of procaine penicillin in oil is intended solely for udder instillations of cattle or subcutaneous injection in fowl, sterility or pyrogens.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, each package shall contain in connection with his request results of the tests and assays listed after each of the following, made by a person accurately representative of samples of the following:

(a) The batch;

(b) For all tests except sterility: 10 packages, each containing approximately equal portions of 300 milligrams.

(c) For all tests except sterility: 10 packages, each containing approximately equal portions of 500 milligrams.

(d) For sterility testing: 10 packages, each containing approximately equal portions of 300 milligrams.

(e) For all tests except sterility: 10 packages, each containing approximately equal portions of 500 milligrams.

(f) For sterility testing: 10 packages, each containing approximately equal portions of 500 milligrams.

(g) No result referred to in subparagraph (d) (ii) of this paragraph, and no sample referred to in subparagraph (d) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(h) Fees. The fees for the services rendered with respect to each batch of procaine penicillin in oil under the regulations in this part shall be:

(1) § 146a.44 (a) except subparagraphs (2) and (4) of that paragraph.

(2) Except as otherwise provided in this paragraph, each package shall bear on its label or labeling as herein:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date ________," the blank being filled in, if crystalline sodium penicillin or potassium penicillin is used, without a diluent, with the date which is 24 months, or if a diluent is used, with the date which is 18 months after the month during which the batch was completed; Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If it is packaged in combination with a container of a solvent, the statement "Warning—Not for injection.

(v) The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification if such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.45 Crystalline penicillin for inhalation therapy—(a) Standards of identity, strength, quality, and purity. Crystalline penicillin for inhalation therapy is crystalline sodium penicillin, with or without one or more suitable and harmless diluents. Its moisture content is not more than 1.5 percent if it is crystalline sodium or potassium penicillin, and not more than 2.5 percent if it is potassium penicillin. The crystalline penicillin used conforms to the requirements of § 146a.24 (a) except subparagraphs (2) and (4) of that paragraph.

(b) Packaging. The immediate container for crystalline penicillin for inhalation therapy shall be a tight container as defined by the U. S. P., its closure shall be one through which a hypodermic needle cannot be introduced; and if a diluent is used in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

§ 146a.46 Crystalline penicillin for inhalation therapy shall be a tight container as defined by the U. S. P., its closure shall be one through which a hypodermic needle cannot be introduced; and if a diluent is used in the U. S. P. or N. F., conform to the standards prescribed therefor by such official compendium.

§ 146a.47 Crystalline penicillin for inhalation therapy shall be a tight container as defined by the U. S. P., its closure shall be one through which a hypodermic needle cannot be introduced; and if a diluent is used in the U. S. P. or N. F., conform to the standards prescribed therefor by such official compendium.
made by him on an accurately representative sample of:

1. The potency and moisture.
2. The penicillin used in making the batch: potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G) crystallinity if it is crystalline such batch has been used in making it; if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

3. Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

1. The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers, before or after each interval at such intervals and throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

2. The penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 80 milligrams if it is not procaine penicillin, and not less than 300 milligrams if it is procaine penicillin, packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b).

3. In case of an initial request for certification and labeling at such intervals during the batch; one package of each container containing approximately 5 grams.

No result referred to in subparagraph (2) (ii) of this paragraph, and no samples collected for this purpose (including any said to be submitted in accordance with subparagraph (d) (1), (ii), and (iii) of this section).

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigation shall be borne by the person who requests certification.

The fee prescribed by paragraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.27 Procaine penicillin for aqueous injection—(a) Standards of identity, strength, toxicity, and purity. Procaine penicillin for aqueous injection is a dry mixture of procaine penicillin and one or more suitable and harmless suspending or dispersing agents, with or without one or more suitable and harmless preservatives and buffer substances, or it is an aqueous suspension of procaine penicillin and one or more suitable and harmless suspending or dispersing agents, buffer substances, and preservatives, except that preservatives are not required if the immediate container is packaged to contain a single dose and is not more than 12 milliliters or if it is an aqueous suspension of the drug if it may contain procaine hydrochloride in a concentration not exceeding 2 percent and one or more suitable and harmless suspending or dispersing agents. It is so purified that:

1. If it is an aqueous suspension of the drug, each container or each milliliter shall contain not less than 300,000 units;

2. It is sterile;

3. If it is the dry mixture of the drug, its moisture content is not more than 4.2 percent;

4. If it is nonpyrogenic;

5. It is nontoxic; and

6. Its pH in saturated aqueous solution is not less than 5.0 and not more than 7.5.

The procaine penicillin used conforms to the requirements of § 146a.44 (a) (1) Other substances, if its name is recognized in the U. S. P., or its equivalent, conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P., or its equivalent, and shall be sterile at the time of filling and closing, shall be so sealed that the container cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless, transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without destroying or diminishing its effectiveness, unless it is the aqueous suspension of the drug and it is packaged to contain a single dose. If it is the dry mixture of the drug, each such container shall contain 300,000 units, 600,000 units, 900,000 units, 1,500,000 units, 1,500,000 units, or 3,000,000 units, unless it is intended solely for veterinary use and it is consistently so labeled. Each such container may be packaged in combination with a container of a suitable aqueous diluent. If it is the aqueous suspension of the drug, each such container shall contain more than 12 milliliters (unless it is packaged to contain a single dose) and not more than 12 milliliters (unless it is intended solely for veterinary use and is consistently so labeled) and each shall be filled with a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered as the single or multiple doses.

(c) Labeling. Each package shall bear on its label or labeling, as hereinafter indicated, the following:

On the outside wrapper or container and the immediate container:

1. The batch mark;

2. The number of units in the immediate container;

3. The statement "Expiration date ———", the blank being filled in, if it is the dry mixture of the drug, which is 36 months, or if it is the aqueous suspension of the drug, with the date which is 12 months after the month during which the batch was certified, if such date is not to exceed the date which is 48 months, if it is the dry mixture of the drug, and 18 months or 24 months, if it is the aqueous suspension of the drug, after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and accepts showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section. Provided, however, that such expiration date may be omitted if the immediate container is packaged in an individual wrapper or container;

4. The statement "For intramuscular use only" and

5. If the drug contains preservatives or added procaine hydrochloride, the name and quantity of each such added ingredient.

(2) On the immediate container, if it is a dry mixture of the drug, the conditions under which suspensions made from such drug should be stored, and the statement "Sterile suspension may be kept at room temperature for 1 week, or in a refrigerator for 3 weeks, without significant loss of potency," unless such information is contained in a circular or other labeling within or attached to the package.

(3) On the outside wrapper or container:

1. The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is consistently so labeled.

2. If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug; by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request. Provided, however, that such reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

3. If it is the aqueous suspension of the drug, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)" unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section.
of this section after having been stored at room temperature.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug may be obtained by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Requests for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of procaine penicillin for aqueous injection shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of such procaine penicillin was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, one package of each ingredient used in making the batch, and the waste produced in making the batch; the date on which the latest assay of such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of such batch was completed, the number of units in each of such packages, and the weight of the drug and the number of units in the immediate container.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request a sample consisting of the following:

(i) For all tests except sterility 10 packages.

(ii) For sterility testing; 10 packages.

Such samples shall be collected by taking single immediate containers at such intervals that no sample referred to in subparagraph (ii) of this section is less than 10 or more than 17 immediate containers.

(b) Packaging. Each immediate container shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall state such content as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of ephedrine penicillin shall bear on its Outside, wrapper or container and the immediate container as hereinafter indicated the following:

(1) The batch mark.

(2) The weight of the drug and the number of units in the immediate container.

(3) The statement “Expiration date

(4) The statement “For manufacturing uses only.”


(d) Requests for certification, check tests and assays; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of ephedrine penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the weight of the drug and the number of units in each package, the date on which such sample was previously submitted, the date on which the latest assay of the drug comprising such batch is packaged for dispensing, the number of packages of each size in such batch, the weight of the drug and the number of units in each package, and the weight of the drug and the number of units in the immediate container.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility 10 packages.

(ii) For sterility testing; 10 packages.

Each such package shall contain approximately 300 milligrams taken from a different part of each batch, and each package shall be filled in accordance with the requirements of paragraph (b) of this section.

(3) In connection with the contents of this section, the request for certification of batches of another drug in the manufac-
amination of such immediate containers that investigations other than the examinations described in this chapter shall be
rendered with respect to each batch and assays as are so requested.
(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (1) and (3) of this section; and

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed under subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is collected by an advance deposit maintained in accordance with §146.8 (d) of this chapter.

§146a.49 Ephedrine penicillin tablets—(a) Standards of identity, strength, quality, and purity. Ephedrine penicillin tablets are tablets composed of ephedrine penicillin and one or more buffer substances, with or without one or more suitable and harmless diluents, binders, and lubricants. The potency of each tablet is not less than 30,000 units. Its moisture content is not more than 1.5 percent. When a tablet is dissolved as directed the potency of such solution is not less than 95 percent of the labeled potency after it has been kept for one day at a temperature of 15°C. (59°F) Such solution is isotonic, and has a pH of 6.0 ± 0.2. The ephedrine penicillin used conform to the requirements of §146a.48 (a) for ephedrine penicillin except subparagraphs (2) and (4) of §146a.48 (a)

Each buffer substance and preservative used in such tablets shall be recognized in the U.S.P. or N.F., conform to the standards prescribed therefor by such official compendium.

(b) Packaging. Unless each tablet is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U.S.P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The foil or film container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the container or enclosure of the foil or film, enclosure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of tablets ephedrine penicillin shall bear, on its label or labeling as hereinafter indicated, the following:

(1) The batch mark;
(2) The number of units in each tablet of the batch;
(3) The statement "Expiration date—'______';" the blank being filled in with the date which is 24 months after the month during which the batch was certified; Provided, however, That such expiration date shall be from the immediate container if such immediate container is packaged in an individual wrapper or container;

(4) A statement giving the method of dissolving the tablets, and a statement that distilled water U. S. P. should be used;

(5) The potency per milliliter after the tablets are dissolved as will not cause any change in the strength, quality, or purity of the contents;

(6) The statement "Warning—Not for injection or oral use"; and

(7) The conditions under which the solution should be stored including a reference to its instability when stored under other conditions, and a statement "Prepare a fresh solution each 24 hours."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled;

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent to such veterinarian on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package;

(iii) On the label or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request;

(iv) If a brochure or other printed matter containing information for other veterinary uses of such drug by the laity is ephedrine penicillin (G) crystaline, and the penicillin G content if it is ephedrine penicillin G.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request, in the quantities hereafter beac indicated, a representative sample of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tabletting that the quantities tabled during the intervals are approximately equal.

(ii) The ephedrine penicillin used in making the batch; six packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of §146a.48 (b)

(iii) In case of an initial request for certification, each buffer substance, diluent, binder, and lubricant used in making the batch; one package of each, each containing approximately 5 grams.

(d) No result referred to in subparagraph (3) (ii) of this paragraph, and no sample referred to in subparagraph (3) (i) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for services rendered with respect to each batch of ephedrine penicillin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (1) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (1) and (3) of this section.

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed under subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.8 (d) of this chapter.

§146a.50 Procaine penicillin and buffered crystalline penicillin for aqueous
injection. Procaine penicillin and buffered crystalline penicillin for aqueous injection conforms to all requirements prescribed by § 146a.47 for the dry mixture of procaine penicillin and the number of units of buffered crystalline penicillin in the immediate container; the circular or other labeling within or attached to the package, if it is packaged for dispensing, shall bear, in lieu of the statement prescribed by § 146a.47 (c) (2) the statement "Sterile suspension may be kept in refrigerator for _______ week(s) without significant loss of potency," the blank being filled in with the figure "1," or if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him does not lose significant potency after having been stored in a refrigerator for 4 weeks, the blank may be filled in with the figure "4," unless it is packaged to conform with paragraph (b) of this section.

(d) In addition to complying with the requirements of § 146a.47 (d) a person who requests certification of a batch of procaine penicillin and the number of units of buffered crystalline penicillin in the immediate container; the circular or other labeling within or attached to the package, if it is packaged for dispensing, shall bear, in lieu of the statement prescribed by § 146a.47 (c) (2) the statement "Sterile suspension may be kept in refrigerator for _______ week(s) without significant loss of potency," the blank being filled in with the figure "1," or if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him does not lose significant potency after having been stored in a refrigerator for 4 weeks, the blank may be filled in with the figure "4," unless it is packaged to conform with paragraph (b) of this section.

(e) The fee for the services rendered with respect to each immediate container in the sample of buffered crystalline penicillin submitted in accordance with the provisions of § 146a.47 shall be $4.00.

§ 146a.51 Buffered penicillin powder, penicillin powder with buffered aqueous diluent—(a) Standards of identity, strength, quality, and purity. Buffered penicillin powder is a mixture of crystalline penicillin or penicillin G and suitable buffer substances, with or without probenecid, sodium salicylate and a suitable antihistamine agent, with or without one or more suitable sulfonamides, and with or without the addition of one or more suitable and harmless dyes, colorings, and flavorings. Penicillin powder with buffered aqueous diluent is a packaged combination of one immediate container of crystalline penicillin or procaine penicillin, with or without suitable and harmless diluents, and one immediate container of an aqueous diluent containing suitable buffer substances and suitable and harmless preservatives, colorings, and flavorings. Its dry weight content is not less than 1.0 percent, except if it contains procaine penicillin its moisture content is not more than 2.0 percent. The crystalline penicillin used conforms to the requirements of § 146a.24 (a) for crystalline penicillin, except subparagraphs (2) and (4) of that paragraph. The procaine penicillin used conforms to the requirements of § 146a.44 paragraphs (2) and (3) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therby for such official compound.

(b) Packaging. In all cases the immediate container of buffered penicillin powder shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limits therein approved by the standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each immediate container may be packaged in combination with a container of a suitable and harmless aqueous vehicle, with or without probenecid, and with or without one or more suitable sulfonamides.

(c) Labeling. Each package of buffered penicillin powder or penicillin powder shall bear on its label or labeling, as hereafter indicated, the following:

(i) On the outside wrapper or container and the immediate container;

(ii) The batch mark;

(iii) The number of units in the immediate container;

(iv) If the batch contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient in the immediate container;

(v) The name of each buffer substance, with or without probenecid;

(vi) The statement "Expiration date ________" the blank being filled in with the date which is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 36 months after the month during which the batch was certified if it is crystalline penicillin or penicillin G, or a person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(vii) The statement "Warning—Not for injection."

(2) On the outside wrapper or container;

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling if it contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this section, after the name "buffered penicillin powder," wherever it appears, the words "with ________ (the blank being filled in with the common or usual name of each such other ingredient)." in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian is available, and such statement is to be sent so to such veterinarian on request.

(d) Request for certification; samples.

(1) In addition to complying with the requirements of § 146a.3 of this chapter, a person who requests certification of a
batch of buffered penicillin powder shall submit with his request a statement showing the batch mark, the number of packages in each such container and the quantity of each ingredient used in making such batch, the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each such container, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (1) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(I) The batch; if buffered penicillin powder or penicillin powder with diluents: potency and moisture; if penicillin powder, the penicillin content if it is crystalline sodium or potassium penicillin, the penicillin powder or penicillin powder with diluents:

(ii) Each package of immediate containers required by § 146a.45 of this chapter for the issuance of a certificate, the cost of such investigations.

(f) Fees. The fee for the services rendered with respect to each batch of buffered penicillin powder under the regulations in this part shall be:

(i) An advance deposit main-

(ii) (i) $4.00 for each immediate con-

(iii) $3,000 units of buffered penicillin in oil shall submit with his request a statement showing the batch mark and (unless it was previously sub-

(iv) $5.00 for each immediate con-

(v) In case of an Initial request for certification, each other ingredient other than the procaine penicillin and the number of units of procaine penicillin; and for each 60-milligram portion, 500 milligrams if it is pro-

(a) They are intended solely for veter-

(b) If they contain added vitamins or minerals, the labels bear the name and quantity of each such substance and a statement that they are intended only for furnishing additional vitamins and minerals while animals are eating less feed.

(c) The labels shall bear a statement that solutions prepared with the drugs are stable for not more than 24 hours.

(d) The circular or other labeling within or attached to the package bears a statement that the tablets are intended for the prevention or treatment of the following conditions, and further, directions and warn-

(e) That each ingredient used in mak-

(f) That each ingredient used in mak-

(g) That each ingredient used in mak-

(h) That each ingredient used in mak-

(i) That each ingredient used in mak-

(j) That each ingredient used in mak-

(k) That each ingredient used in mak-

(l) That each ingredient used in mak-

(m) That each ingredient used in mak-

(n) That each ingredient used in mak-

(o) That each ingredient used in mak-

(p) That each ingredient used in mak-

(q) That each ingredient used in mak-

(r) That each ingredient used in mak-

(s) That each ingredient used in mak-

(t) That each ingredient used in mak-

(u) That each ingredient used in mak-

(v) That each ingredient used in mak-

(w) That each ingredient used in mak-

(x) That each ingredient used in mak-

(y) That each ingredient used in mak-

(z) That each ingredient used in mak-

{A} That each ingredient used in mak-

{B} That each ingredient used in mak-

{C} That each ingredient used in mak-

{D} That each ingredient used in mak-

{E} That each ingredient used in mak-

{F} That each ingredient used in mak-

{G} That each ingredient used in mak-

{H} That each ingredient used in mak-

{I} That each ingredient used in mak-

{J} That each ingredient used in mak-

{K} That each ingredient used in mak-

{L} That each ingredient used in mak-

{M} That each ingredient used in mak-

{N} That each ingredient used in mak-

{O} That each ingredient used in mak-

{P} That each ingredient used in mak-

{Q} That each ingredient used in mak-

{R} That each ingredient used in mak-

{S} That each ingredient used in mak-

{T} That each ingredient used in mak-

{U} That each ingredient used in mak-

{V} That each ingredient used in mak-

{W} That each ingredient used in mak-

{X} That each ingredient used in mak-

{Y} That each ingredient used in mak-

{Z} That each ingredient used in mak-
§ 146a.54 Penicillin-streptomycin ointment (penicillin-streptomycin mineral oil suspension), penicillin-dihydrostreptomycin ointment, and penicillin-dihydrostreptomycin ointment contains cobalt, preservatives, sulfonamides, and histamine.

(1) It contains not less than 2,000 units of penicillin per gram.

(2) It contains not less than 10 milligrams of streptomycin or dihydrostreptomycin per gram, unless it is intended solely for veterinary use and is conspicuously so labeled. The streptomycin used conforms to the standards prescribed by §146a.40 of this chapter, except that:

(a) Penicillin-streptomycin ointment and penicillin-dihydrostreptomycin ointment conform to all requirements of §146a.40 for penicillin ointment, except that:

(1) Each bougie contains not less than 25 milligrams of streptomycin or dihydrostreptomycin.

(b) In lieu of the directions prescribed for penicillin ointment by §146a.40 (c) (1) (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each bougie.

(c) In addition to complying with the requirements of §146a.40 (d), a person who requests certification of a batch of penicillin-streptomycin bougies or penicillin-dihydrostreptomycin bougies shall submit with his request a statement showing the batch mark (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch, conforming to the standards prescribed by §146a.40 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of batches submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.55 Penicillin-streptomycin bougies; penicillin - dihydrostreptomycin bougies. (a) Penicillin-streptomycin bougies and penicillin-dihydrostreptomycin bougies conform to all requirements prescribed by §146a.40 for penicillin bougies, except paragraph (c) (1) (iv) of that section, and are subject to all procedures prescribed by §146a.40 for penicillin bougies.

(1) Each bougie contains not less than 25 milligrams of streptomycin or dihydrostreptomycin.

(2) In lieu of the directions prescribed for penicillin bougies by §146a.40 (c) (1) (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each bougie.

(c) In addition to complying with the requirements of §146a.40 (d), a person who requests certification of a batch of streptomycin or dihydrostreptomycin bougies shall submit with his request a statement showing the batch mark (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch, conforming to the standards prescribed by §146a.40 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of batches submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.57 Procaine penicillin and streptomycin in oil; procaine penicillin and dihydrostreptomycin in oil. (a) Procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil conform to all requirements prescribed in §§146a.40 and 146a.45 for procaine penicillin in oil for udder instillations of cattle or subcutaneous injection in fowl, except that:

(1) It contains not less than 2.0 milligrams of streptomycin or dihydrostreptomycin per milliliter. The streptomycin used conforms to the standards prescribed by §146b.103 of this chapter, except subparagraphs (2), (4), and (5) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed by §146b.101 (d) of this chapter.

(b) In lieu of the directions prescribed in §146a.40 (c) (2) each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each bougie. He shall also submit in connection with his request a sample consisting of not less than 60 bougies; penicillin-streptomycin or penicillin-dihydrostreptomycin bougies shall submit with his request a statement showing the batch mark (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch, conforming to the standards prescribed by §146a.40 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of batches submitted in accordance with the requirements prescribed therefor by this official compendium.

(3) In lieu of the labeling prescribed for procaine penicillin in oil by §146a.45 (c) (1) (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed by this section shall be $4.00.

§ 146a.56 Penicillin-bacitracin ointment. (a) Penicillin-bacitracin ointment and preparations prescribed by §146a.26 for penicillin ointment and is subject to all procedures prescribed by §146a.40 for penicillin ointment, except that:

(1) Each package shall bear on the outside wrapper or container the number of units of penicillin and the number of milligrams of bacitracin in each bougie.

(2) It contains not less than 100 units of bacitracin per gram.

(b) In lieu of the directions prescribed for penicillin ointment by §146a.40 (c) (1) (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of bacitracin per gram.

(c) In addition to complying with the requirements of §146a.40 (d) a person who requests certification of a batch of penicillin-bacitracin ointment shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays of the bacitracin used in making the batch, conforming to the standards prescribed by §146a.40 (b) of this chapter.

(d) The fee for the services rendered with respect to each immediate container in the sample of batches submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.
procake penicillin and streptomycin in oil or procaine penicillin and dihydrostreptomycin in oil shall contain with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline streptomycin; the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the solution on the strength and size labeling, shall be so scaled that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength of the solution. The contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless (unless it is intended solely for veterinary use) transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Unless it is intended solely for veterinary use and is conspicuously so labeled, each such container shall contain 300,000 units, 600,000 units, 1,500,000 units or 3,000,000 units of procaine penicillin or crystalline sodium penicillin or potassium penicillin or tetracycline penicillin G or a mixture of procaine penicillin and crystalline sodium penicillin or potassium penicillin or tetracycline penicillin G and not less than 0.25 gram of streptomycin or dihydrostreptomycin for each 300,000 units of penicillin, except if it is a mixture of two salts of pentamidine, it shall contain not less than 100,000 units of procaine penicillin or crystalline sodium penicillin or potassium penicillin for each 300,000 units of procaine penicillin. Each such container may be packaged in combination with a container of a solvent, water for injection U. S. P., or physiological salt solution U. S. P.

(c) Labeling. Each package shall bear on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units of each salt of penicillin in the immediate container;

(iii) The number of grams of streptomycin or dihydrostreptomycin in the immediate container;

(iv) The statement "Expiration date ___

(blank being filled in with the date which is 42 months after the month in which the batch was certified: Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(v) The statement "For Intramuscular use only"; and

(vi) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repackaging," when packaged and sealed as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is intended for dispensing for veterinary use:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug;

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

Such circular or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer such drug when batch-marked, the number of packages of each size in such batch, the number of units of each salt of penicillin, and the number of grams of streptomycin or dihydrostreptomycin used in making such batch were completed, the date on which the latest assay of the penicillin or streptomycin or dihydrostreptomycin used in making such batch was completed, the quantity of each ingredient conforming to the requirements prescribed therefor by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(4) Except as otherwise provided by subparagraph (5) of this paragraph, a person who requests certification of a batch of penicillin and streptomycin or penicillin and dihydrostreptomycin shall submit with his request a statement showing the results and the date of the latest tests of the streptomycin or dihydrostreptomycin used in making the batch, the number of units of each salt of penicillin, and the number of grams of streptomycin or dihydrostreptomycin used in making each such batch, the batch mark, and (unless they were previously submitted) the dates on which the latest assays of the penicillin and streptomycin or dihydrostreptomycin used in making each such batch were completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient conforming to the requirements prescribed therefor by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(5) The procaine penicillin used to make the batch; potency, crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(6) The crystalline sodium or potassium penicillin used in making the batch; potency, crystallinity, heat stability, penicillin K content (unless it is crystalline penicillin G), and the penicillin G content if it is crystalline penicillin G.

(7) The 2-phenylpentylamine penicillin G used in making the batch; potency, crystallinity, heat stability, penicillin K content, and specific rotation.

(8) The streptomycin or dihydrostreptomycin used in making the batch; potency, histamine content, streptomycin or dihydrostreptomycin in dihydrostreptomycin and crystallinity if it is crystalline dihydrostreptomycin.
such batch is packaged for dispensing, such person shall submit in connection with his request in the quantities hereinafter indicated accurately representative samples of the following:

(i) The batch:

(a) For all tests except sterility: one immediate container for each 5,000 immediate containers in such batch, but in no case less than 12 or more than 19 immediate containers.

(b) For sterility testing: 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging as the batch that the quantities packaged during the intervals are approximately equal.

(ii) The procaine penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 146a.44 (b).

(iii) The crystaline penicillin used in making the batch, 3 packages containing approximately equal portions of not less than 250 milligrams each packaged in accordance with the requirements of § 146a.24 (a).

(iv) The L-phenylalanine penicillin G used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 146a.64 (b).

(v) The streptomycin or dihydrostreptomycin used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(vi) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(d) If such batch is packaged for repackaging, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility: 12 approximately equal portions of at least 2 grams.

(ii) For sterility testing: 10 approximately equal portions of at least 0.5 gram.

Each such portion shall be taken from a different part of such batch, and each shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

5. No result referred to in subparagraph (2) (ii) (iii) and (iv) of this paragraph, and no sample referred to in subparagraph (3) (ii) (iii) and (iv) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(i) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (a) (ii) (iii) (iv) (v) (vi) and (d) (i) of this section; and

(ii) A reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it, or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request. Provided that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

5. Request for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin tooth powder shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date which the latest assay of the penicillin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the lot was certified, the expiration date, the date which the batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(ii) Unless otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of tests and assays listed after each of the following, marked on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, heat stability, and the penicillin G content if it is crystalline sodium or potassium penicillin G.

(iii) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(iii) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (2) (ii) of this paragraph is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch of
 sections, and except that:
(1) Each batch shall contain not less than 50 units of bacitracin. The bacitracin used conforms to the standards prescribed by § 146a.30 for penicillin troches, except paragraph (1) of that section, and except that:
(a) The number of units of crystalline penicillin used conforms to the standards prescribed by § 146a.30 for penicillin troches, except paragraph (5) of this paragraph, if it is crystalline; (b) content if it is crystalline
(b) Packaging. In all cases the immediate containers shall be tincture containers as defined by the U. S. P., shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as to prevent the escape of solvent, such request shall be collected by taking a sample consisting of not less than 30 units per milligram.
(2) In lieu of the labeling prescribed for penicillin troches by § 146a.30 (c) (1) (i) each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of units of bacitracin that the quantities in each immediate container shall be of such composition as to prevent the escape of solvent.
(2) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request the results of tests and retests listed after each of the following representative sample of:
On the label or labeling as hereinafter indicated accurately representing and (unless it was previously submitted) the results and the date of the latest tests and assays of the batch used in making the batch for potency, toxicity, moisture, and pH. Each person shall also submit in connection with his request a sample consisting of not less than 50 troches of such batch and (unless it was previously submitted) a statement showing the batch mark, the number of packages in such batch, the number of units of penicillin and the number of units of bacitracin in each package, the batch marks, and (unless they were previously submitted) the dates on which the latest assays of the penicillin and bacitracin used in making such batch were completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making such batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.
(3) The batch mark, and in addition to complying with the requirements of § 146a.30 (d) a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages in such batch, the number of units of penicillin and the number of units of bacitracin in each package, the batch marks, and (unless they were previously submitted) the dates on which the latest assays of the penicillin and bacitracin used in making such batch were completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making such batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.
(2) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request in the quantities hereinafter indicated accurately representing and (unless it is crystalline penicillin G) and the penicillin G content if it is crystalline penicillin G.
(iii) The bacitracin used in making the batch; potency, crystallinity, heat stability, penicillin K content (unless it is crystalline penicillin G) and the penicillin G content if it is crystalline penicillin G.
(iii) The bacitracin used in making the batch; potency and toxicity.
(iv) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request the quantities hereinafter indicated accurately representing and (unless it is crystalline penicillin G) and the penicillin G content if it is crystalline penicillin G.
(iv) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request the quantities hereinafter indicated accurately representing and (unless it is crystalline penicillin G) and the penicillin G content if it is crystalline penicillin G.
(i) The batch:
(a) For all tests except sterility— one immediate container for each 5,000 immediate containers in such batch, but in no case less than 10 or more than 17 immediate containers.
(b) For sterility testing; 10 immediate containers.
Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.
(ii) The crystalline penicillin used in making the batch; 3 packages, each containing approximately equal portions of not less than 250 milligrams, packaged in accordance with the requirements of § 146a.24 (b).
(iii) The bacitracin used in making the batch; 3 packages, each containing approximately 0.5 gram packaged in
RULES AND REGULATIONS

§ 146a.64 L-Ephedrine penicillin G (penicillin G L-ephephrine salt) — (a) Standards of identity, strength, quality and purity. L-Ephedrine penicillin G is the semi-stable compound levo-N-methyl-1, 2-diphenyl-2-hydroxyethylamine salt of penicillin G, prepared from crystalline penicillin G and crystalline dl-N-methyl-1, 2-diphenyl-2-hydroxyethylamine hydrochloride (93 percent purity and a melting point of 268.5° C. ± 2.5° C.). It contains not less than 85 percent of the L-enantiomer, N-methyl-1, 2-diphenyl-2-hydroxyethylamine salt of penicillin G. It is so purified and dried that:

1. Its potency is not less than 500 units per milligram.
2. It is sterile.
3. It is nonpyrogenic.
4. It is not toxic.
5. Its moisture content is not more than 1.5 percent.
6. Its pH in a saturated aqueous solution is not less than 5 and not more than 7.5.
7. Its specific rotation in water-acetone (1:1) at 20° C. is +125° ± 5°.

(b) Packaging. In all cases the immediate container shall be a tight container as defined. Each such container shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will cause no change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its outside wrapper or container the name of the drug as defined, the batch mark, the number of units in the immediate container, the expiration date, and the statement “Manufactured by the U. S. P., shall be sterile at the time of filling and closing, and shall be so sealed that the contents cannot be used without destroying the seal.” The immediate container shall be of colorless transparent glass or sesame oil with or without an oily material to make it opaque. It is sterile. Its moisture content is not more than 1 percent. The L-ephephrine penicillin G used conforms to the requirements of § 146a.64.

(d) Request for certification, check tests and assays; samples. (1) In addition to complying with the requirements of § 146a.64, the person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, heat stability, the penicillin G content, and specific rotation.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

1. For all tests except sterility 10 packages.
2. For sterility testing: 10 packages. Each such package shall contain approximately 300 milligrams taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken from each package by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted requests for tests and assays not required for the batch when used in such other drugs.

The Commissioner shall report to such manufacturer results of such check tests and assays on such samples.

(e) Fees. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146a.65 of this chapter.

§ 146a.65 L-Ephedrine penicillin G in oil — (a) Standards of identity, strength, quality, and purity. L-Ephedrine penicillin G in oil is a suspension of L-ephephrine penicillin G in refined peanut oil or sesame oil with or without a mixture of one or more suitable and harmless dispersing agents. Its potency is 500,000 units per milliliter unless it is packaged and labeled solely for veterinary use. It is sterile. Its moisture content is not more than 1 percent. The L-ephephrine penicillin G used conforms to the requirements of § 146a.64.

(b) Packaging. The immediate container shall be of colorless transparent glass (unless it is packaged to contain a single dose), so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, and shall be so sealed that the contents cannot be used without destroying the seal. The immediate container shall be of such composition as will not cause any change in the strength, quality or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. It is sterile. Its moisture content is not more than 1 percent. The L-ephephrine penicillin G used conforms to the requirements of § 146a.64.

(c) Labeling. Each package shall bear on its label or labeling as hereinafter indicated, the following:

1. On the outside wrapper or container and the immediate container of the package:

   (i) The batch mark.
   (ii) The number of units per milliliter of the batch.
   (iii) The statement “Expiration date __________,” the blank being filled in accordance with paragraph (d) (i) and (3) of this section; and

2. If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146a.65 of this chapter.

§ 146a.66 L-Ephedrine penicillin G in oil — (a) Standards of identity, strength, quality, and purity. L-Ephedrine penicillin G in oil is a suspension of L-ephephrine penicillin G in refined peanut oil or sesame oil with or without a mixture of one or more suitable and harmless dispersing agents. Its potency is 500,000 units per milliliter unless it is packaged and labeled solely for veterinary use. It is sterile. Its moisture content is not more than 1 percent. The L-ephephrine penicillin G used conforms to the requirements of § 146a.64.

(b) Packaging. The immediate container shall be of colorless transparent glass (unless it is packaged to contain a single dose), so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, and shall be so sealed that the contents cannot be used without destroying the seal. The immediate container shall be of such composition as will not cause any change in the strength, quality or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. It is sterile. Its moisture content is not more than 1 percent. The L-ephephrine penicillin G used conforms to the requirements of § 146a.64.

(c) Labeling. Each package shall bear on its label or labeling as hereinafter indicated, the following:

1. On the outside wrapper or container and the immediate container of the package:

   (i) The batch mark.
   (ii) The number of units per milliliter of the batch.
   (iii) The statement “Expiration date __________,” the blank being filled in accordance with paragraph (d) (i) and (3) of this section; and

2. If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146a.65 of this chapter.

§ 146a.67 L-Ephedrine penicillin G in oil — (a) Standards of identity, strength, quality, and purity. L-Ephedrine penicillin G in oil is a suspension of L-ephephrine penicillin G in refined peanut oil or sesame oil with or without a mixture of one or more suitable and harmless dispersing agents. Its potency is 500,000 units per milliliter unless it is packaged and labeled solely for veterinary use. It is sterile. Its moisture content is not more than 1 percent. The L-ephephrine penicillin G used conforms to the requirements of § 146a.64.

(b) Packaging. The immediate container shall be of colorless transparent glass (unless it is packaged to contain a single dose), so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, and shall be so sealed that the contents cannot be used without destroying the seal. The immediate container shall be of such composition as will not cause any change in the strength, quality or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. It is sterile. Its moisture content is not more than 1 percent. The L-ephephrine penicillin G used conforms to the requirements of § 146a.64.

(c) Labeling. Each package shall bear on its label or labeling as hereinafter indicated, the following:

1. On the outside wrapper or container and the immediate container of the package:

   (i) The batch mark.
   (ii) The number of units per milliliter of the batch.
   (iii) The statement “Expiration date __________,” the blank being filled in accordance with paragraph (d) (i) and (3) of this section; and
with the date which is 18 months after the month during which the batch was certified. The expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(ii) There is a statement “For intramuscular use only” and “Shake well” and

(v) The name of each oil used in making the batch, and, if aluminum monostearate is used as the dispersing agent, the quantity used.

(2) On the outside wrapper or container, the statement “Caution: Federal law prohibits dispensing without prescription,” unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Request for certification, samples.

(1) In addition to complying with the requirements of §146.2 of this chapter, a person, who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the l-ephenamine penicillin G used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each ingredient used in making such batch conforms to the standards prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (e) of this paragraph, such person shall submit in connection with his request results of tests and assays of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, and moisture.

(ii) The l-ephenamine penicillin G used in making the batch; potency, sterility, pyrogenicity, toxicity, moisture, pH, crystallinity, heat stability, penicillin G content, and specific rotation.

(3) Except as otherwise provided by subparagraph (f) of this paragraph, such person shall submit in connection with his request, results of tests and assays of the following, made by him on accurately representative samples of the following:

(i) The batch:

(a) For all tests except sterility one package for each 500 packages in the batch, but in no case less than 3 packages or more than 12 packages.

(b) For sterility testing; 10 packages. Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(iii) The l-ephenamine penicillin G used in making the batch:

(a) For all tests except sterility 10 packages, each containing approximately equal portions of not less than 300 milligrams.

(b) For sterility testing; 10 packages, each containing approximately equal portions of not less than 300 milligrams.

Each such portion shall be packaged in accordance with the requirements of §146a.2 of this chapter.

(iii) In case of an initial request for certification, one package containing approximately 150 grams of the peanut oil or sesame oil used and one package containing approximately 5 grams of each dispersing agent used.

(4) No result referred to in subparagraph (d) of this paragraph, and no result referred to in paragraph (d) of this chapter, is required if such result or sample has been previously submitted.

(e) Fees. The fee prescribed by paragraph (d) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with paragraph (b) of this section; and

(f) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by paragraph (d) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with paragraph (b) of this section.

§146a.68 l-Ephenamine penicillin G for aqueous injection—(a) Standards of identity, strength, quality, and purity. l-Ephenamine penicillin G for aqueous injection is a dry mixture of l-ephenamine penicillin G and one or more suitable and harmless suspending or dispersing agents, with or without one or more suitable and harmless preservatives and buffer substances, or it is an aqueous suspension of l-ephenamine penicillin G and one or more suitable and harmless suspending or dispersing agents, buffer substances, and preservatives, except that preservatives are not required if the immediate container is packaged to contain a single dose and is conspicuously so labeled. It is so purified that:

(1) If it is an aqueous suspension of the drug, each container or each milliliter shall contain not less than 300,000 units, unless it is packaged and labeled solely for veterinary use;

(2) It is sterile;

(3) If it is the dry mixture of the drug, its moisture content is not more than 1.5 percent;

(4) It is nonpyrogenic;

(5) It is nontoxic; and

(6) pH of the aqueous aqueous solution is not less than 5.0 and not more than 7.5.

l-Ephenamine penicillin G used conforms to the requirements of §146a.64 (a). Each other substance used, if its name is recognized by U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(g) Packaging. In all cases the immediate containers shall be tight containers as defined by law to be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes to causes which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers, including closures, or in a container of the material or closure or destroying its effectiveness, unless it is the aqueous suspension of the drug and it is packaged to contain a single dose. If it is the dry mixture of the drug, each such container shall contain not less than 1 milliliter (unless it is packaged to contain a single dose) and not more than 10 milliliters (unless it is packaged and labeled solely for veterinary use) and each shall be filled with a volume in excess of that designated, which excess is to permit the withdrawal and the administration of the volume indicated, whether administered in either single or multiple doses.

(h) Labeling. Each package shall bear on its label or labeling as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(a) The batch mark;

(b) The number of units in the immediate container;

(ii) The statement “Expiration date...” the blank being filled in, if it is the dry mixture of the drug, with the date which is 18 months, or if it is the aqueous suspension of the drug, with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 24 months after the month in which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays needed to permit the withdrawal and the administration of the volume indicated, whether administered in either single or multiple doses for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: Provided, however, That...
such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container; (iv) The statement "For Intramuscular use only" must accompany the veterinary use and is conspicuously so labeled.

(ii) If it is the aqueous suspension of the drug, the statement "Store in a refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)" unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section after having been stored at room temperature in accordance with the requirements prescribed therefor.

(iii) The l-epinephrine penicillin G used in making the batch; potency, crystallinity, heat stability, penicillin G content, and 

(iv) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereafter indicated, accurately representative samples of the following:

(a) The batch;

(b) For sterility testing; 10 immediate containers.

(ii) In case of an initial request for certification, each other ingredient used in making the batch, one package of each containing approximately 5 grams.

(3) In case of an initial request for certification of a batch which is to be packaged for dispensing, the quantities hereafter indicated, accurately representative samples of the following:

(a) For all tests except sterility: one immediate container for each 5,000 immediate containers in such batch, but in no case less than 10 or more than 17 immediate containers.

(b) For sterility testing; 10 immediate containers.

(4) If such batch is packaged for re-packing, one package of each containing approximately 5 grams.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(6) The fee prescribed by subparagraph (1) of this paragraph shall accompany each request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.07 Procaine penicillin in streptomycin sulfate solution, procaine penicillin in dihydrostreptomycin sulfate solution.—(a) Standards of identity, strength, quality, and purity. Procaine penicillin in streptomycin sulfate solution is procaine penicillin suspended in an aqueous solution of streptomycin sulfate, and dihydrostreptomycin sulfate solution is procaine penicillin suspended in an aqueous solution of dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate, consisting one or more suitable and harmless buffer substances, preservatives, and suspending or dispersing agents, and it may contain one or more suitable and harmless stabilizing agents and procaine making the concentration not exceeding 2 percent. It is so purified that:

(1) Each milliliter shall contain not less than 100,000 units of procaine penicillin and not less than 0.25 gram of streptomycin sulfate or dihydrostreptomycin sulfate, but each immediate container shall contain not less than 300,000 units of procaine penicillin and not less than 0.25 gram of streptomycin sulfate or dihydrostreptomycin sulfate;

(ii) It is sterile;

(iii) It is nonpyrogenic;

(iv) It is nontoxic; and

(v) Its pH is not less than 5.0 and not more than 8.0.

The procaine penicillin used conforms to the requirements prescribed by § 146a.44 (a) and other substances used conforms to the requirements prescribed by § 146b.101 (a) of this chapter. The dihydrostreptomycin sulfate used conforms to the requirements prescribed by § 146b.106 (a) of this chapter. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents shall not be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limits applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be
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penicillin and the number of milligrams container that after having been stored for within or attached to the package, if it dispensing and it law prohibits dispensing without pre-

ing use or repacking, "when manufacturing use or repacking," when with § 146.3 of this chapter, for the

mixture: (i) The name and quantity of Each ingredient used in making the batch, and po-

tency, histamine di-

hydrostreptomycin, and crystallinity in

(1) The batch mark.

(2) The statement "Expiration date — blank" being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays show-

ing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed

(3) As otherwise provided by subparagraph (5) of this paragraph, no sample referred to in subparagraph (2) (i), (ii), or (iii) of this paragraph shall be packaged in separate container

Examination, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, and if each immediate container is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(b) Standards of identity, strength, quality, and purity. Benzathine penicillin G is the crystalline N,N-dibenzylamidemethylenediamine salt of penicillin G. It contains not less than 83 percent by weight of the N,N-dibenzylamidemethylenediamine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 1050 units per milligram.

(2) It is sterile.

(3) It is nontoxic.

(4) It is nonpyrogenic.

(5) Its moisture content is not more than 8 percent.

(6) Its pH in a saturated aqueous solution is not less than 7.0 and not more than 7.5.

Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and clos-
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ing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond that otherwise unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.
(2) The weight of the drug and the number of units in the immediate container.
(3) The statement "Expiration date ____________", the blank being filled in with the date which is 36 months after the month during which the batch was certified:

Provided, however That such expiration date may be omitted if the information contained in a circular or other labeling as hereinafter indicated, the immediate container is packaged in an individual wrapper or container.

20,000 units per

5%.

250 mg.

20,000 units per

5%.

250 mg.

20,000 units per

5%.

250 mg.

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20,000 units per

5%.

250 mg.
(I) The batch; average potency per milliliter if it is the oral suspension, average potency per immediate container if it is a dry mixture, pH, and moisture if it is a dry mixture of the drug and penicillin-dihydrostreptomycin, bacitracin ointment, and penicillin-dihydrostreptomycin bacitracin ointment conform to all requirements prescribed by § 146a.54 for penicillin-dihydrostreptomycin bacitracin ointment and penicillin-dihydrostreptomycin ointment, except that:

(I) It contains not less than 500 units of bacitracin per gram of ointment.

(II) The benzathine penicillin G used in making the batch; potency, toxicity, moisture, pH, and purity of each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(III) The benzathine penicillin G used in making the batch; 10 packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146a.54 for penicillin-dihydrostreptomycin and crystallinity, and the penicillin G content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, each such investigation, other than the examination of such immediate containers, is necessary to determine whether or not such batches meet the requirements of this chapter.

(4) Each such investigation shall consist of:

(a) A sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the streptomycin used in making the batch, packaged in accordance with the requirements of § 146a.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with requirements prescribed therefor by this section shall be $4.00.

§ 146a.71 Penicillin-streptomycin-dental cones; penicillin-dihydrostreptomycin-dental cones. (a) Penicillin-streptomycin dental cones and penicillin-dihydrostreptomycin dental cones conform to all requirements prescribed by § 146a.54 for penicillin-dental cones and are subject to all procedures prescribed by that section for penicillin dental cones, except that:

(1) Each cone contains not less than 25 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except under the regulations of § 146a.54 for penicillin-dental cones and are subject to all procedures prescribed by that section for penicillin dental cones, except that:

(2) Each cone contains not less than 25 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except that:

(3) Each cone contains not less than 25 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except that:

(4) Each cone contains not less than 25 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except that:

(5) Each cone contains not less than 25 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except that:

§ 146a.70 Penicillin-streptomycin-bacitracin ointment; penicillin-dihydrostreptomycin-bacitracin ointment. (a) Penicillin-streptomycin-bacitracin ointment and penicillin-dihydrostreptomycin-bacitracin ointment conform to all requirements prescribed by § 146a.54 for penicillin-dihydrostreptomycin-bacitracin ointment.

(1) It contains not less than 500 units of bacitracin per gram of ointment.

(2) In addition to the labeling prescribed by § 146a.54 (b) each package shall bear on the outside wrapper or container the number of units of bacitracin per gram of ointment.

(3) In addition to complying with requirements of § 146a.54 (c) a person who requests certification of a batch shall submit with his request a statement showing the batch mark (and (unless previously submitted) the results and the date of the latest tests and assays of the bacitracin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than 1.5 gram of each of the bacitracin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(4) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.72 Dihydrostreptomycin ester penicillin G hydriodide (penicillin G diethylaminoethyl ester hydroiodide salt of penicillin G). It contains not less than 50 percent by weight of G-diethylaminoethyl ester hydroiodide salt of penicillin G. It is non-pyrogenic.

§ 146a.73 (a) Standards of identity, strength, quality, and purity. Dihydrostreptomycin ester penicillin G hydriodide is the crystalline diethylaminoethyl ester hydroiodide salt of penicillin G. It contains (1) its potency after hydrolysis not less than 500 units per milligram.

(b) It is sterile.

(c) It is non-pyrogenic.

(d) It is not toxic.

§ 146a.74 Moisture content if it is dihydrostreptomycin.

§ 146a.75 Potency, toxicity, pH. It was previously submitted)

§ 146a.76 Lipids, non-pyrogenicity, and purity.

§ 146a.77 pH. It is non-pyrogenic.

§ 146a.78 (a) Expiration date. The expiration date may be extended by the certificate holder, if the expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container. The certificate holder may extend the expiration date by the certificate holder, if the expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

§ 146a.79 “Expiration date—______,” the batch being filled in with the date which is 24 months after the expiration date.

§ 146a.80 The statement “Caution: Federal law prohibits dispensing without prescription.”

§ 146a.81 Request for certification, checks tests and assays; samples. (1) In addition to complying with the requirements of § 146a.54 (c) of this chapter who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the
batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date of the batch. The latest date of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and analyses made by him for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, and the penicillin G content.

(2) Such person shall submit with his request an appropriately representative sample of the batch, consisting of the following:

(i) For all tests except sterility: 10 packages.

(ii) For sterility testing: 10 packages.

Each such package shall contain approximately 300 milligrams taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which it is to be used, the nearest assay of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drugs. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(b) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (1) and (3) of this section.

(2) If the Commissioner considers that investigations other than the examination of immediate containers are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter, for the issuance of a certificate, the cost of such investigations shall be paid by the person requesting them.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.3 (d) of this chapter.

§146a.75 Dithy laminoethyl ester penicillin G hydroiodide for aqueous injection (penicillin G, dithy laminoethyl ester hydroiodide for aqueous injection)—

(a) Standards of identity, strength, quality, and purity. Dithy laminoethyl ester penicillin G hydroiodide for aqueous injection is dithy laminoethyl ester penicillin G hydroiodide and one or more suitable and harmless suspending or dispersing agents, with or without one or more suitable and harmless preservatives and buffer substances. It is so purified and dried that:

(1) It is sterile.

(2) Its moisture content is not more than 1 percent.

(3) It is nonpyrogenic.

(4) It is nontoxic.

(5) The pH of a saturated aqueous solution is not less than 5.0 and not more than 7.5.

The dithy laminoethyl ester penicillin G hydroiodide used conforms to the requirements of §146a.74 (a) If each substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate containers shall be tight containers as defined by §146a.73 and shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be immediate containers of colorless transparent glass, or a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying the vacuum it may have. Each such container shall contain 500,000 units or multiples thereof up to and including 5,000,000 units, and each may be packaged in combination with a container of a suitable aqueous diluent.

(c) Labeling. Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container: (1) The batch mark.

(ii) The number of units in the immediate container.

(iii) The statement "Expiration date ____________", the blank being filled in with the date which is 24 months after the month during which the batch was certified: Provided, however That such expiration date may be determined by the person from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "For intramuscular use only."

(ii) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is intended solely for veterinary use and is conspicuously so labeled.

(iii) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(1) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug on the label. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary purposes of such drug may be obtained. Such veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iv) If it is intended solely for veterinary use and is not conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug on the label.

(v) If it is intended solely for veterinary use and is not conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug on the label.

(vi) The conditions under which suspensions of the drug may be stored, and the statement "Sterile suspension may be kept at room temperature for 7 days, or in refrigerator for 3 weeks, without significant loss of potency."

(d) Request for certification; samples. (1) In addition to complying with the requirements of paragraph (b) of this section, a person who requests certification of a batch shall submit with his request a statement showing the batch that the quantities in each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the dithy laminoethyl ester penicillin G hydroiodide used in making such batch was completed, the number of units in each such package, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(ii) Such request shall be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: potency, sterility, moisture, pyrogens, toxicity, pH.

(ii) The diethylaminoethyl ester penicillin G hydroiodide in making the batch; potency, crystallinity, penicillin G content.

(iii) Except as otherwise provided by subparagraph (6) of this paragraph, if such batch is packaged for dispensing such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: (a) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 2 or more than 17 immediate containers.

(b) For sterility testing: 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packed during the intervals are approximately equal.

(ii) The diethylaminoethyl ester penicillin G hydroiodide used in making the batch: 3 packages shall contain approximately equal portions of not less than 500 milligrams each, packaged in accordance with the requirements of §146a.74 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams, and such number of such packages as are necessary to make complete assays with respect to each batch.
aqueous diluent which is not recognized by the U. S. P., or when any change is made in the composition of such diluent; 5 packages of the diluent included in the combination.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages.

Such each package shall contain approximately 300 milligrams, taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (ii), (a) (ii), (ii) (iv) and (3) (i) of this section.

(2) The Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 of this chapter.

§ 146a.76 Penicillin-streptomycin implantation pellets; penicillin-dihydrostreptomycin implantation pellets—(a) Standards of identity, strength, quality, and purity. Penicillin-streptomycin implantation pellets, penicillin-dihydrostreptomycin implantation pellets are pellets composed of crystalline penicillin or procaine penicillin and streptomycin or dihydrostreptomycin, with or without the addition of one or more suitable and harmless diluents, binders, and lubricants. Each pellet contains not less than 5,000 units of penicillin and not less than 0.5 milligrams of streptomycin or dihydrostreptomycin. Its moisture content is not more than 5 percent. The crystalline penicillin conforms to the requirements of § 146d.24 (a) except subparagraphs (2) and (3) of that paragraph. The procaine penicillin conforms to the requirements of § 146a.44 (a) except subparagraphs (2) and (3) of that paragraph. The streptomycin used conforms to the requirements of § 146b.101 (a) of this chapter, except subparagraphs (2) and (3) of that paragraph. The dihydrostreptomycin used conforms to the requirements prescribed therefor by § 146b.103 of this chapter, except the standards for sterility and pyrogens. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the requirements prescribed therefor by such official compendium.

(b) Packaging. Unless each pellet is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reseal, the batch shall not be approved. Such container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the pellets by a plug of cotton or similar material. The composition of the immediate container or of the foil or film enclosure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit theretofore in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label or labeling as hereinafter indicated, accurately representative samples of the following:

(1) The batch mark.

(2) The number of units of penicillin in each pellet.

(3) The number of milligrams of streptomycin or dihydrostreptomycin in each pellet of the batch.

(4) The statement "For veterinary use only."

(5) The statement "Expiration date ________" the blank being filled in with the date which is 18 months after the month during which the batch was completed, except that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(6) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions and warnings for the veterinary use of such drug or batch of such drug, and any circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other than the veterinary user by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Request for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the number of packages of each size in such batch, the batch marks and (unless they were previously submitted) the dates on which the latest assays of the penicillin and streptomycin or dihydrostreptomycin used in making the batch were completed, the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each pellet, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that such ingredient conforms to the requirements prescribed therefore by such section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, unless an accurately representative sample of:

(i) The batch; potency, moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, streptomycin content if it is procaine penicillin K content; and if it is crystalline penicillin G or procaine penicillin G, and the procaine penicillin G or procaine penicillin G.

(iii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, histamine content, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one pellet for each 5,000 pellets in the batch, but in no case less than 30 pellets or more than 100 pellets, collected by taking single pellets from such batch throughout the interval of time of tabletting the batch that the tablets labeled with the intervals are approximately equal.

(II) The penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is crystalline penicillin and not less than 300 milligrams if it is procaine penicillin, each taken from a different part of each batch and packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b)

(III) The streptomycin or dihydrostreptomycin used in making the batch; 5 packages, each containing approximately 0.5 gram, taken from a different part of such batch and packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(iv) In case of an initial request for certification, samples of such batch, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fees for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each pellet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (11) and (III) of this paragraph; $10.00 for each package in the samples submitted in accordance with paragraph (d) (11) and (II) of this section.

(2) If the Commissioner considers that investigations other than examination of such pellets and packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the
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7.5. Benzathine penicillin G for aqueous injection—(a) Standards of identity, strength, quality, and purity. Benzathine penicillin G for aqueous injection is a dry mixture of benzathine penicillin G and one or more suitable and harmless suspending or dispersing agents and with or without one or more suitable and harmless preservatives, buffer substances, and local anesthetics; or it is an aqueous suspension of benzathine penicillin G and one or more suitable and harmless suspending or dispersing agents, buffer substances, and preservatives and with or without one or more suitable and harmless preservatives, buffer substances, and local anesthetics. It is so purified that:

(1) If it is an aqueous suspension of the drug, each container or each milliliter shall contain not less than 300,000 units.

(2) It is sterile.

(3) If it is the dry mixture of the drug, its moisture content is not more than 0.2 percent.

(4) It is nonpyrogenic.

(5) It is nontoxic.

(6) Its pH in saturated solution is not less than 5.0 and not more than 7.5.

The benzathine penicillin G used conforms to the requirements of § 146a.77 paragraph (a).

(b) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile and pure. Each container, whether single or multiple doses, shall be so sealed that the contents cannot be destroyed by any means and shall be of such composition as will cause no change in the drug, quality or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless, (unless it is intended solely for veterinary use) transparent glass, closed by a substance through which a hygroscopic needle may be introduced and withdrawn without removing any of its effervescence. If it is the dry mixture of the drug, each such container shall contain 300,000 units, 600,000 units, 900,000 units, 1,200,000 units, 1,500,000 units, 2,400,000 units, or 3,000,000 units, unless it is intended solely for veterinary use and is conspicuously so labeled. Each such container shall be so packaged in combination with a container of suitable aqueous diluent. If it is the aqueous suspension of the drug, each such container shall contain not less than 1 milliliter (unless it is packaged to contain a single dose) and not more than 10 milliliters (unless it is intended solely for veterinary use) and each shall be filled with a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whichever is larger, in either single or multiple doses.

(c) Labeling. Each package shall bear, on its label or labeling as heretofore indicated:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units in the immediate container.

(iii) The statement “Expiration date - - - - - - - -.” the blank being filled in, if it is a dry mixture of the drug, with the date which is 18 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 24 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section; Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement “For intramuscular use only.”

(v) If the drug contains preservatives or anesthetics, the name and quantity of each such added ingredient.

(b) On the outside wrapper or container:

(i) If it is the aqueous suspension of the drug, the statement “Store below 15°C. (59°F.)” or “Store below 15°C. (59°F.) unless the manufacturer certifies that such drug is intended solely for veterinary use of such drug by the labeler. Such statement may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the labeler. Such statement may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer such drug.

(c) For sterility testing; 10 immediate containers. Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that each package packaged during the intervals are approximately equal.

(d) The benzathine penicillin G used in making the batch shall be certified, except that the blank may be filled in with the date which is 24 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture (unless it is an aqueous suspension of the drug), pyrogens, toxicity, pH.

(ii) The benzathine penicillin G used in making the batch; potency, penicillin G content, crystallinity.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch.

(a) For all tests except sterility: one immediate container for each 5,000 immediate containers in such batch, but in no case less than 10 or more than 17 immediate containers.

(b) For sterility testing; 10 immediate containers.
(4) In case of an initial request for certification of a batch of benzathine penicillin G for aqueous injection which is to be packaged in combination with an aqueous diluent which is not recognized by the U. S. P., or when any change is made in the composition of the aqueous diluent, five packages of the diluted included in the combination.

(4) If such batch is packaged for repackaging and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (1) (a) or (ii), (iii), (iv), and (v) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146a.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146a.6 (d) of this chapter.

§ 146a.78 Benznzathine penicillin G and buffered crystalline penicillin G for aqueous injection. (a) Benzathine penicillin G and buffered crystalline penicillin for aqueous injection shall be packaged in accordance with all requirements prescribed by § 146a.77 for the dry mixture of penicillin G for aqueous injection, and subject to all procedures prescribed by § 146a.77.

(b) The fee for the services rendered with respect to each immediate container in the sample of buffered crystalline penicillin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.79 Chloroprocaine penicillin O (penicillin O chloroprocaine salt) — (a) Standard of identity, strength, quality, and purity. Chloroprocaine penicillin O is the crystalline 2-chloroprocaine salt of penicillin O prepared from 2-chloroprocaine hydrochloride (98 percent purity and a melting point of 171°-176° C.) and crystalline penicillin O. It contains not less than 85 percent of the 2-chloroprocaine salt of penicillin O and not more than 0.5 percent of the 2-chloroprocaine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 650 units per milligram.

(2) It is sterile.

(3) It is nonpyrogenic.

(4) It is nontoxic.

(5) Its moisture content is not more than 4.2 percent.

(b) pH. Its pH in saturated aqueous solution is not less than 5.0 and not more than 7.5.

(c) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without breaking the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond the limit therefor in applicable standards except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(d) Labeling. Each package of chloroprocaine penicillin O shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated the following:

(1) The batch mark.

(2) The weight of the drug and the number of units in the immediate container.

(3) The statement "Expiration date ________", the blank being filled in with the date which is 30 months after the month in which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For manufacturing use only."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(f) Request for certification, check tests and assays; samples. (1) In addition to complying with the requirements of § 146a.2 of this chapter, a person who requests certification of a batch of chloroprocaine penicillin O shall submit with his request a statement showing the batch mark, the number of units of chloroprocaine penicillin O, and the number of units of buffered crystalline penicillin G and the number of units of benzathine penicillin G in each immediate container of the batch. He shall also submit in connection with his request a sample consisting of three packages containing approximately equal portions of not less than 250 milligrams each of the buffered crystalline penicillin used in making the batch. If such batch is packaged for re-packing, each portion in the sample packages shall be of the same size as that portion in the batch. If such batch is packaged for dispensing, each portion in the sample packages shall be of such composition as will be sterile at the time of filling and closing the batch. If such batch is packaged for repacking, each portion in the sample packages shall be of such composition as will be sterile at the time of filling and closing the batch.

(2) Such person shall submit in connection with his request an accurately representative sample of the batch:

(a) For all tests except sterility; 10 packages.

(b) For sterility testing; 10 packages.

(c) For check tests and assays (except expiration date); 10 packages.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which chloroprocaine penicillin O is to be used, the manufacturer of a batch which is so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(g) The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (1) (a) or (ii), (iii), (iv), and (v) of this section.
are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.3 (d) of this chapter.

§ 146a.80 Chloroprocaine penicillin O for aqueous injection. Standards of identity, strength, quality, and purity.

Chloroprocaine penicillin O for aqueous injection is a dry mixture of chloroprocaine penicillin O and one or more suitable and harmless suspending or dispersing agents, with or without one or more suitable and harmless buffer substances. It is so purified and dried that:

(1) It is sterile.

(2) Its moisture content is not more than 4.2 percent.

(3) It is nonpyrogenic.

(4) It is nontoxic.

(5) The chloroprocaine aqueous solution is not less than 5.0 and not more than 7.5.

The chloroprocaine penicillin O used conforms to the requirements of § 146a.79 (a) Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefore by such official compendium.

(6) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying or dispersing agents, with or without one or more suitable and harmless buffer substances. It is so purified and dried that:

(1) It is sterile.

(2) Its moisture content is not more than 4.2 percent.

(3) It is nonpyrogenic.

(4) It is nontoxic.

(5) The chloroprocaine aqueous solution is not less than 5.0 and not more than 7.5.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.3 (d) of this chapter.

§ 146a.81 Penicillin-streptomycin vaginal suppositories; penicillin-dihydro-
streptomycin vaginal suppositories. (a) Penicillin vaginal suppositories and penicillin-dihydrostreptomycin vaginal suppositories conform to all requirements prescribed by § 146a.36 for penicillin vaginal suppositories and are subject to all procedures prescribed for that section for penicillin vaginal suppositories, except that:

(1) Each suppository shall contain not less than 200 milligrams of streptomycin or dihydrostreptomycin, and the number of milligrams of streptomycin or dihydrostreptomycin in each suppository shall be closed in a transparent glass which meet the test for tight containers as defined by the U.S. P. Each such glass container shall be so sealed that the contents cannot be used without destroying such seal and shall not be opened through which a hypodermic needle may be introduced and withdrawn without destroying its effectiveness. The immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(2) Each package shall bear on the outside wrapper or container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each suppository of the batch.

In addition to complying with the requirements of § 146a.36 (d) a person who requests certification of a batch of penicillin-dihydrostreptomycin vaginal suppositories shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark, and by whom the batch was certified, except that the dates of the latest tests and assays of the penicillin, streptomycin or dihydrostreptomycin, and bacitracin used in making the batch shall be submitted in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(1) The batch; potency, sterility, and moisture.

(b) Each package of the drug shall bear on its label or labeling, as hereinafter indicated, the following:

(i) On the outside wrapper or container and in the immediate container:

(1) The batch mark.

(2) The number of units of penicillin and bacitracin, the number of milligrams of streptomycin or dihydrostreptomycin, and the quantity of sodium caprylate in each milliliter of the batch.

(2) The statement "For cedadelante use only."

(iv) The statement "Expiration date ________," the blank being filled in with the date which is not more than 12 months from the date which the batch was certified, except that the blanket may be filled in with the date which is 18 months after the month during which the batch was certified, if the person who requests certification has submitted to the Comissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an outer container which is properly labeled.

(c) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of the following:

(1) The batch: potency, toxicty, sterility, moisture, pH, crystallinity if it is crystalline penicillin, heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(2) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, sterility, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(d) (i) The bacitracin used in making the batch; potency, toxicity, sterility, moisture, and pH.

(ii) The penicillin used in making the batch: potency, toxicity, sterility, moisture, and pH.

(iii) The streptomycin or dihydrostreptomycin used in making the batch: potency, toxicity, sterility, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is dihydrostreptomycin sulfate.

(iv) The bacitracin used in making the batch: potency, toxicity, sterility, moisture, and pH.

(v) (a) Of all tests except sterility, one package for each 500 units of bacitracin in the batch, but in no case less than 5 packages or more than 12 packages.

(b) For sterility testing: 10 packages.

Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch:

(a) For all tests except sterility: 5 packages, or in the case of crystalline penicillin, 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is not procaine penicillin, and not less than 300 milligrams if it is procaine penicillin.

(b) For sterility testing: 10 packages, each containing approximately equal portions of 300 milligrams.

Such samples shall be packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b)
(iii) The streptomycin or dihydrostreptomycin used in making the batch: (a) For all tests except sterility—5 packages containing approximately equal portions of not less than 0.5 gram.
(b) For sterility testing; 10 packages, each containing approximately equal portions of 0.5 gram.

Such samples shall be packaged in accordance with the requirements of §146b.101 (b) of this chapter.

(iv) The bacitracin used in making the batch: (a) For all tests except sterility—6 packages, each containing approximately equal portions of not less than 0.5 gram.
(b) For sterility testing; 10 packages, each containing approximately equal portions of 0.5 gram.

Such samples shall be packaged in accordance with the requirements of §146b.401 (b) of this chapter.

(v) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No test to be made in subparagraph (2) (ii) (iii) and (iv) of this paragraph, and no sample referred to in subparagraph (3) (ii) (iii) and (iv) of this paragraph, is required if such results or samples have previously been submitted.

(e) Fees. The fee for the services rendered with respect to each batch of penicillin-streptomycin-bacitracin dental paste or penicillin-dihydrostreptomycin-bacitracin dental paste under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (a) (i) (ii) (iii) (v) (a) (iv) (a) and (v) of this section.

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigation shall be determined by the Commissioner.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.8 (d) of this chapter.

§146a.84 Penicillin and dihydrostreptomycin-streptomycin sulfates, procaine penicillin in dihydrostreptomycin-streptomycin sulfates solution—(a) Standards of identity, strength, quality, and purity. Penicillin and dihydrostreptomycin-streptomycin sulfates and procaine penicillin in dihydrostreptomycin-streptomycin sulfates solution conform to the standards prescribed by §146b.113 (a) of this chapter for dihydrostreptomycin-streptomycin sulfates, except that:

(1) It contains dry procaine penicillin, benzathine penicillin G, crystalline sodium penicillin G, procaine penicillin, or a mixture of any combination of such salts, or it contains procaine penicillin suspended in an aqueous solution of dihydrostreptomycin-streptomycin sulfates.

The procaine penicillin used conforms to the requirements prescribed for crystalline penicillin by §146a.24 (a) The benzathine penicillin G and procaine penicillin used conform to the requirements prescribed by §146a.68 (a)

(2) It may contain suitable and harmless buffer substances, preservatives, suspending, dispersing, and stabilizing agents. Each such substance, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefore by such official compendium.

(3) The moisture content of the dry mixture is not more than 3.5 percent, except if it contains procaine penicillin its moisture content is not more than 4.2 percent, and if it contains benzathine penicillin G its moisture content is not more than 6 percent.

(4) The pH of a solution or a suspension prepared as directed in its labeling is not less than 5.0 and not more than 7.5.

(b) Packaging. It shall be packaged in accordance with the requirements prescribed by §146b.58 (c) except that each package shall bear on the outside wrapper or container and the immediate container the number of units of each salt of penicillin, the number of milligrams of dihydrostreptomycin, and the number of milligrams of streptomycin in the immediate container. If it is the suspension of the drug, it shall be labeled in accordance with the requirements prescribed by §146a.67 (c) except that each package shall bear on the outside wrapper or container and the immediate container the number of units of procaine penicillin, the number of milligrams of dihydrostreptomycin, and the number of milligrams of streptomycin in the immediate container.

(i) The batch: (a) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 13 (14, if it contains benzathine penicillin G) or more than 10 immediate containers.

(b) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The procaine penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 300,000 units of penicillin, 0.15 gram dihydrostreptomycin, and 0.15 gram streptomycin.

(iii) The crystalline penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 250 milligrams, each packaged in accordance with the requirements of §146b.24 (b)

(iv) The benzathine penicillin G used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of §146a.68 (b)

(v) The dihydrostreptomycin and streptomycin used in making the batch; 3 packages containing approximately equal portions of not less than 190 milligrams, each packaged in accordance with the requirements of §146b.101 (b) of this chapter.

(vi) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) If such batch is packaged for re-packing such person shall submit with the request a sample consisting of the following:

(i) For all tests except sterility—13 (14, if it contains benzathine penicillin G) approximately equal portions of at least 5 grams.

(ii) For sterility testing; 10 approximately equal portions of at least 0.5 gram.

Each such portion shall be taken from a different part of each such batch and each shall be packaged in a separate container and in accordance with the re-
(5) No result referred to in subparagraph (3) (ii), (iii), (iv) and (v) of this paragraph and no result referred to in subparagraph (3) (ii), (iii), (iv) and (v) of this paragraph is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each immediate container in the sample submitted in accordance with the requirements prescribed therefor by this section shall be §4.00.

§ 146a.66 Benzathene penicillin G and procaine penicillin for aqueous injection. Each package of benzathene penicillin G and procaine penicillin for aqueous injection contains to all requirements, and is subject to all procedures, prescribed by §146a.77 for benzathene penicillin G for aqueous injection, except that:

(a) Each package shall contain not less than 300,000 units of benzathene penicillin G and not less than 300,000 units of procaine penicillin. The procaine penicillin shall conform to the requirements prescribed therefor by §146a.44 (a)

(b) If the number of units of the drug, its moisture content is not more than 6.0 percent.

(c) In lieu of the directions for labeling prescribed by §146a.77 (c) (1) (ii) and (iii) each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of benzathene penicillin G and the number of milligrams of procaine penicillin in each immediate container, in the case of aqueous injection, except that:

(a) Each immediate container shall contain not less than 200,000 units of benzathene penicillin G, 200,000 units of procaine penicillin, and 100,000 units of buffered crystalline penicillin G used conforms to the requirements prescribed therefor by §146a.56.

(b) Its moisture content is not more than 6 percent.

(c) Each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of benzathene penicillin G in the immediate container, and its referred date shall be 36 months after the month during which the batch was certified.

(d) In addition to complying with the requirements of §146a.56 (d) (1) a person who requests certification of a batch of benzathene penicillin for aqueous injection shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the benzathene penicillin G used in making the batch for potency, crystallinity, penicillin K content (unless it is procaine penicillin G) and the penicillin G content if it is procaine penicillin G, and the number of units of benzathene penicillin G in each container of the batch.

(e) Each tablet contains not less than 20 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed therefor by §146b.101 (a) of this chapter except that:

(1) Each tablet contains not less than 20 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed therefor by §146b.101 (a) of this chapter except that:

(2) The fee for the services rendered with respect to each immediate container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by this section shall be §4.00.

§ 146a.87 Penicillin-barbitron-neomycin ointment; penicillin-barbitron-neomycin oil. Penicillin-barbitron-neomycin ointment and penicillin-barbitron-neomycin oil are subject to all procedures prescribed by §146a.56 for penicillin-barbitron ointment, except that:

(a) It contains not less than 5.0 milligrams of neomycin and not less than 28 units of barbitron per gram, unless it is procaine penicillin conforming to the standards prescribed for veterinary use. The neomycin used conforms to the standards prescribed by §146a.410 (a) (2) of this chapter.

(b) In addition to complying with the requirements of §146a.56 (d) (1) a person who requests certification of a batch of penicillin-barbitron-neomycin ointment or penicillin-barbitron-neomycin oil in oil shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and dates of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than seven immediate containers of the batch and (unless it was previously submitted) a sample consisting of five packages of the neomycin used in making the batch, containing approximately 0.5 gram each.

(d) The fee for the services rendered with respect to each tablet in the sample of streptomycin submitted in accordance with the requirements prescribed therefor by this section shall be §4.00.

§ 146a.85 Benzathene procaine-buffered crystalline penicillin for aqueous injection. Benzathene procaine-buffered crystalline penicillin for aqueous injection conforms to all requirements prescribed by §146a.50 for procaine penicillin and buffered crystalline penicillin for aqueous injection, except paragraph (b) of that section is subject to all procedures prescribed by §146a.50 for procaine penicillin and buffered crystalline penicillin for aqueous injection, except that:

(a) Each immediate container shall contain not less than 200,000 units of benzathene penicillin G, 200,000 units of procaine penicillin, and 100,000 units of buffered crystalline penicillin G used conforms to the requirements prescribed therefor by §146a.56.

(b) Its moisture content is not more than 6 percent.

(c) Each package shall bear on the outside wrapper or container and the immediate container the number of units of benzathene penicillin G and the number of units of procaine penicillin in each immediate container if it is the aqueous suspension of the drug, or the number of units of benzathene penicillin G and the number of units of procaine penicillin in the immediate container if it is the dry mixture of the drug, and the statement, "Expiration date ________", the blank being filled in, if it is the aqueous suspension of the drug, with the date which is 18 months or, if it is the dry mixture of the drug with the date which is 30 months after the month during which the batch was certified. Provided, however, the date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(d) In addition to complying with the requirements of §146a.77 (a) (1) a person who requests certification of a batch of benzathene penicillin G and procaine penicillin for aqueous injection shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the benzathene penicillin G used in making the batch for potency, crystallinity, penicillin K content (unless it is procaine penicillin G) and the penicillin G content if it is procaine penicillin G, and the number of units of benzathene penicillin G in each milliliter of the batch, if it is the aqueous suspension of the drug, or the number of units of procaine penicillin in each milliliter of the drug. He shall also submit in connection with his request a sample consisting of three packages containing each batch, each containing not less than 500 milligrams each of the procaine penicillin used in making the batch. If such batch is packaged for repackaging, each portion in the sample required by §146a.77 (d) (1) (i) shall consist of the equivalent of approximately 600 milligrams in lieu of 400 milligrams.

(e) The fee for the services rendered with respect to each immediate container in the sample of procaine penicillin submitted in accordance with the requirements prescribed therefor by this section shall be §4.00.
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(2) In lieu of the labeling prescribed for penicillin tablets by § 146a.27 (d), a person who requests certification of a batch of penicillin-streptomycin tablets or penicillin-dihydrostreptomycin tablets shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, histamine content, melting point range, and if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin, and the number of milligrams of streptomycin or dihydrostreptomycin in each tablet of the batch. He shall also submit in connection with his request a sample consisting of not less than 30 tablets and (unless it was previously submitted) a sample of undiluted aqueous solution containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146a.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container that is subject to all procedures prescribed for neomycin by § 146a.101 (a) shall be $4.00.

(c) Statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(d) The labels bear an expiration date that is not less than 24 months after the month during which the batch was last assayed and released by the manufacturer.

(e) The labels bear a statement that solutions prepared with the drugs are stable for not more than 24 hours.

(f) The circular or other labeling within or attached to the package bears information that antibiotics are used for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Chorea respiratory disease (sars infection) in chickens.

(ii) Bute comb (mud fever, nonspecific infectious enteritis) in poultry.

§ 146a.89 Procaine penicillin-streptomycin-neomycin in oil; procaine penicillin-dihydrostreptomycin-neomycin in oil; procaine penicillin-streptomycin-neomycin ointment; procaine penicillin-dihydrostreptomycin-neomycin ointment. Procaine penicillin-streptomycin-neomycin ointment or procaine penicillin-dihydrostreptomycin-neomycin ointment conforms to all requirements and is subject to all procedures prescribed by § 146a.54 for procaine penicillin-streptomycin-neomycin ointment and procaine penicillin-dihydrostreptomycin ointment, except that:

(a) It contains not less than 2.0 milligrams of neomycin per milliliter. The neomycin used conforms to the requirements prescribed for neomycin by § 146a.410 (a) (2) of this chapter.

(b) Each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of neomycin in each milliliter of the batch, and its expiration date shall be 12 months after the month during which the batch was certified, except that the expiration date shall be not less than 3 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays that show that such drug as prepared by him is stable for such period of time: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

§ 146a.10 Propanolol and benzathine penicillin G in streptomycin sulfate solution, procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution, procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution, procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution, procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution. Procaine penicillin and benzathine penicillin G in streptomycin sulfate solution and procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution conform to all requirements and are subject to all procedures prescribed by § 146a.67 for procaine penicillin in streptomycin sulfate solution and procaine penicillin in dihydrostreptomycin sulfate solution except that:

(a) Each milliliter shall contain not less than 100,000 units of procaine penicillin, not less than 100,000 units of benzathine penicillin G, and not less than 0.25 gram of streptomycin sulfate or dihydrostreptomycin sulfate, but each immediate container shall contain not less than 200,000 units of procaine penicillin, not less than 200,000 units of benzathine penicillin G, and not less than 0.5 gram of streptomycin sulfate or dihydrostreptomycin sulfate. The benzathine penicillin G used conforms to the requirements prescribed for benzathine penicillin G by § 146a.67 (d) (1) (i), each package shall bear on the outside wrapper or container and the immediate container the number of units of procaine penicillin, the number of units of benzathine penicillin G, and the number of grams of streptomycin sulfate or dihydrostreptomycin sulfate in each milliliter of the batch.

(b) In lieu of the directions prescribed by § 146a.67 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of procaine penicillin, the number of units of benzathine penicillin G, and the number of grams of streptomycin sulfate or dihydrostreptomycin sulfate in each milliliter of the batch.

(c) In addition to complying with the requirements of § 146a.67 (d) a person who requests certification of a batch shall also submit in connection with his request a sample consisting of 3 packages containing approximately equal portions of not less than 0.5 gram each of the benzathine penicillin G used in making the batch for potency, crystallinity, and penicillin G content, and the number of units of benzathine penicillin G in each milliliter of the batch. He shall also submit in connection with his request a sample consisting of 3 packages containing approximately equal portions of not less than 0.5 gram each of the benzathine penicillin G used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of 3 packages containing approximately equal portions of not less than 0.5 gram each of the benzathine penicillin G used in making the batch for potency, toxicity, moisture, and pH.

§ 146a.91 Benzathine penicillin G and streptomycin; benzathine penicillin G and dihydrostreptomycin. Benzathine penicillin G and streptomycin; benzathine penicillin G and dihydrostreptomycin conform to all requirements prescribed in § 146a.67 (b) for procaine penicillin in streptomycin sulfate solution and procaine penicillin in dihydrostreptomycin sulfate solution except that:

(a) Each milliliter shall contain not less than 100,000 units of benzathine penicillin G, and not less than 0.25 gram of streptomycin sulfate or dihydrostreptomycin sulfate, but each immediate container shall contain not less than 200,000 units of benzathine penicillin G, and not less than 0.5 gram of streptomycin sulfate or dihydrostreptomycin sulfate. The benzathine penicillin G used conforms to the requirements prescribed for benzathine penicillin G by § 146a.67 (d) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of benzathine penicillin G in each milliliter of the batch. He shall also submit in connection with his request a sample consisting of 3 packages containing approximately equal portions of not less than 0.5 gram each of the benzathine penicillin G used in making the batch for potency, crystallinity, and penicillin G content, and the number of units of benzathine penicillin G in each milliliter of the batch.

(b) In lieu of the directions prescribed by § 146a.67 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of benzathine penicillin G, and the number of grams of streptomycin sulfate or dihydrostreptomycin sulfate in each milliliter of the batch.

(c) In addition to complying with the requirements of § 146a.67 (d) a person who requests certification of a batch shall also submit in connection with his request a sample consisting of 3 packages containing approximately equal portions of not less than 0.5 gram each of the benzathine penicillin G used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of 3 packages containing approximately equal portions of not less than 0.5 gram each of the benzathine penicillin G used in making the batch for potency, toxicity, moisture, and pH.
mements prescribed by § 146a.77 for the dry mixture of benzathene penicillin G for aqueous injection and are subject to all procedures prescribed by that section for benzathene penicillin G for aqueous injection except that:
- (a) It contains not less than 0.5 gram of streptomycin or dihydrostreptomycin for each 100,000 units of benzathene penicillin.

(b) In lieu of the directions for labeling prescribed by § 146a.77 (c) (1) (ii), each package shall bear on the outside wrapper the number of units of penicillin and the number of grams of streptomycin or dihydrostreptomycin in the immediate container.

c) In addition to complying with the requirements of § 146a.77 (d) a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for each immediate container the number of units of penicillin and the number of grams of streptomycin or dihydrostreptomycin in each immediate container.

d) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.92 Tablets benzathene penicillin G and crystalline penicillin. Tablets benzathene penicillin G and crystalline penicillin conform to all requirements prescribed therefor by § 146a.27 for penicillin tablets and are subject to all procedures prescribed by that section for penicillin tablets, except that:
(a) Each tablet contains not less than 100,000 units of benzathene penicillin G and not less than 100,000 units of crystalline penicillin sodium or potassium penicillin.
(b) Their moisture content is not more than 4 percent.
(c) In lieu of the directions for labeling prescribed for penicillin tablets by § 146a.27 (c) (1) (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of each salt of penicillin.

(d) A person who requests certification of a batch shall submit in connection with his request an accurately representative sample of the batch, consisting of not less than 30 tablets.

§ 146a.93 Penicillin-streptomycin powder. Penicillin-streptomycin powder and penicillin-dihydrostreptomycin powder conform to all the requirements prescribed therefor by § 146a.27 for penicillin-streptomycin tablets and penicillin-dihydrostreptomycin tablets, except that:
(a) Each gram contains not less than 50,000 units of penicillin and not less than 5 milligrams of streptomycin or dihydrostreptomycin.

(b) In lieu of the labeling prescribed by § 146a.88 (a) (2), each package shall bear by his request a statement showing the batch mark, the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each gram and the statement “Expiration date _______,” the blank being filled in with the date which is 12 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(c) In lieu of the minimum number of tablets prescribed by § 146a.88 (a) (3), a person who requests certification of a batch shall submit with his request a sample of the batch consisting of 1 immediate container of each 5,000 immediate containers but in no case less than 6 or more than 12 immediate containers. Such sample shall be collected by taking 3 packages consisting of approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements prescribed for penicillin tablets by § 146a.101 (b) of this chapter.

(d) The fee for the services rendered with respect to each immediate container in the sample submitted in accordance with the requirements prescribed by paragraph (c) of this section shall be $4.00.

(e) Exemption of penicillin-streptomycin powder and penicillin-dihydrostreptomycin powder for veterinary use with the requirements prescribed therefor by § 146a.18 for veterinary use.

§ 146a.94 Dibenzyamine penicillin G (dibenzyamine penicillin G salt)—
(a) Standards of identity, strength, quality, and purity. Dibenzyamine penicillin G is the crystalline dibenzylamine salt of penicillin G. It contains not less than 65 percent by weight of the dibenzyamine salt of penicillin G. Each such drug is so purified and dried that:
1. Its potency is not less than 970 units per milligram.
2. It is sterile.
3. It is nontoxic.
4. It is nonpyrogenic.
5. Its moisture content is not more than 4.0 percent.
6. Its pH in saturated aqueous solution is not less than 5.0 and not more than 7.5.

(b) Packaging. In all cases the immediate containers shall be tight containers as defined by the U.S. P., shall be sterile at the time of filling and closing, and shall be so constructed that they cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practices shall be disregarded.

(c) Labeling. Each package shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:
1. The batch mark.
2. The weight of the drug and the number of units in the immediate container.
3. The statement “Expiration date _______” the blank being filled in with the date which is 12 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

4. The statement “For manufacturing use only.”

5. The statement “Caution: Federal law prohibits dispensing without prescription.”

6. Request for certification, checks, tests and assays; samples. (1) In addition to complying with the requirements of § 146a.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and unless it is previously submitted, the date on which the last assay of the drug comprising such batch was completed. Such request shall be accompanied or followed
by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, and the penicillin G content.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility—10 packages.

(ii) For sterility test; 10 packages.

Each such package shall contain approximately 300 milligrams taken from different parts of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which dibenzylamine penicillin G is to be used, the manufacturer of a batch that is to be so used may request the Commissioner to make check tests and assays on such batch, in accordance with the regulations as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph and the results of such check tests and assays not required for the batch when used in such other drug, the Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (1) and (3) of this section.

(2) If the Commissioner considers that investigations other than the examination of such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.3 (d) of this part.

§146a.95 Dibenzylamine penicillin and potassium penicillin powder buffered—(a) Standards of identity, strength, quality, and purity. Dibenzylamine penicillin and potassium penicillin powder, buffered, is a dry mixture of dibenzylamine penicillin G and potassium penicillin G, with or without one or more suitable sulfonamides, and with one or more suitable and harmless buffer substances, colorings, and flavorings. It shall contain not less than 100,000 units of potassium penicillin G for each 200,000 units of dibenzylamine penicillin G. Its moisture content is not more than 1 percent. Its pH is not less than 5.5 and not more than 7.5. The dibenzylamine penicillin G used conforms to the requirements of §146a.94 (a) except subparagraphs (2) and (3) of that paragraph. The potassium penicillin used conforms to the requirements of §146a.24 (a) for potassium penicillin, except subparagraphs (2) and (4) of that paragraph.

Each other ingredient used, if its name is recognized in the U. S. P. or N. F. conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Each immediate container shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label or labeling, as herein-after indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(I) The batch mark.

(ii) If it is units of dibenzylamine penicillin and the number of units of potassium penicillin in the immediate container.

(iii) If it contains sulfonamides, the name and quantity of each in the immediate container.

(iv) The name of every ingredient used in making the batch.

(d) Statement "Expiration date—Not for injection." The statement "Expiration date—Not for injection." shall be:

(1) The batch mark.

(2) Such person shall submit with his request results of tests and assays listed after each of the following, made by him on an accurately representative sample of:

(I) The batch; potency and moisture.

(II) The dibenzylamine penicillin G used in making the batch; potency, toxicity, moisture, pH, crystallinity, and penicillin G content.

(III) The potassium penicillin G used in making the batch; potency, toxicity, moisture, pH, penicillin G content, crystallinity, and heat stability.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of tests and assays listed after each of the following, made by him on an accurately representative sample of:

(I) The batch; potency and moisture.

(II) The dibenzylamine penicillin G used in making the batch; potency, toxicity, moisture, pH, penicillin G content.

(III) The potassium penicillin G used in making the batch; potency, toxicity, moisture, pH, penicillin G content, crystallinity, and heat stability.

(4) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(I) The batch; 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 or more than 12 immediate containers, collected to show that each the containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(II) The dibenzylamine penicillin G used in making the batch; 3 packages, each containing approximately equal portions of not less than 800 milligrams packaged in accordance with the requirements of §146a.24 (b).

(III) The potassium penicillin G used in making the batch; 3 packages, each containing approximately equal portions of not less than 350 milligrams packaged in accordance with the requirements of §146a.24 (b).

(4) In case of an initial request for certification, each other ingredient used in the batch; 1 package of each containing approximately 5 grams.

(4) No request for certification in subparagraph (2) (ii) and (iii) of this paragraph, and no sample referred to in subparagraph (3) (ii) and (iii) of this
paragraph, is required if such results or samples have been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (2) (i), (ii), (iii) and (iv) of this section.

(2) If the Commissioner considers that investigations other than the examination of units necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.96 Dibenzylation penicillin and streptomycin in oil; dibenzylamine penicillin and dihydrostreptomycin in oil. Dibenzylation penicillin and streptomycin in oil and dibenzylamine penicillin and dihydrostreptomycin in oil are required to conform to all the requirements prescribed by § 146a.57 for procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil and are subject to all the procedures prescribed by § 146a.57 for procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil, except dibenzylamine penicillin is used in lieu of procaine penicillin. The dibenzylamine penicillin used conforms to the requirements of § 146a.94 (a) except subparagraph (2) and (4) of that paragraph.

§ 146a.97 Hydrambamine penicillin G (hydrambamine penicillin G salt)—(a) Standards of identity, strength, quality, and purity. Hydrambamine penicillin G is the crystalline salt K.N.-bis-(dehydroabscetil) ethylenediamine dipenicillin in oil and contains not less than 95 percent. It is so purified and dried that:

(1) Its potency is not less than 845 units per milligram.

(2) It is nontoxic.

(3) Its moisture content is not more than 2 percent.

(4) Its pH in a saturated aqueous solution is not less than 4.0 and not more than 7.5.

(5) Its extinction coefficient E1% is not less than 8 at 276 millimicrons.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.

(2) The number of units per milligram and the number of grams in the immediate container.

(3) The statement "Expiration date ________" the blank being filled in with the date that is 24 months after the month during which the batch was certified:

Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For use in the manufacture of nonparenteral drugs only."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) Request for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, and the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch of each lot of such drug as the batch was certain.

(2) Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(3) On the outside wrapper or container:

(a) The batch mark.

(b) The number of units in each milliliter of the batch.

(c) The name of each buffer substance and the name and quantity of each preservative used in making the batch.

(4) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(5) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) for the use of the drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such information is contained in a circular or other labeling within or attached to the package.

(6) On the circular or other labeling:

(a) The term "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(b) The name of each buffer substance and the name and quantity of each preservative used in making the batch.

(7) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) Request for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such
Capsules crystalline penicillin G (capsules crystalline penicillin G potassium, capsules crystalline penicillin G sodium)—(a) Standards of identity, strength, and purity. Capsules, containing crystalline penicillin G, are crystalline penicillin G, sodium or potassium, with or without one or more suitable and harmless buffer substances, vitamin substances, and other substances. The potency of each capsule is not less than 75,000 units per mg. Capsules with the blank printed on the outside wrapper or container conform to the requirements prescribed for crustalline penicillin G tablets by § 146a.27 (b) (c), (d), and (e), except that:

(1) If it is for use in the preparation of oral solutions, each capsule contains a statement that the batch is of the same potency as the batch from which the capsules were made and which may be filled out immediately.

(b) Packaging; labeling; request for certification. Each capsule must be packaged in accordance with the requirements prescribed for capsules crystalline penicillin G tablets by § 146a.27 (c) and (d) of this section, except that:

(1) Each capsule shall be labeled with the name of the vitamin ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(2) It shall be labeled with an expiration date that is 16 months, after the month during which the batch was certified, except that the batch may be filled in with the date that is 12 months after the month during which the batch was certified.

(c) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each capsule in the samples submitted in accordance with paragraph (d) (3) (ii) (ii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.99 Capsules crystalline penicillin G (capsules crystalline penicillin G benzathene penicillin G and procaine penicillin G in oil conforms to all requirements prescribed for benzathene penicillin G and procaine penicillin G, except that:

(1) Each milliliter contains not less than 150,000 units each of benzathine penicillin G and procaine penicillin G, unless it is intended solely for veterinary use and is conspicuously so labeled. The benzathene penicillin G used conforms to the requirements of § 146a.68 (a) (2) Its moisture content is not more than 4.0 percent.

(2) In lieu of the directions for labeling prescribed for procaine penicillin in oil by § 146a.45 (a) (d) each package shall bear on the outside wrapper or container and the immediate container the number of units of benzathine penicillin G and the number of units of procaine penicillin G in each milliliter of the batch.

(4) In addition to complying with the requirements of § 146a.45 (d), a person who requests certification of a batch shall submit with his request a sample of the batch showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the benzathene penicillin G used in making the batch and of the emergency streptomycin, sterility, pyrogens, toxicity, moisture, pH, crystallinity, and penicillin G content, and the number of units each of benzathine penicillin G and procaine penicillin G in each milliliter of the batch. He shall also submit in connection with his request a sample consisting of not less than 4 packages of the batch and (unless it was previously submitted) a sample of the benzathene penicillin G used in making the batch, consisting of 20 packages, each containing approximately equal portions of not less than 300 milligrams.

(b) The fee for the services rendered with respect to each package of benzathine penicillin G submitted in accordance with the requirements prescribed herefor by this section shall be $2.00.

§ 146a.101 Benzathene penicillin G-procaine penicillin G-streptomycin in oil; benzathine penicillin G-streptomycin in oil; benzathine penicillin G-dihydrostreptomycin in oil.

(a) Benzathenic penicillin G-procaine penicillin G-streptomycin in oil and benzathine penicillin G-procaine penicillin G-dihydrostreptomycin in oil conform to all requirements and are subject to all procedures prescribed by § 146a.105 for benzathine penicillin G and procaine penicillin G in oil, except that:

(1) Each milliliter shall contain not less than 250 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed by § 146a.105 (a) of this chapter. The dihydrostreptomycin used conforms to the standards prescribed by § 146a.105 of this chapter.

(b) Its moisture content is not more than 4 percent.
lin G, and the number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch.

(3) In addition to complying with the requirements of §146a.101 (a) (4) a person who requests certification of a batch shall submit with his request a statement showing the batch mark

(2) The number of units per milliliter of the batch and the number of units of benzathine penicillin G and procaine penicillin, and the number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch. He shall also submit in connection with his request a sample consisting of not less than 5 immediate containers of the batch and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146a.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted, for all tests except sterility, in accordance with the requirements prescribed by this section, shall be $10.00.

§ 146a.103 Penicillin V (phenoxymethyl penicillin)—(a) Standards of identity, strength, quality, and purity. Phenoxymethyl penicillin V is crystalline phenoxymethyl penicillin. It contains not less than 90 percent of penicillin V. It is so purified and dried that:

(1) Its potency is not less than 1,500 units per milligram.

(2) It is nontoxic.

(3) Its moisture content is not more than 2.0 percent.

(4) Its pH in a saturated aqueous solution is not less than 2.5 and not more than 4.5.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.

(2) The number of units per milliliter of the batch and the number of grams in the immediate container.

(3) The statement "Expiration date ______________", the blank being filled in with the date that is 12 months after the month during which the batch was certified; Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(d) The statement "For use in the manufacture of nonparenteral drugs only."

(e) The statement "Caution: Federal law prohibits dispensing without prescription."

(f) Request for certification, samples.

(1) In addition to complying with the requirements of § 145.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of units of penicillin in the batch, and the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, pH, crystallinity, and penicillin V content.

(g) Such person shall submit with his request an accurately representative sample of the batch, consisting of 10 packages, each containing approximately 50 milligrams taken from a different part of such batch in accordance with the requirements of paragraph (b) of this section.

(h) Fees. The fee for the services rendered with respect to each batch under the requirements in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an annual payment made in accordance with § 146a.27 (c) (1) of this chapter.

§ 146a.106 Tablets benzathine penicillin G and penicillin V (a) Tablets benzathine penicillin G and penicillin V conform to all requirements and are subject to all procedures prescribed in § 146a.103 (a) (4) and (7). Such person shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the polymyxin used in making the batch, packaged in accordance with the requirements prescribed therefor in applicable standards, except that:

(a) They contain not less than 5,000 units of polymyxin B per single-dose container. The polymyxin B used conforms to the requirements prescribed for polymyxin B by § 146b.107 (a) of this chapter.

(b) In lieu of the labeling prescribed by § 146a.57 (a) (3) each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin, the number of milligrams of streptomycin or dihydrostreptomycin, and the number of units of polymyxin B per milliliter or per prescribed dose, if it contains one or more of the active ingredients specified in § 146a.57 (a) (2) the name and quantity of each; the statement "For udder instillation of cattle only" and the statement "Expiration date ______________", the blank being filled in with the date that is 12 months after the month during which the batch was certified. Each package shall also bear on its label and labeling, if it contains one or more of the active ingredients specified in § 146a.57 (a) (2) after the name "penicillin-streptomycin-polyoxymycin in oil," whenever it appears, the words "with ______________" (the blank being filled in with the common or usual name of each active ingredient) in juxtaposition with such name.

(c) In addition to complying with the provisions of § 146a.57 (a) (4) a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the polymyxin used in making the batch for potency and toxicity. He shall also submit in connection with his request a sample consisting of not less than 6 immediate containers of the batch and
(unless it was previously submitted) a sample consisting of 5 packages containing equal portions of not less than 0.5 gram each of the polymyxin used in making the batch.

(d) The fee for the services rendered with respect to each immediate container in the batch shall be computed in accordance with the requirements prescribed therefor by this section shall be $4.00.

PART 146b—CERTIFICATION OF STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) AND STREPTOMYCINIC- (OR DIHYDROSTREPTOMYCINIC-) CONTAINING DRUGS

Sec. 146b.101 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride, streptomycin sulfa, streptomycin ointment, dihydrostreptomycin sulfate.

146b.102 Streptomycin ointment; dihydrostreptomycin ointment.

146b.103 Dihydrostreptomycin sulfate, crystalline dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride, dihydrostreptomycin tablets; dihydrostreptomycin tablets.

146b.104 Streptomycin for topical use; streptomycin ointment with ________ for topical use.

146b.105 Streptomycin sulfate solution; dihydrostreptomycin sulfate solution.

146b.107 Streptomycin - polymyxin - bacitracin tablets.

146b.108 Streptomycin syrup, streptomycin and kaolin in gel; dihydrostreptomycin syrup; dihydrostreptomycin and kaolin in gel.

146b.109 Streptomycin - bacitracin - polymyxin gauze pads.

146b.110 Streptomycin oint with antifungal agent, streptomycin oint with ________, dihydrostreptomycin oint with antifungal agent, dihydrostreptomycin oint with ________.

146b.111 Streptomycin - kaolin - pectin - aluminum hydroxide gel powder veterinary; dihydrostreptomycin - kaolin - pectin - aluminum hydroxide gel powder veterinary.

146b.112 Streptomycin for inhalation therapy; dihydrostreptomycin for inhalation therapy.

146b.113 Dihydrostreptomycin - streptomycin sulfates.

146b.114 Streptomycin sulfate oral veterinary.

146b.115 Streptomycin sulfate powder oral veterinary; streptomycin sulfate powder oral veterinary.

146b.116 Streptomycetinidene isonicotinyl hydrazine sulfate.

146b.117 Dihydrostreptomycin - streptomycin.

146b.118 Streptomycin - pencilin - sulfonamide with kaolin and pectin; dihydrostreptomycin - pencilin - sulfonamide with kaolin and pectin.

146b.119 Streptomycin hydrochloride solution oral veterinary; streptomycin sulfate solution oral veterinary.

146b.120 Dihydrostreptomycin - streptomycin sulfates with isonicotinic acid hydroxide.

146b.121 Streptomycin-erythromycin ointment.


Sec. 146b.123 Streptomycin - sodium sulfathiazole solution veterinary; dihydrostreptomycin - sodium sulfathiazole solution veterinary.

146b.124 Streptomycin-polymyxin-neomycin ointment; dihydrostreptomycin-polymyxin-neomycin ointment.
in no case less than 5 or more than 12 immediate containers.

(iii) For sterility testing; 10 immediate containers.

Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repackaging or for use as an ingredient in the manufacture of another drug, such person shall submit with his request an accu- rately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 5 packages.

(ii) For sterility testing; 10 packages.

Each such package shall contain approximately 0.5 gram taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(d) In connection with contemplated requests for certification of repackaged batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of such batch shall be so repackaged or used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (a) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the samples submitted in accordance with this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether the batch to which such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.3 (d) of this chapter.

§ 146b.103 Streptomycin ointment; dihydrostreptomycin ointment—(a) Standards of identity, strength, quality, and purity. Streptomycin ointment and dihydrostreptomycin ointment is streptomycin or dihydrostreptomycin in a suitable and harmless ointment base, with or without suitable and harmless dispersing and suspending agents and preservatives. Its potency is not less than 5,000 micrograms per gram of ointment. The streptomycin or dihydrostreptomycin used in making the ointment base conform to the requirements of § 146b.101 (a), except the subparagraphs (2) (4), (5) and (6) of that paragraph. The dihydrostreptomycin used conforms to the requirements of § 146b.101 (a), except the standards for sterility, pyrogen, histamine, and moisture. Each other substance, used if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Streptomycin ointment and dihydrostreptomycin ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U. S. P. and each such tube shall not be larger than the 2-ounce size, except if it is labeled solely for hospital use it may be packaged in immediate containers of glass which meet the test for tight containers as defined by the U. S. P. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in the process of storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of streptomycin ointment or dihydrostreptomycin ointment shall bear on its label or labeling as hereafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of micrograms per gram of the batch.

(iii) If the batch contains preservatives, the name and quantity of each such preservative.

(iv) The statement "Expiration date ————", the blank being filled in with the date which is 24 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper only.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is conspicuously so labeled, adequate directions and warnings for the use of such drug by the laity. Such circular or other labeling may also bear a legend that a batch is labeled or printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Requests for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of streptomycin ointment or dihydrostreptomycin ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided by subparagraph (d) of this paragraph such person shall submit in connection with his request the results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request, in the quantities hereafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers.

(ii) 12 immediate containers unless each such container is packaged for hospital use and contains more than 2 ounces, in which case the sample shall consist of approximately 1 ounce of ointment for each 5,000 immediate containers in the batch, but in no case less than five 1-ounce portions or more than twelve 1-ounce portions. Such sample shall be collected by taking single immediate containers or 1-ounce portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; 5 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b)

(iii) In case of an initial request for certification, the ingredients used in making the ointment base of the batch; one package of each containing approximately 200 grams, except for the suspending and dispersing agents used, in
which case the sample shall consist of approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(d) Fees. The fee for the services rendered with respect to each batch of streptomycin ointment or dihydrostreptomycin ointment under the regulations in this part shall be:

(1) $0.05 for each package in the samples submitted in accordance with paragraph (d) (1), (ii), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.103 Dihydrostreptomycin sulfate, crystalline dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride. (a) Dihydrostreptomycin sulfate is the hydrogenated sulfate salt of a kind of streptomycin of a mixture of two or more such salts; crystalline dihydrostreptomycin sulfate is the hydrogenated sulfate salt of a kind of streptomycin or a mixture of two or more such salts. Each such drug conforms to all procedures prescribed by § 146b.101 for streptomycin sulfate and streptomycin hydrochloride, and is subject to all procedures prescribed by § 146b.101 for streptomycin sulfate and streptomycin hydrochloride, except that:

(1) Its potency is not less than 650 micrograms per milligram, except that if it is crystalline dihydrostreptomycin sulfate its potency shall be not less than 725 micrograms per milligram.

(2) Its content of streptomycin sulfate or streptomycin hydrochloride is not more than 3.0 percent when calculated as streptomycin base, except that if it is crystalline dihydrostreptomycin sulfate its content of streptomycin sulfate is not more than 1.0 percent.

§ 146b.104 Streptomycin tablets; dihydrostreptomycin tablets—(a) Standards of identity, strength, quality, and purity. Streptomycin tablets and dihydrostreptomycin tablets are streptomycin or dihydrostreptomycin tablets with or without sucrose, lactose, kaolin or other suitable finely divided absorbent ingredients, pectin, and dried aluminum hydroxide gel, and with or without the addition of one or more suitable and harmless diluents, binders, lubricants, and flavoring agents.

If it is intended solely for veterinary use and is conspicuously so labeled, it may contain vitamin A, one or more suitable sulfonamides, or both. The potency of each tablet is not less than 50 milligrams. Its moisture content is not more than 5 percent. The streptomycin used conforms to the standards prescribed by § 146b.101 (a), except subparagraphs (2) and (4) of that paragraph or in the case of tablets for veterinary use, streptomycin sulfate conforming to the standards prescribed therefor by § 146b.114 (a) may be used. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103, except the standards for stability of Streptomycin Tablets. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Unless each streptomycin or dihydrostreptomycin tablet is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may be a resilient separate part of the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such that it will not affect the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of streptomycin or dihydrostreptomycin tablets shall bear, on its label or labeling as hereafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The potency of each tablet of the batch;

(iii) The statement "Expiration date...", the blank being filled in with the date which the batch was certified, provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If the batch contains, in addition to streptomycin or dihydrostreptomycin, one or more of the other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient in each tablet.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference statement identifying a readily available medical publication containing information (including contraindication and possible sensitization) adequate for the safe and proper use of the drug by practitioners licensed by law to administer it will be sent to such veterinarian on request.

(d) Request for certification; samples. (1) In addition to complying with the requirements of § 146.3 of this chapter, a person who requests certification of a batch of streptomycin or dihydrostreptomycin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making such batch was completed, the potency of each tablet, the quantity of each ingredient used in making the batch, the date on which such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, in this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and analyses listed after each of the following, made on an accurately representative sample of each:

(i) The batch; average potency per tablet and average weight.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, histamine content, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfates.

(e) Exception. (1) On the label and labeling, if it is sold in addition to streptomycin or dihydrostreptomycin, one or more of the other active ingredients specified in paragraph (a) of this section, after the name "Streptomycin Tablets" or "Dihydrostreptomycin Tablets," the words "with..." (the blank being filled in with the common or usual name of each such other ingredient) in juxtaposition with such name.

(f) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

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such intervals throughout the entire time of packaging that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; five packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of §146b.101 (b)

(iii) In case of an initial request for certification, each other ingredient used in making the batch; five packages containing approximately equal portions of not less than 5 grams each, packaged in accordance with the requirements of §146b.101 (b)

(iv) No result referred to in subpara-

section (2) (i) of this paragraph, and no sample referred to in subpara-

section (2) (ii) of this paragraph, is required if such result or sample has been previously sub-

mitted.

(e) Fees. The fee for the service rendered with respect to each batch of streptomycin or dihydrostreptomycin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (1) of this section; $10.00 for each package in the samples submitted in accordance with paragraph (d) (2) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) of this section, and no fee for each package of the samples submitted in accordance with paragraph (d) (3) (ii) of this paragraph, is required if such fee is covered by an advance deposit made in accordance with §146.8 (d) of this chapter.

§ 146b.105 Streptomycin for topical use; streptomycin with ------ (the blank being filled in with the name of the vehicle if a package combination) for topical use—(a) Standards of identity, strength, quality, and purity. Streptomycin for topical use conforms to all the require-

ments prescribed by §146b.101 (a) for streptomycin, and may be packaged in combination with a container of a suit-

able and harmless vehicle.

(b) Packaging. The immediate con-

tainer of streptomycin for topical use shall be colorless transparent glass so closed as to be a tight container as de-

fined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, qual-

ity, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 30 milligrams.

(c) Labeling. Each package of strep-

tomycin for topical use shall bear on its label or labeling, as hereinafter indi-

cated, the following:

(1) On the outside wrapper or con-

tainer and the immediate container:

(i) The batch mark;

(2) The weight of milligrams in the immediate container;

(3) The statement, "Expiration date _______ , the blank being filled in with the date beta, months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(4) The statement "Caution: Not for Intravenous or systemic medication.

(5) In a package combination, on the immediate container of the vehicle in the combination:

(i) A statement giving the method of dissolving the streptomycin in the vehicle as follows: The solution may be stored at room temperature for 1 week without significant loss of potency".

(ii) The potency per milliliter if the streptomycin has been dissolved therein;

(iii) The statement "Caution: Not for Intravenous or systemic medication.

(6) On the outside wrapper or con-

tainer:

(i) The statement "Caution: Federal law prohibits dispensing without prescrip-

tion. The person requisitioning this medication for dis-

pensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is to be used by a practitioner, reference specifically identifying a readily avail-

able medical publication containing infor-

mation (including contraindications and possible sensitization) adequate for the practitioner to determine whether or not such batch conforms to the standards prescribed by §146b.105 for dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate. Streptomycin sulfate solution is an aqueous solution of streptomycin sulfate. Dihydrotstreptomycin sulfate solution is an aqueous solution of dihydrostreptomycin sulfate or crystalline dihydro-

streptomycin sulfate. Such solution conforms to all standards prescribed by §146b.105 for streptomycin sulfate or §146b.103 for dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate, except the limitation on moisture content, and except that:

(i) The potency per milliliter is not less than 250 milligrams per milliliter and not more than 500 milligrams per milliliter, unless it is intended solely for veterinary use and is conspicuously so labeled.
(2) It contains one or more suitable and harmless preservatives.
(3) Its pH is not less than 5.0 and not more than 8.0.
(4) It may contain one or more suitable and harmless buffer substances and stabilizing agents (except that a substance containing more than one of these ingredients, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers, of colorless (unless it is intended solely for veterinary use and is conspicuously so labeled) or transparent glass closed (for veterinary use) transparent glass closed container if such immediate container is packaged for dispensing it shall be so packaged to contain a single dose. Each such container shall contain not less than 1.0 milliliter and not more than 50 milliliters, unless it is intended solely for veterinary use and is conspicuously so labeled.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U.S. F., shall be sterile and, if filled at any time of manufacturing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers, of colorless (unless it is intended solely for veterinary use and is conspicuously so labeled) or transparent glass closed (for veterinary use) transparent glass closed container if such immediate container is packaged for dispensing it shall be so packaged to contain a single dose. Each such container shall contain not less than 1.0 milliliter and not more than 50 milliliters, unless it is intended solely for veterinary use and is conspicuously so labeled.

(c) Labeling. Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) The name and quantity of each preservative used, and

(ii) The date on which such batch was certified, except that such a batch shall be certified only when the batch has been packaged and is properly labeled, with the standards prescribed by paragraph (a) of this section: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The name and quantity of each preservative used; and

(v) The statement “For manufacturing use,” “For repackaging,” or “For manufacturing use or repackaging,” when packaged for repackaging or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container:

(a) The statement “Store in refrigerated or air conditioned space at not above 65° F., or if not available, Store below 15° C. (59° F.),” unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug is as prepared by him complies with the standards prescribed by paragraph (a) of this section after having been stored at room temperature.

(b) The statement “Caution: Federal law prohibits dispensing without prescription,” unless it is packaged for dispensing and is intended solely for veterinary use and is conspicuously so labeled.

(c) On the circular or other labeling within or attached to the package, if it is packaged for repackaging or for use as an ingredient in the manufacture of another drug:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug;

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer such drug, shall be sent to such veterinarian on request.

(d) Request for certification, check tests and assays; samples. (1) In addition to the requirements prescribed by §146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams or grams dissolved in each of such packages, the date on which the latest assay of that drug was completed, and if it is crystalline dihydrostreptomycin sulfate it is dihydrotreptomycin sulfate, the batch mark and (unless it was previously submitted) the date on which the latest assay of the crystalline dihydrostreptomycin sulfate used in making such batch was completed.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed hereafter included, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, toxicity, pyrogens, histamine content, pH, and streptomycin content, if it is dihydrostreptomycin sulfate or crystalline dihydrostreptomycin crystalloid.

(ii) If crystalline dihydrostreptomycin sulfate is used in making the batch; potency and crystallinity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch, if packaged for dispensing;

(c) For all tests except sterility: one immediate container for each 5,000 immediate containers in such batch, but in no case less than 5 or more than 12 immediate containers.

(b) For sterility testing: 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire-time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(II) The batch, if packaged for repackaging or for use in the manufacture of another drug:

(a) For all tests except sterility: 5 packages.

(b) For sterility testing: 10 packages.

Each such package shall contain approximately 2 milliliters taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(iii) If crystalline dihydrostreptomycin sulfate is used in making the batch, 2 immediate containers containing approximately 0.5 gram each, packaged in accordance with the requirements of §146b.101 (b)

(iv) In case of an initial request for certification, each ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (d) (i) of this paragraph, and each sample referred to in subparagraph (2) (d) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(5) In connection with contemplated requests for certification of repackaged batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of the batch which is to be so repackaged or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (2) (d) (iii) of this paragraph. From the information required pursuant to subparagraph (2) (d) (iii) of this paragraph, (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) Fees. The fee for the services rendered with regard to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (a), (d) (3) (b), (d) (3) (c); and

(2) $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (a), (d) (3) (c), and (d) (4); and

(3) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of §146.8 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such request may be made by an endorsement deposit maintained in accordance with §146.8 (f) of this chapter.

§146b.107 Streptomycin-polymyxin-B-acillin tablets (a) Standards of identity, strength, quality, and purity. Streptomycin-polymyxin-B-acillin tablets are tablets composed of streptomycin, polymyxin, and bacitracin in combination. Without the addition of one or more suit-
able and harmless buffer substances, dilaunets, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 500 units of polymyxin B, and 5,600 units of bacitracin. Its moisture content is not more than 3%. The streptomycin used conforms to the standards prescribed therefor by §146b.101 (a) except subparagraphs (2) and (4) of that paragraph. The polymyxin used is produced by the growth of Bacillus polymyxa, has a potency of 3,600 units per milligram, and is nontoxic. The bacitracin used conforms to the standards prescribed therefor by §146e.401 (a) of this chapter, except subparagraphs (1) and (4) of that paragraph.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is impossible to indicate exactly on the label and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also be a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(c) Labeling. Each package shall bear, on its label or labeling, as hereinafter indicated, the following:

(1) The batch number.

(i) The number of milligrams of streptomycin in each tablet of the batch.

(ii) The number of units of polymyxin B in each tablet of the batch.

(iii) The number of units of bacitracin in each tablet of the batch.

(iv) The number of units of bacitracin in each tablet of the batch.

(v) The statement "Expiration date ________", in which the latest assay of the streptomycin, polymyxin, and bacitracin used in making such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (d) of this paragraph, such person shall submit in connection with his request a statement describing the test performed and the result referred to in subparagraph (a) of this section.

(d) Fee for the services rendered with respect to each batch of streptomycin-polymyxin-bacitracin tablets under the regulations in this part shall be:

(i) $0.03 for each tablet in the sample submitted in accordance with paragraph (d) (1) of this section; $0.05 for each package in the samples submitted in accordance with paragraphs (2) (1), (3), (4), and (5) of this section; and

(ii) If the Commissioner considers that investigations, other than examination of such tablets and packages are necessary to determine whether or not such batch complies with the requirements of §146b.103, the cost of such investigations.

The fees prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146b.103 (d) of this chapter.

§146b.103 Streptomycin syrup, streptomycin and polymyxin in gel; dihydrostreptomycin syrup, dihydrostreptomycin and polymyxin in gel—(a) Standards of identity, strength, quality and purity. Streptomycin and polymyxin in syrup and dihydrostreptomycin and polymyxin in syrup are streptomycin or dihydrostreptomycin dissolved in a suitable and harmless diluent that contains one or more suitable and harmless preservatives. Streptomycin and polymyxin in gel are streptomycin or dihydrostreptomycin dissolved or suspended in a suitable and harmless preservative, such as gelatin and one or more suitable and harmless preservatives, with or without one or more suitable and harmless suspending agents, dispersing, or flavoring agents and water or without water, bismuth glycolarsanilate, bismuth magma, suitable mineral salts, or procaine hydrochloride. Its potency is not less than 10 international units per milliliter. Each other substance used, if its name is recognized in the U.S. P. or N.F., conforms to the standards prescribed therefor by §146b.103, except the standards for sterility, pyrogen, and moisture. Each other substance used, if
its name is recognized in the U. S. P or
N. F., conforms to the standards pro-
certified, if the person who requests the
ments therein. In applicable standards, except that minor
quadrate with such name.
and is conspicuously so labeled, adequate di-
method of making the batch, the quantity of each in-
cept shall be sent to such veter-
ance, unless it is packaged for dis-
the regulations in this part shall be:
malysanilate, bis.
other labeling within or attached to the
in the sample submitted in accordance with
(paragraph (d) (3) (ii) of this section; and
 freezes with respect to each batch un-
arsamitate, bismuth glycolylarsanilate, bis.
other labeling may also bear a
as such drug by a veterinarian licensed by law to
the batch; one package of
each containing approximately 5 grams,
(preferred to be referred to in paragraph (2) (ii) of this paragraph, and
etermine whether or not such batch com-
mentary, or a reference to a brochure or
2. The fee for the services rendered with respect to each batch un-
lected solely for veterinary use and is con-
fection or labeling as hereinafter
labels may be omitted if the in-
y, the words “bismuth glycolyl-
exists are necessary to deter-
section, is required if such result or sample has been pre-
batch, the batch mark
conspicuously so labeled, adequate di-
o, "dihydrostreptomy-
for criteria, the cost of such investi-
not be less than 1 milligram of strepto-
1,000 units of polymyxin B. It is sterile. Its
in the standards prescribed thereby by § 146b.107 (a) except subparagraphs
the standards prescribed therefor by § 146b.107 (a) (the absorbent
gauze pads are absorbent gauze
section, the sample submitted in accordance with § 146b.101 (a)
the quantities here-
In addition to complying with the
but its potency is not less than 30 units per
conforms to the standards prescribed thereby by § 146b.107 (a) (the absorbent
gauze used conforms to the standards prescribed thereby by the U. S. P
the U. S. P for such batch complies with the requirements of § 146b.101 (b)
and (unless it was previously sub-
cept to the standards prescribed there-
tricity, and purity of the
changes so caused which are normal and
package, if it is intended for dispensing and it is in-
fect to the standards prescribed therefor, if any, by this section.
for certification unless such fee
required therefor.
ments of such packages are necessary to
products. Such a circular or other labeling
of such mark, the number of packages of each
made by him on an accurately represen-
tive sample of:
the standards prescribed therefor by § 146b.101 (a) except subparagraphs
(batch of the batch; average potency per milliliter for
of this paragraph, and
nary for the services rendered with respect to each batch under
for each package in the
in the standards prescribed thereby by § 146b.107 (a) (the absorbent
gauze pads are absorbent gauze
in the standards prescribed thereby by § 146b.107 (a) (the absorbent
gauze pads are absorbent gauze
preparation of the streptomycin used in
nary for the services rendered with respect to each batch under
for each package in the
and (unless it was previously sub-
cept to the standards prescribed there-
tricity, and purity of the
changes so caused which are normal and
package, if it is intended for dispensing and it is in-
fect to the standards prescribed therefor, if any, by this section.
for certification unless such fee
required therefor.
ments of such packages are necessary to deter-
batch, the batch mark
conspicuously so labeled, adequate di-
now exists or unavoidable in good packaging, storage,
distribution practice shall be disre-
guarded.
batch, the batch mark
conspicuously so labeled, adequate di-
now exists or unavoidable in good packaging, storage,
distribution practice shall be disre-
guarded.
batch, the batch mark
conspicuously so labeled, adequate di-
now exists or unavoidable in good packaging, storage,
distribution practice shall be disre-
guarded.
batch, the batch mark
conspicuously so labeled, adequate di-
now exists or unavoidable in good packaging, storage,
distribution practice shall be disre-
guarded.
The streptomycin used conforms to the standards prescribed therefor by §146b.101 (a), except subparagraphs (2), (4), (5) and (6) of that paragraph. The dihydrostreptomycin used conforms:

(a) To the standards prescribed therefor by §146b.103 (a), except the standards for sterility, pyrogens, histamine, and moisture.

(b) That such drug as prepared by him is harmless preservatives, dissolved or contained in the pad, to the standards prescribed therefor by §146.8

(c) Such samples

Fees.

The batch mark.

(a) The batch mark in making the batch: five packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of §146b.101 (b) of this section.

(b) In case of an initial request for certification fraud is apparent, the date that is the date of the first month of storage

(c) (2) Except as otherwise provided in this paragraph, and no sample referred to in subparagraph (3) (ii), (iii), (iv), and (v) of this paragraph, and if no sample referred to in subparagraph (3) (ii), (iii), (iv), and (v) of this paragraph, is required if such result or sample has been previously submitted.

(d) The number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch.

(e) The name and quantity of each antifungal agent and preservative used.

(f) The statement "Expiration date _______ " the blank being filled in with the date which is 24 months after the month during which the batch was certified.

(g) That such expiration date may be omitted from the immediate container if such container is packaged in an individual wrapper or container.

(h) On the outside wrapper or container and the immediate container:

(i) (1) The outside wrapper or container shall be glass, so closed as to be a tight container as defined by the U. S. P., and of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(j) Labeling. Each package shall bear, on its label or labeling as hereinafter specified:

(k) The batch mark.

(l) The number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch.

(m) The name and quantity of each antifungal agent and preservative used.

(n) The statement "Expiration date _______" the blank being filled in with the date which is 24 months after the month during which the batch was certified.

(o) That such expiration date may be omitted from the immediate container if such container is packaged in an individual wrapper or container.

(p) On the outside wrapper or container:

(q) (1) The outside wrapper or container shall be glass, so closed as to be a tight container as defined by the U. S. P., and of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(r) Labeling. Each package shall bear, on its label or labeling as hereinafter specified:

(s) The batch mark.

(t) The number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch.

(u) The name and quantity of each antifungal agent and preservative used.

(v) The statement "Expiration date _______" the blank being filled in with the date which is 24 months after the month during which the batch was certified.

(w) That such expiration date may be omitted from the immediate container if such container is packaged in an individual wrapper or container.

(x) On the outside wrapper or container:

(y) (1) The outside wrapper or container shall be glass, so closed as to be a tight container as defined by the U. S. P., and of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(z) Labeling. Each package shall bear, on its label or labeling as hereinafter specified:

{itemized list of conditions with corresponding subsections...}
determine whether or not such batch
nation of such packages are necessary to
that investigations other than exami-

ples submitted
be:
rendered with respect to each batch
under the regulations in this part shall
result or sample has been previously sub-

graph (2) 0 of this paragraph, and no

in making the batch;
certification each other ingredient used
the requirements of § 146b.101

streptomycin used in making the batch;

during the intervals are approximately
the batch that the quantities packaged
mediate containers at such intervals
containers, collected

such person shall submit in connection
such batch was completed, the potency per

of such drug

complies with the requirements of § 146.3
of this chapter for the issuance of a cer-
tificate, the cost of such investigations.
The fee prescribed by subparagraph (1)
of this paragraph shall accompany the
request for certification unless such fee
is paid in advance; and in such case the
batch shall be maintained in accordance with § 146.8 (d) of
this chapter.
§ 146b.111 Streptomycin-kaolin-pectin-

Aluminum hydroxide gel powder veterinary—(a) Standards. of identity, strength, quality and purity. Streptomy-

kaolin-pectin-aluminum hydroxide gel powder veterinary is strep-
tomycin or dihydrostreptomycin, kaolin, pectin, and dried aluminum hydroxide of 1 or more suitable and harmless diluents, coloring, and flavorings. Its content of streptomycin or dihydrostreptomycin is not less than 37.5 milligrams per gram of streptomycin or 37.5 milligrams per gram of dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103, except the standard for identity and purity. Each other substance used, if its name is recog-
nized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium. (b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the streptomycin used in making the batch, but in no case less than 5 or more than 12 immediate containers, collected by taking single im-
mediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydro-

streptomycin used in making the batch;
potency, toxicity, pH, streptomycin con-

if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydro-

streptomycin sulfate.

(iii) Except as otherwise provided by
subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities here-

inafter indicated, accurately representa-
tive samples of the following:

(i) The batch; average potency per milliliter, pH.

(ii) The streptomycin or dihydro-

streptomycin used in making the batch;
potency, toxicity, pH, streptomycin con-

if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydro-

streptomycin sulfate.

(iv) No result referred to in subpara-
graph (2) of this paragraph, and no sample referred to in subparagraph (3) of this paragraph, is required if such result or sample has been previously sub-
mitted.

(v) Fees. The fees for the services rendered with respect to each batch under the regulations in this part shall be:

$4.00 for each package in the sam-
ple submitted in accordance with para-
graph (2) (i), (ii), and (iii) of this section.
If the Commissioner considers that investigations other than exami-
nation of such packages, are necessary to
determine whether or not such batch
immediate container is packaged in an
individual wrapper or container.

(v) The statement "For veterinary
use only."

(2) On the circular or other labeling
within or attached to the package, direc-
tions and precautions adequate for the
use of such powder, including:

(i) Clinical Indications.

(ii) Dosage and administration.

(iii) Contraindications.

(iv) Untoward effects that may ac-
company administration.

If two or more such immediate contain-
ers are in such package, the number of
such circulars or other labeling shall not be less than the number of such containers.

(d) Request for certification, samples.

(1) In addition to complying with the
requirements of § 146.2 of this chapter, a
person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making the batch was completed, the potency per gram of powder, the quan-
tity of each ingredient used in making the
batch, the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(ii) Except as otherwise provided in
subparagraph (4) of this paragraph, each such person shall submit with his request results of the tests and assays listed after each of the following, made by him on an accurately rePro-
sentative sample of:

(i) The batch; average potency per gram of powder and average moisture.

(ii) The streptomycin or dihydro-

streptomycin used in making the batch;
potency, toxicity, pH, streptomycin con-

if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydro-

streptomycin sulfate.

(iii) Except as otherwise provided by
subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities here-

inafter indicated, accurately representa-
tive samples of the following:

(i) The batch; average potency per gram of powder and average moisture.

(ii) The streptomycin or dihydro-

streptomycin used in making the batch;
potency, toxicity, pH, streptomycin con-

if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydro-

streptomycin sulfate.

(iii) The streptomycin or dihydro-

streptomycin used in making the batch;
potency, toxicity, histamine content, moisture, pH, streptomycin or dihydro-

streptomycin sulfate.

(iv) The streptomycin or dihydro-

streptomycin used in making the batch;
potency, toxicity, histamine content, moisture, pH, streptomycin or dihydro-

each, packaged in accordance with the requirements of § 146b.101 (b).
(iii) In case of an initial request for certification of tests of streptomycin used in making the batch; one package of each containing approximately 5.0 grams.

(4) No request referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(c) Fees. The fee for the service rendered with respect to each batch under the regulations in this part shall be:
(1) $1.00 for each immediate container in the same submitted in accordance with paragraph (d) (3) (i) of this section;
(2) $10.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) of this section;
(3) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.3 (2) of this chapter.

§ 146b.112 Streptomycin for inhalation therapy; dihydrostreptomycin for inhalation therapy.—(a) Standards of identity, strength, quality, and purity. Streptomycin for inhalation therapy and dihydrostreptomycin for inhalation therapy are streptomycin or dihydrostreptomycin, with or without one or more suitable and harmless diluents. The streptomycin used conforms to the requirements of § 146b.101 (a) except § 146b.101 (a) (2) and (4) and except that if it is packaged with inert gases its moisture content is not more than 0.5 percent. The dihydrostreptomycin used conforms to the requirements of § 146b.103 (a) except the standards for sterility and pyrogens, and except that if it is packaged with inert gases its moisture content is not more than 0.5 percent. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefore by such official compendium.

(b) Packaging. The immediate container of streptomycin for inhalation therapy and dihydrostreptomycin for inhalation therapy shall be a tight container as defined by the U. S. P., its closure shall be one through which a hypodermic needle cannot be introduced; and such container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Such each container shall contain not less than 50 milligrams, and may contain one or more suitable and harmless inert gases or each may be packaged in combination with a compatible inert gas or a compatible inert gas and harmless solvent.

(c) Labeling. Each package shall bear on its label or labeling as hereinafter indicated, the following:
(1) The batch mark.
(2) The number of milligrams in the immediate container, or, if it is packaged with one or more inert gases, the number of grams that shall be ejected when used as directed in the labeling or on the label, such package shall be labeled as having been used;
(3) The statement “Expiration date ______,” the blank being filled in with the date which is 24 months if it is packaged with inert gases, or 48 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is not contained in an individual wrapper or container.

(d) Request for certification; samples.
(1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of streptomycin for inhalation therapy or dihydrostreptomycin for inhalation therapy shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by one or more representative packages made by him on the batch for potency and moisture if the streptomycin or dihydrostreptomycin has been previously submitted; or for potency, moisture, pH, histamine content, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin, if the streptomycin or dihydrostreptomycin has not been previously submitted. If such batch, or any part hereof, is to be packaged in combination with a container of a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

Each such container shall submit with his request accurately representative samples of the following:
(1) The batch:
(a) If the streptomycin or dihydrostreptomycin used has not been previously submitted; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers (or if it is packaged with inert gases, not less than 7 immediate containers and not more than 12 immediate containers) or more than 12 immediate containers.

(b) If the streptomycin or dihydrostreptomycin used has not been previously submitted; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 12 immediate containers or more than 125 immediate containers.

Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging that the quantities packaged during the intervals are approximately equal.

(ii) If it is packaged with inert gases and the streptomycin or dihydrostreptomycin used has not been previously submitted; 5 packages of each of the immediately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iii) In case of original certification or for the certification of a batch which is to be packaged in combination with a solvent which is not recognized by the U. S. P., or when any change is made in the composition of such solvent, five packages of the solvent included in the combination.

(f) Fee. The fee for the services rendered with respect to each batch under this section is to be paid in accordance with paragraph (d) (2) (i) and (ii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.2 of this chapter, such request shall also be accompanied by a statement of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit main-
RULES AND REGULATIONS

Section 146b.113  Dihydrostreptomycin

(a) Standards of identity, strength, quality, and purity.  Dihydrostreptomycin-streptomycin sulfate is a mixture of equal parts of crystalline dihydrostreptomycin and streptomycin sulfate.  It is so purified and dried that:

- It is sterile.
- It is nontoxic.
- It is nonpyrogenic.
- It contains no histidine or histamine like substance.
- Its moisture content is not more than 0.5 percent.
- Its pH in aqueous solution containing 0.1 gram of dihydrostreptomycin and 0.1 gram of streptomycin per milliliter is not less than 4.5 and not more than 7.0.

(b) Packaging.  It shall be packaged in accordance with the requirements prescribed by § 146b.101 (a) except that each package shall contain equal parts of 0.5 gram of crystalline dihydrostreptomycin and 0.5 gram of streptomycin or multiples of such salt up to and including 100 grams of dihydrostreptomycin and 50.0 grams of streptomycin.

(c) Labeling.  It shall be labeled in accordance with the requirements prescribed by § 146b.101 (c) except that each label shall show the quantity of each immediate container, the number of grams of dihydrostreptomycin, the number of grams of streptomycin and the total number of grams of both salts in the immediate container.

(d) Request for certification, samples.  (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a bulk shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch marks, and (unless they were previously submitted) the date on which the latest assay of the dihydrostreptomycin and streptomycin used in making the batch were completed, the content of dihydrostreptomycin and streptomycin in each container together with the fact that the latest assay of the drug comprised such batch was completed.  If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements described therefor by this section.

(2) Except as otherwise provided by subparagraph (b) of this paragraph, each package shall contain in connection with its request results of the tests and assays listed after each of the following made by him on an accurately representative sample of the batch:

(i) The batch; content of dihydrostreptomycin and streptomycin, sterility, toxicity, pyrogens, histamine content, moisture, and pH.

(ii) The dihydrostreptomycin and streptomycin used in making the batch; potency, and if crystalline dihydrostreptomycin is used, crystallinity.

(3) Except as otherwise provided by subparagraph (b) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(a) For all tests except sterility-one immediate container for each 5,000 immediate containers in the batch but in no case less than 6 or more than 12 immediate containers.

(b) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking a sample immediately at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The dihydrostreptomycin used in making the batch; 2 packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146b.101 (b)

(iii) The streptomycin used in making the batch; one package containing approximately 0.5 gram packaged in accordance with the requirements of § 146b.101 (b)

(4) If such batch is labeled for repackaging, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility-6 packages.

(ii) For sterility testing; 10 packages.  Each such package shall contain not less than 0.5 gram of dihydrostreptomycin and 0.5 gram of streptomycin taken from different parts of such batch, and each shall be packaged in accordance with the requirements of § 146b.101 (b)

(5) No result referred to in subparagraph (2) of this paragraph, and no sample referred to in subparagraphs (3) and (4) of this paragraph, is required if such result or sample has been previously submitted under the regulations in this part shall be:

(1) $10.00 for each immediate container in the samples submitted in accordance with paragraph (d) (1) (a) and (d) (i) of this section; $4.00 for each sample submitted in accordance with paragraph (d) (2) (b) and (ii) of this section; and

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for issuance of a certificate, the cost of such investigations.  The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.114  Streptomycin sulfate oral veterinary—(a) Standards of identity, strength, quality, and purity.  Streptomycin sulfate oral veterinary is the sulfate salt of a kind of streptomycin or a mixture of two or more kinds of such drug so purified and dried that:

(1) Its potency is not less than 450 micrograms per milligram.

(2) It is nontoxic.

(3) Its moisture content is not more than 14.0 percent.

(4) Its pH in aqueous solution of 0.2 gram per milliliter is not less than 3.0 and not more than 7.0.

(b) Packaging.  In all cases the immediate containers shall be tight containers as defined by the U. S. P.  The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefrom in applicable standards, except that minor changes so caused which do not normally result in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling.  Each package of streptomycin sulfate oral veterinary shall bear on its outside wrapper or container and the immediate container:

(1) The batch mark.

(2) The number of milligrams of streptomycin per gram and the number of grams of the drug in the immediate container.

(3) The statement “Expiration date——,” the blank being filled in with the date which is not later than 36 months after the month during which the batch was certified; Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement “For use only in the manufacture of oral veterinary drugs.”

(d) Request for certification, samples.  (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the
number of packages of each size in the batch, the number of milligrams of streptomycin per gram, and the total number of grams of streptomycin in each package shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, and purity of each immediate container.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of 5 packages each containing approximately 1.0 gram of the streptomycin, from a different part of such batch, and each shall be packaged in accordance with the requirements of § 146.3 of this chapter.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) of this section.

(2) If the Commissioner considers that investigations, other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.115 Streptomycin sulfate powder oral veterinary; streptomycin sulfate granules oral veterinary—p. Standards of identity, strength, quality, and purity. Streptomycin sulfate powder oral veterinary or streptomycin sulfate granules oral veterinary is streptomycin sulfate oral veterinary with one or more suitable and harmless diluents and stabilizing agents. Its potency is not less than 333 micrograms per milligram. Its moisture content is not more than 7.0 percent. The streptomycin sulfate oral veterinary used conforms to the standards prescribed by § 146b.114 (a) Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed thereby by such official compendium.

(b) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate containers shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label or labeling as hereafter indicated, the following:

(i) The batch mark.

(ii) The number of milligrams of streptomycin per gram and the number of grams in each immediate container.

(iii) The statement “Expiration date” accompanies a statement “Valid until,” the blank being filled in with the date which is 36 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the labels of not more than 1.0 gram of each containing approximately 1.0 gram of such immediate container is packaged in an individual wrapper or container.

(iv) The statement “For oral veterinary use only.”

(v) The statement “For manufacturing use,” “For repackaging,” or “For manufacturing use or repackaging,” when packaged for repackaging or for use as an ingredient in the preparation of another drug, as the case may be.

(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary use of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Request for certification; samples. (1) In order to conform with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark and the date on which the latest assay of the streptomycin sulfate oral veterinary used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug was completed, and a statement that each other ingredient used conforms to the requirements prescribed therefor, if any, by this section.

(2) As otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the manner prescribed, an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The streptomycin sulfate oral veterinary used for the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, an accurately representative sample of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, unless each such container is packaged to contain more than 15 grams, in which case the sample shall consist of 15 grams for each 5,000 immediate containers in the batch, but in no case less than 15 gram portions or more than 15 gram portions. Such samples shall be collected by taking single immediate containers or 15 gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin sulfate oral veterinary used in making the batch; 5 packages containing approximately equal portions of not more than 1.0 gram of each containing approximately 5 grams.

(iii) In case of an initial request for certification, the other ingredients used in making the batch are necessary to determine whether or not such batch complies with the requirements of § 146b.114 (b).

(iv) No request referred to in subparagraph (2) of this paragraph, and no sample referred to in subparagraph (3) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) of this section.

(2) If the Commissioner considers that investigations other than the examination of the immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(1) Exemption of streptomycin sulfate powder oral veterinary and streptomycin sulfate granules oral veterinary from certification. Streptomycin sulfate powder oral veterinary and streptomycin sulfate granules oral veterinary that conform to the requirements of paragraphs (a), (b), and (c) of this section shall be exempt from the requirements of sections 502 (d) and 503 of the act, if they comply with all the following:

(i) The labels bear an expiration date that is not more than 36 months after the month during which the batch was last assayed and released by the manufacturer.

(ii) If they contain added vitamins or minerals, the labels bear the name and quantity of each such substance and a statement that such substances are present only for nutritional purposes and not for use as vitamins and minerals while animals are eating less feed.

(iii) The labels bear a statement that solutions prepared with the drugs are stable for not more than 6 months.

(iv) The circular or other labeling within or attached to the package bears information that only the antibiotics are intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Bacterial enteritis in swine.

(ii) Bacterial coccidiosis.

(iii) Bacterial respiratory disease (abomasal infection) in chickens.

(iv) Blue comb (mud fever, nonspecific infectious enteritis) in poultry.
§ 146b.116 Streptomycyelidene isomcotinyl hydrazine sulfate—(a) Standards of identity, strength, quality, and purity. Streptomycyelidene isomcotinyl hydrazine sulfate is the crystalline sulfide compound of streptomycin and isomcotinyl acid hydrazide. It is so purified and dried that:

1. It contains not less than the equivalent of 583 micrograms of streptomycin per milligram and its isomcotinyl acid hydrazide equivalent content is not less than 13.75 percent.
2. It is not toxic.
3. It is nontoxic.
4. It is nonpyrogenic.
5. It contains no histamine nor histamine-like substance.
6. Its moisture content is not more than 5 percent.
7. Its pH in an aqueous solution containing the equivalent of 0.2 gram of streptomycin per milliliter is not less than 4.5 and not more than 7.5.
8. Its extinction coefficient, E 1% 1 cm, is not less than 150 at 269 millimicrons.

The streptomycin used conforms to the requirements of § 146b.101 (a). The isomcotin acid hydrazide used has a purity of not less than 98 percent and it has a melting point of not less than 169° C. and not more than 172° C.

(b) Packaging. It shall be packaged in accordance with the requirements of § 146b.101 (b) except that each immediate container shall contain an equivalent of not less than 1.0 gram of streptomycin.

(c) Labeling. It shall be labeled in accordance with the requirements of § 146b.101 (c), except that in lieu of the labeling prescribed by subparagraph (1)

(ii) of paragraph (e) each package shall bear on the outside wrapper or container and the immediate container the number of grams of equivalent streptomycin activity, the equivalent number of grams of isoncotin acid hydrazide, and the number of grams of streptomycyelidene isomcotinyl hydrazine sulfate in the immediate container, and its expiration date shall be 36 months after the month during which the batch was certified.

(d) Request for certification, check tests and assays; samples. (1) In addition to complying with the requirements of § 146.5 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of grams of streptomycin, isomcotin acid hydrazide, and streptomycyelidene isomcotinyl hydrazine sulfate in each package and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, pyrogens, histamine content, moisture, pH, crystallinity, and extinction coefficient. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for distribution or intended for use in connection with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility—six packages, each containing the equivalent of approximately 1 gram of streptomycin activity.

(ii) For sterility testing: 10 packages, each containing the equivalent of approximately 0.5 gram of streptomycin activity.

Each such package shall be taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repackaged batches or batches of another drug in connection with his request, each such container shall bear on the outside wrapper or container and the immediate container the number of grams of dihydrostreptomycin, the number of grams of streptomycin, and the total number of grams of both salts in each milliliter of the immediate container.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations prescribed in this section shall be:

1. $10.00 for each immediate container in the samples submitted in accordance with paragraph (c) of this section.
2. $1.00 for each plan of packaging submitted in connection with his request unless such fee is covered by an advance deposit maintained in accordance with § 146b.113 (d) of this chapter.

§ 146b.117 Dihydrostreptomycin-streptomycin sulfates solution—(a) Standards of identity, strength, quality, and purity. Dihydrostreptomycin-streptomycin sulfates solution shall conform to the standards prescribed for dihydrostreptomycin-streptomycin sulfates. Such solution conforms to all standards prescribed by § 146b.113 (a) for dihydrostreptomycin-streptomycin sulfates, except that the moisture content is not more than 7.5.

(b) Packaging. It shall be packaged in accordance with the requirements of § 146b.106 (b)

(c) Labeling. It shall be labeled in accordance with the requirements of § 146b.106 (e) for streptomycin sulfate solution, except in lieu of subparagraph (1) (d) of that paragraph each package shall bear on the outside wrapper or container and the immediate container the number of grams of dihydrostreptomycin, the number of grams of streptomycin, and the total number of grams of both salts in each milliliter of the immediate container.

(d) Request for certification, samples. In addition to complying with the requirements of § 146b.113 (d), a person who requests certification of a batch shall submit in connection with his request one package containing approximately 5.0 grams of each other ingredient used in making the batch.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations prescribed in this section shall be:

1. $10.00 for each immediate container in the samples submitted in accordance with paragraph (c) of this section.
2. $1.00 for each plan of packaging submitted in connection with his request unless such fee is covered by an advance deposit maintained in accordance with § 146b.113 (d) of this chapter.

§ 146b.118 Streptomycin-penicillin-sulfonamide with kaolin and pectin, dihydrostreptomycin-penicillin-sulfonamide with kaolin and pectin—(a) Standards of identity, strength, quality, and purity. Streptomycin-penicillin-sulfonamide with kaolin and pectin and dihydrostreptomycin-penicillin-sulfonamide with kaolin and pectin are dry mixtures of streptomycin, dihydrostreptomycin, streptomycin sulfate, crystalline penicillin G (sodium or potassium), one or more suitable sulfonamides, kaolin, and pectin, with or without bismuth subcarbonate and with or without suitable and harmless preservatives, colorings, and flavorings. Its moisture content is not more than 2 percent. The pH of a suspension prepared as directed in its labeling is not less than 6.5 and not more than 7.5. The streptomycin used conforms to the standards prescribed.
thereof by § 146b.101 (a) except sub-paragraphs (2) and (4) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.100 except the standards for sterility and pyrogens. The crystalline penicillin G used conforms to the standards prescribed therefor by § 146a.24 (a) of this chapter, except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall contain not less than 1.6 gram of streptomycin or dihydrostreptomycin and not less than 1,200,000 units of penicillin. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable shall be disregarded.

(c) Labeling. Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(i) The batch mark.
(ii) The number of units of penicillin in the immediate container.
(iii) The statement "Expiration date

(vi) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspiciously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drugs to be licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That such reference is not required if the information is contained in a circular or other labeling within or attached to the package.

(iv) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspiciously so labeled, adequate directions for the veterinary use of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(i) The batch mark.
(ii) The statement "Expiration date

(vi) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspiciously so labeled.

(c) Labeling. Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(i) The batch mark.
(ii) The number of units of penicillin in the immediate container.
(iii) The statement "Expiration date

(vi) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspiciously so labeled.

(iv) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspiciously so labeled, adequate directions for the veterinary use of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(i) The batch mark.
(ii) The statement "Expiration date

(vi) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspiciously so labeled.

(iv) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspiciously so labeled, adequate directions for the veterinary use of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(i) The batch mark.
(ii) The statement "Expiration date

(vi) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspiciously so labeled.

(iv) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspiciously so labeled, adequate directions for the veterinary use of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.
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and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on the outside wrapper or container and the immediate container:

(1) The batch mark.
(2) The number of milligrams of streptomycin in each milliliter of the immediate container.
(3) The statement “Expiration date ________” the blank being filled in with the date which is 12 months after the month during which the batch was last assayed and released by the manufacturer.

(b) Packaging. Streptomycin-erythromycin ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label, or label or label, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.
(ii) The number of milligrams of streptomycin and the number of milligrams of erythromycin in each gram or milliliter of the batch.
(iii) If it contains one or more sulfonamides, the name and quantity of each such ingredient in each gram or milliliter of the batch.
(iv) The statement “For veterinary use only.”
(v) The statement “Expiration date ________” the blank being filled in with the date that is 12 months after the month during which the batch was certified; Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(d) Registration for certification, samples. (1) In addition to complying with the requirements of § 146b.101 of this chapter, a person who requests certification of a batch shall submit with such request or in one or more mailings to the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers.
(ii) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each containing approximately 5 grams.
(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the quantities hereinafter indicated, in accordance with paragraph (d) (2) of this section.
(2) In lieu of the directions prescribed by § 146b.113 (c) it shall be labeled in accordance with the requirements prescribed by § 146b.101 (c) except that each label shall be outside wrapper or container and the immediate container the number of grams of dihydrostreptomycin, the number of grams of streptomycin and the number of milligrams of isonicotinic acid and hydrostreptomycin in each package shall bear on the outside wrapper or container:

(1) The name and quantity of each preserving used.
(2) The statement “For oral veterinary use only.”
(d) Registration for certification, samples. (1) In addition to complying with the requirements of § 146b.101 of this chapter, a person who requests certification of a batch shall submit with such request or in one or more mailings to the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers.
(ii) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each containing approximately 5 grams.
(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the quantities hereinafter indicated, in accordance with paragraph (d) (2) of this section.
(2) In lieu of the directions prescribed by § 146b.113 (c) it shall be labeled in accordance with the requirements prescribed by § 146b.101 (c) except that each label shall be outside wrapper or container and the immediate container the number of grams of dihydrostreptomycin, the number of grams of streptomycin and the number of milligrams of isonicotinic acid and hydrostreptomycin in each package shall bear on the outside wrapper or container:

(1) The batch mark.
(ii) The number of milligrams of streptomycin and the number of milligrams of erythromycin in each gram or milliliter of the batch.
(iii) If it contains one or more sulfonamides, the name and quantity of each such ingredient in each gram or milliliter of the batch.
(iv) The statement “For veterinary use only.”
(v) The statement “Expiration date ________” the blank being filled in with the date that is 12 months after the month during which the batch was certified; Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(b) Packaging. Streptomycin-erythromycin ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label, or label or label, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.
(ii) The number of milligrams of streptomycin and the number of milligrams of erythromycin in each gram or milliliter of the batch.
(iii) If it contains one or more sulfonamides, the name and quantity of each such ingredient in each gram or milliliter of the batch.
(iv) The statement “For veterinary use only.”
(v) The statement “Expiration date ________” the blank being filled in with the date that is 12 months after the month during which the batch was certified; Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(d) Registration for certification, samples. (1) In addition to complying with the requirements of § 146b.113 (d) a person who requests certification of a batch shall submit with the request a statement showing the number of grams of isonicotinic acid hydrostreptomycin in each package, and in case of an initial request for certification, a sample consisting of approximately 5.0 grams of the isonicotinic acid hydrostreptomycin used in making the batch.
(e) Fees. The fee for the services rendered with respect to each sample of isonicotinic acid hydrostreptomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00. § 146b.121 Streptomycin-erythromycin ointment—(a) Standards of identity, strength, quality, and purity. Streptomycin-erythromycin ointment shall contain streptomycin and erythromycin in a suitable and harmless ointment base, with or without one or more suitable sulfonamides and with or without suitable and harmless dispersing and suspending agents. Its moisture content is not more than 1.0 percent. It contains per gram not less than 3 milligrams of streptomycin and not less than 150 milligrams of erythromycin. The streptomycin used conforms to the requirements of § 146b.101 (a) except § 146b.101 (a) (3), (4) and (5). The erythromycin used is produced by the growth of Streptomyces erythreus, has a potency of not less than 850 micrograms per milligram (on the anhydrous basis), is nontoxic, has a maximum solubility of 20 percent, and its pH in a saturated aqueous solution is not less than 8 and not more than 10.5, and it gives a characteristic color test with acetone and hydrochloric acid. Each other substance used conforms to the standards prescribed therefor by such official compendium.

(d) Composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label, or label or label, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.
(ii) The number of milligrams of streptomycin and the number of milligrams of erythromycin in each gram or milliliter of the batch.
(iii) If it contains one or more sulfonamides, the name and quantity of each such ingredient in each gram or milliliter of the batch.
(iv) The statement “For veterinary use only.”
(v) The statement “Expiration date ________” the blank being filled in with the date that is 12 months after the month during which the batch was certified; Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

2. In the case of streptomycin-erythromycin ointment, wherever it appears, the name “streptomycin-erythromycin ointment” shall be substituted for the name “streptomycin-erythromycin ointment” as hereinafter indicated:
Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Requests for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the dates on which the latest tests and assays listed after each of the following, covered by an examination performed in accordance with § 146.3 (d) of this chapter.

§ 146.122 Streptomycin-chlorotetracycline-chloramphenicol-bacitracin dental cement; dihydrostreptomycin-chlorotetracycline-chloramphenicol-bacitracin dental cement;—(a) Standards of identity, strength, quality and purity. Streptomycin—chlorotetracycline—chloramphenicol-bacitracin dental cement and dihydrostreptomycin-chlorotetracycline-chloramphenicol-bacitracin dental cement are streptomycin or dihydrostreptomycin, chlorotetracycline, chloramphenicol, and bacitracin in a base that is a mixture of inorganic oxides and salts. Its moisture content is not more than 1 percent. It contains not less than 1.0 milligram of streptomycin or dihydrostreptomycin, not less than 1.0 milligram of chloramphenicol, and not less than 50 units of bacitracin per gram. The streptomycin used conforms to the standards prescribed by § 146b.101 (a), except § 146b.101 (a) (2), (4) and (5). The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103, except the standards for sterility, pyrogens, and histamine. The chlorotetracycline used conforms to the standards prescribed by § 146c.201 (a) of this chapter, except § 146c.201 (a) (2), (4), and (9). The chloramphenicol used conforms to the standards prescribed by § 146d.301 (a) of this chapter, except § 146d.301 (a) (2), (4), and (6). The bacitracin used conforms to the standards prescribed by § 146e.401 (a) of this chapter, except § 146e.401 (a) (2) and (4). Each other ingredient used, if its use is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Each batch of dental cement shall be packaged in immediate containers of transparent glass that shall meet the test for tight containers as defined by the U.S. P., and so sealed that the contents cannot be used without destroying such seal. The immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit thereon in applicable standards, except that minor changes of color or appearance that are unavoidable in good packaging, storage, and distribution practice shall be disregarded.

Labeling. Each package shall bear on its label or labeling, as herein indicated, the following:

(1) § 4.00 for each package in the samples submitted in accordance with paragraph (d) (2), (ii), (iii), (iv) of this section.

(2) In the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall be disregarded. Such fees shall be covered by an examination performed in accordance with § 146.3 (d) of this chapter.

§ 146.122 Streptomycin-chlorotetracycline-chloramphenicol-bacitracin dental cement; dihydrostreptomycin-chlorotetracycline-chloramphenicol-bacitracin dental cement;—(a) Standards of identity, strength, quality and purity. Streptomycin—chlorotetracycline—chloramphenicol-bacitracin dental cement and dihydrostreptomycin-chlorotetracycline-chloramphenicol-bacitracin dental cement are streptomycin or dihydrostreptomycin, chlorotetracycline, chloramphenicol, and bacitracin in a base that is a mixture of inorganic oxides and salts. Its moisture content is not more than 1 percent. It contains not less than 1.0 milligram of streptomycin or dihydrostreptomycin, not less than 1.0 milligram of chloramphenicol, and not less than 50 units of bacitracin per gram. The streptomycin used conforms to the standards prescribed by § 146b.101 (a), except § 146b.101 (a) (2), (4) and (5). The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103, except the standards for sterility, pyrogens, and histamine. The chlorotetracycline used conforms to the standards prescribed by § 146c.201 (a) of this chapter, except § 146c.201 (a) (2), (4), and (9). The chloramphenicol used conforms to the standards prescribed by § 146d.301 (a) of this chapter, except § 146d.301 (a) (2), (4), and (6). The bacitracin used conforms to the standards prescribed by § 146e.401 (a) of this chapter, except § 146e.401 (a) (2) and (4). Each other ingredient used, if its use is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Each batch of dental cement shall be packaged in immediate containers of transparent glass that shall meet the test for tight containers as defined by the U.S. P., and so sealed that the contents cannot be used without destroying such seal. The immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit thereon in applicable standards, except that minor changes of color or appearance that are unavoidable in good packaging, storage, and distribution practice shall be disregarded.

Labeling. Each package shall bear on its label or labeling, as herein indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(a) The batch mark.

(b) The number of milligrams of streptomycin or dihydrostreptomycin, chlorotetracycline, and chloramphenicol and the number of units of bacitracin in each gram of the batch.

(c) The statement "Expiration date: [the blank below filled in with the date that is 12 months after the month during which the batch was certificated."

(d) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription."

(e) On the circular or other labeling on or attached to the package, if it is packaged for dispensing, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(f) Request for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the number of packages of each size in such batch, the batch mark and (unless they were previously submitted) the dates of the latest tests and assays of the streptomycin or dihydrostreptomycin, chlorotetracycline, chloramphenicol, and bacitracin used in making the batch.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Potency and moisture.

(ii) The streptomycin and chlorotetracycline used in making the batch: Potency, toxicity, pH, moisture, and color-identity test, if it is chlorotetracycline.

(iii) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(a) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers or more than 12 immediate containers, collected by taking single samples at random from each of the equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146d.101 (b)

(b) The streptomycin used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146d.101 (b)

(c) The chloramphenicol used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146d.101 (b)

(iv) In case of an initial request for certification, the ingredients used in making the cement base of the batch: 1 package of each, containing approximately 200 grams, except for the suspending or dispersing agents and sulfonamides used, in which case the sample shall consist of approximately 5 grams.

(v) No result referred to in subparagraph (2) (i) of this paragraph, and no samples referred to in subparagraph (2) (ii) and (iii) of this paragraph, is required if all tests or samples have been previously submitted.

(c) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

§ 146.2 of this chapter, a person who requests certification of a batch shall submit in connection with his request results of the tests and assays listed after each of the following, covered by an examination performed in accordance with § 146.3 (d) of this chapter.
containing approximately equal portions of not less than 60 milligrams.

(iv) The chloramphenicol used in making the batch: 10 packages, each containing approximately equal portions of not less than 0.5 gram.

(v) The bacitracin used in making the batch: 6 packages, each containing approximately equal portions of not less than 0.5 gram.

(vi) In the case of an initial request for certification, each other ingredient used in making the batch: 1 package of each containing approximately 8 grams.

(vii) A request referred to in subparagraph (2) (ii), (iii) (iv), and (v) of this paragraph, and no sample referred to in subparagraph (3) (ii), (iii) (iv), and (v) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

1. $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) (ii), (iii) (iv), (v), and (vi) of this section.

2. If the Commissioner considers that investigations of the type prescribed therefor in connection with such investigations. The fee prescribed by subparagraph (1) (i) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146h (d) of this chapter.

§ 146.123 Streptomycin-sodium sulfathiazole solution veterinary; dihydrostreptomycin-sodium sulfathiazole solution veterinary. (a) Standards of identity, strength, quality, and purity. Streptomycin-sodium sulfathiazole solution veterinary and dihydrostreptomycin-sodium sulfathiazole solution veterinary are streptomycin or dihydrostreptomycin and sodium sulfathiazole dissolved in a suitable and harmless vehicle. Each milliliter contains not less than 35 milligrams of streptomycin or dihydrostreptomycin and not more than 25 milligrams of sodium sulfathiazole. It is sterile. It is nontoxic. It is nonpyrogenic. It contains no histamine or histamine-like substance. Its pH is not less than 6.5 and not more than 8.0. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a) except subparagraph (b) The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103, the standard for moisture. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Each batch of streptomycin or dihydrostreptomycin, polymyxin B, and neomycin ointment and dihydrostreptomycin-polymyxin-neomycin ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U.S.P. The contents of the immediate container shall be such as will not cause any change in the strength, quality, and purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(i) The name of each component employee is :

(ii) The number of milligrams of streptomycin or dihydrostreptomycin, the number of milligrams of polymyxin B, and the number of units of polymyxin B in each such batch.

(iii) If the batch contains one or more sulfonamides, the name and quantity of each such ingredient per gram of the batch.

(iv) The statement "For veterinary use only."
Section 146c.201 Chlortetracycline hydrochloride. Chlortetracycline hydrochloride shall be packaged in multiple packages containing approximately equal portions of not less than 0.5 gram each.

(ii) The neomycin B used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each.

(v) In case of an initial request for certification the ingredients used in making the batch: 1 package of each ointment-base ingredient, containing approximately 200 grams; 1 package of each suspension-base ingredient used, containing approximately 5 grams; 1 package of each sulfonamide used, containing approximately 5 grams.

The results referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph and the samples referred to in subparagraph (3) (ii) (iii) and (iv) of this paragraph are not required if such results or samples have been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be: (1) $4.00 per package in the samples submitted in accordance with paragraph (d) (i), (ii), (iii), (iv), and (v) of this section.

(2) If the Commissioner considers that investigation other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigation shall be borne by the person applying therefor.

The fee prescribed by subparagraph (1) of this paragraph, as well as the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.3 (d) of this chapter.

PART 146C—CERTIFICATION OF CHLOROTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS

Sec. 146c.201 Chlortetracycline hydrochloride. Chlortetracycline hydrochloride, when labeled, shall be packaged in multiple packages containing approximately equal portions of not less than 0.5 gram each.

(ii) The neomycin B used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each.

(v) In case of an initial request for certification the ingredients used in making the batch: 1 package of each ointment-base ingredient, containing approximately 200 grams; 1 package of each suspension-base ingredient used, containing approximately 5 grams; 1 package of each sulfonamide used, containing approximately 5 grams.

The results referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph and the samples referred to in subparagraph (3) (ii) (iii) and (iv) of this paragraph are not required if such results or samples have been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be: (1) $4.00 per package in the samples submitted in accordance with paragraph (d) (i), (ii), (iii), (iv), and (v) of this section.

(2) If the Commissioner considers that investigation other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigation shall be borne by the person applying therefor.

The fee prescribed by subparagraph (1) of this paragraph, as well as the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.3 (d) of this chapter.

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Sec. 146c.216 Chlortetracycline hydrochloride. Chlortetracycline hydrochloride shall be packaged in multiple packages containing approximately equal portions of not less than 0.5 gram each.

(ii) The neomycin B used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each.

(v) In case of an initial request for certification the ingredients used in making the batch: 1 package of each ointment-base ingredient, containing approximately 200 grams; 1 package of each suspension-base ingredient used, containing approximately 5 grams; 1 package of each sulfonamide used, containing approximately 5 grams.

The results referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph and the samples referred to in subparagraph (3) (ii) (iii) and (iv) of this paragraph are not required if such results or samples have been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be: (1) $4.00 per package in the samples submitted in accordance with paragraph (d) (i), (ii), (iii), (iv), and (v) of this section.

(2) If the Commissioner considers that investigation other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigation shall be borne by the person applying therefor.

The fee prescribed by subparagraph (1) of this paragraph, as well as the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.3 (d) of this chapter.

(iii) The polymyxin B used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each.
(iv) A statement of the conditions under which such solutions should be stored, including a reference to their instability when stored under other conditions, and a statement "Sterile solutions must be injected immediately after preparation."

(d) Request for certification. The request for certification must be in accordance with §146.3 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed; and if it is intended for intravenous use contains buffer substances, the date and the results of the latest test for potency of the chlortetracycline used in making such batch. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogen, ion exchange, crystallinity (if it is the crystalline salt), moisture, and pH. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility: 1 immediate container for each 5,000 immediate containers in such batch, but in no case less than 8 or more than 15 immediate containers.

(ii) For sterility testing: 10 immediate containers.

Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility: 5 packages, each containing approximately 0.5 gram.

(ii) For sterility testing: 10 packages, each containing approximately 40 milligrams.

Each such package shall be packaged in accordance with the requirements of paragraph (6) of this section.

(4) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer shall request that such broth is to be so repacked or used as to permit the Commissioner to make tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(5) If such batch is intended for intravenous use and it contains buffer substances, such person shall submit in connection with his request (unless it has been previously submitted) one immediate container containing approximately 0.5 gram of the chlortetracycline used in making such batch.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i) (2) and (4) of this section; $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (5) of this section.

(2) If the Commissioner considers that investigations, other than examinations of such immediate containers, are necessary to determine whether or not the batch conforms with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.8 (d) of this chapter.

§146c.203 Chlortetracycline ointment (chlortetracycline hydrochloride ointment) chlortetracycline calcium ointment, chlortetracycline calcium cream, tetracycline hydrochloride ointment (tetracycline hydrochloride in oil suspension)—(a) Standards of identity, strength, quality, and purity. Chlortetracycline ointment is crystalline chlortetracycline hydrochloride or chlortetracycline calcium in a suitable and harmless ointment base. Tetracycline hydrochloride ointment is crystalline tetracycline hydrochloride in a suitable and harmless ointment base. It may contain a suitable local anesthetic, cortisone, or an ester of cortisone or hydrocortisone, or a local anesthetic, the name and quantity of each such substance.

The statement "Expiration date _______," the blank being filled in with the date which is 24 months, if it is chlortetracycline calcium ointment or tetracycline hydrochloride ointment, or 30 months, if it is chlortetracycline hydrochloride ointment, after the month during which the batch was certified. Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container, if it is packaged for institutional use by man or if it contains cortisone, hydrocortisone, or an ester of cortisone or hydrocortisone, the statement "Caution: Federal law prohibits dispensing without prescription."

The statement Expansion date ______, the blank being filled in with the date which is 24 months, if it is chlortetracycline calcium ointment or tetracycline hydrochloride ointment, or 30 months, if it is chlortetracycline hydrochloride ointment, after the month during which the batch was certified. Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(3) On the label and labeling, if it contains one or more of the active ingredients specified in paragraph (a) of this section and the name "chlortetracycline ointment," "chlortetracycline calcium ointment," "chlortetracycline calcium cream," or "tetracycline hydrochloride ointment," wherever it appears, the words "with a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such ointment by practitioners licensed by law to administer such drug; or a reference to a brochure or other printed matter containing such information, and a statement that this name shall not be used in connection with such name, the blank being _______

(b) Packaging. The ointment shall be packaged in collapsible tubes which are well-closed containers as defined by the U. S. P., or in containers of glass or plastic that are tight and are identified by the U. S. P. Unless it is labeled solely for hospital use, each such container shall contain not more than 2 ounces, except if it is intended for ophthalmic use, such as the chlortetracycline shall contain not more than ½ ounce, if it is a collapsible tube, or more than ½ ounce if it is a tight container. Each such container shall be of such composition as will render the contents beyond any limit thereafter in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practices shall be disregarded.

(c) Labeling. Each package of ointment shall bear on its label or labeling: as hereinafter indicated:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark; (ii) The potency, expressed as the equivalent of chlortetracycline or tetracycline hydrochloride; (iii) It contains preservatives, cortisone, hydrocortisone, or an ester of cortisone or hydrocortisone, or a local anesthetic, the name and quantity of each such substance;

The statement "Expiration date _______", the blank being filled in with the date which is 24 months, if it is chlortetracycline calcium ointment or tetracycline hydrochloride ointment, or 30 months, if it is chlortetracycline hydrochloride ointment, after the month during which the batch was certified. Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container, if it is packaged for institutional use by man or if it contains cortisone, hydrocortisone, or an ester of cortisone or hydrocortisone, the statement "Caution: Federal law prohibits dispensing without prescription."

The statement Expansion date ______, the blank being filled in with the date which is 24 months, if it is chlortetracycline calcium ointment or tetracycline hydrochloride ointment, or 30 months, if it is chlortetracycline hydrochloride ointment, after the month during which the batch was certified. Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(3) On the label and labeling, if it contains one or more of the active ingredients specified in paragraph (a) of this section and the name "chlortetracycline ointment," "chlortetracycline calcium ointment," "chlortetracycline calcium cream," or "tetracycline hydrochloride ointment," wherever it appears, the words "with a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such ointment by practitioners licensed by law to administer such drug; or a reference to a brochure or other printed matter containing such information, and a statement that this name shall not be used in connection with such name, the blank being _______"
(d) Requests for certification, samples.

(1) In addition to complying with the requirements of §146.2 of this chapter, a person who requests certification of a batch of ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date upon which the latest assay of the batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient, if it is tetracycline hydrochloride. 

(iii) The cortisone or hydrocortisone, a circular or other labeling within or attached to the package bearing adequate directions and warnings for prophylactic use by man, or for the veterinary use of such ointment. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other uses of such ointment may be obtained by practitioners under law by adminstering such drug will be sent on request to such a practitioner.

(iv) The statement “Expiration date ______” the blank being filled in with the date which is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 36 months or 48 months after the month during which the batch was certified, when such person who requests certification has submitted to the Commissioner results of tests and assays showing that after being stored for such period of time such drug, as prepared by him complies with the standards prescribed therefor by paragraph (a) of this section: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement “Caution: Federal law prohibits dispensing without prescription.”

(ii) If it is packaged for dispensing, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(d) Requests for certification; samples.

(1) In addition to complying with the requirements of §146.2 of this chapter, a person who requests certification of a batch of troches shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline hydrochloride used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the chlortetracycline or tetracycline hydrochloride used in making the batch, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) Each package of troches shall bear, on its label or labeling as hereinafter indicated, the following:

(1) The batch mark;

(2) The number of milligrams in each troche of the batch;

(3) If it contains a preservative, the name and quantity of each ingredient;

(4) No result referred to in subparagraph (d) (ii), of this paragraph, and no sample referred to in subparagraph (d) (iii), of this paragraph, is required if such label or sample has been previously submitted.

(5) Fees. The fee for the services rendered with respect to each batch of ointment under the regulations in this part shall be $1.00 for each package in the sample submitted in accordance with paragraph (d) (i), (ii), and (iii) of this subsection; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

§146c.203 Chlortetracycline troches (chlortetracycline hydrochloride troches) tetracycline hydrochloride troches—(a) Standards of identity. Chlortetracycline troches and tetracycline hydrochloride troches shall be composed of crystalline chlortetracycline or crystalline tetracycline hydrochloride and one or more suitable and harmless diluents, binders, and lubricants, with or without one or more inactive and harmless preservatives, colorings, and flavorings. The potency of each troche is not less than 5 milligrams; the moisture content is not more than 2 percent. The chlortetracycline used conforms to the requirements of §146c.201 (a) except §146c.201 (a) (1), (2), (4) and (5) but its potency is not less than 750 micrograms per milligram. The tetracycline hydrochloride used conforms to the requirements of §146c.218 (a), except §146c.218 (a) (2), (4) and (5). Each other substance used, if its name is required in the standard prescribed therefor by such official compendium.

(b) Packaging. Unless each troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U.S. P. except the provision that it shall be capable of tight closure, the immediate container shall be a tight container as defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit set forth in applicable standards; except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(1) Each package of troches shall bear, on its label or labeling as hereinafter indicated, the following:

(1) The batch mark;

(II) The number of milligrams in each troche of the batch;

(III) If it contains a preservative, the name and quantity of each ingredient; and

(IV) The statement “Expiration date ______” the blank being filled in with the date which is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 36 months or 48 months after the month during which the batch was certified, when such person who requests certification has submitted to the Commissioner results of tests and assays showing that after being stored for such period of time such drug, as prepared by him complies with the standards prescribed therefor by paragraph (a) of this section: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.
(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The batch; one troche for each 5,000 troches, or 500 troches, or less than 50 troches, collected by taking single troches at such intervals throughout the entire time the troches are being made that the quantities made during the intervals are approximately equal.

(2) The tetracycline or tetracycline hydrochloride used in making the batch; 10 packages, each containing approximately equal portions of not less than 50 milligrams, packaged in accordance with the requirements of § 146c.201(b).

(3) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) or (3) of this paragraph or in the sample referred to in subparagraph (3) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch of troches under the regulations in this part shall be:

(1) $1.00 for each troche in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section, and

(2) If the Commissioner considers that investigations, other than examination of such troches, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by the deposit made, in accordance with § 146.8 (d) of this chapter.

§ 146c.204 Chlorotetracycline capsules (chlortetracycline hydrochloride capsules) tetracycline hydrochloride capsules; tetracycline capsules—(a) Standards of identity, strength, quality, and purity. Chlorotetracycline capsules, tetracycline hydrochloride capsules, and tetracycline capsules are capsules composed of crystalline chlorotetracycline, tetracycline hydrochloride, or tetracycline, with or without one or more suitable sulfonamides and with or without one or more suitable buffers and hydrosulfates. Each package contains not fewer than 50 milligrams of chlorotetracycline hydrochloride, tetracycline hydrochloride, or tetracycline, unless it is intended solely for veterinary use and is conspicuously so labeled.

(1) The moisture content is not more than 2 percent of the weight of the package, not more than 5 percent if it contains tetracycline hydrochloride or tetracycline. The chlorotetracycline used conforms to the requirements of § 146c.201 (a), (2), (3), and (4) and (5).

(2) The tetracycline hydrochloride used conforms to the requirements of §§ 146c.218 (a), except § 146c.201 (a), (3), and (4). The tetracycline used conforms to the requirements of § 146c.220 (a) each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed thereby for such official compendium.

(b) Packaging. Unless each capsule is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight re-closure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the capsules by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as to prevent any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that the container closure used in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in each capsule of the batch;

(iii) If it contains preservatives, sulfonamides, or vitamin substances, the name and quantity of each such ingredient;

(iv) The statement "Expiration date --------", the blank being filled in with the date that is 60 months after the month during which the batch was certified, if it is chlorotetracycline hydrochloride, or with the date that is 36 months after the month during which the batch was certified if it is tetracycline hydrochloride or tetracycline, or with the date that is 24 months after the month during which the batch was certified if it contains tetracycline hydrochloride, or tetracycline.

(2) If the batch contains more than one vitamin ingredient, each other substance used in making the batch was certified if it contains one or more vitamin substances, in the statement that such substance or substances may be used in making such batch was completed, the number of milligrams in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the chlorotetracycline, tetracycline hydrochloride, or tetracycline used in making such batch was completed, the assay results of the tests and examinations and warnings for the veterinary use and is conspicuously so labeled.

(d) Requests for certification; samples. (1) In addition to complying with the requirements of § 146c.201 of this chapter, a person who requests certification of such batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlorotetracycline, tetracycline hydrochloride, or tetracycline used in making such batch was completed, the number of milligrams in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug contained in such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor; if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and examinations listed after each of the following, made by an accurately representative sample of:

(i) The batch; average potency per capsule and average moisture.

(ii) The chlorotetracycline, tetracycline hydrochloride, or tetracycline used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient, if it is chlorotetracycline hydrochloride or tetracycline.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and examinations hereinafter indicated, accurately representative samples of the following:

(i) The batch; one capsule for each 5,000 capsules in the batch, but in no case more than 20 capsules, collected by taking single capsules at such intervals throughout the entire time of preparation that the
quantities encapsulated during the intervals are approximately equal.

(ii) The chlortetracycline, tetracycline hydrochloride, or tetracycline used in making the batch, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146.c.201 (b).

(iii) In the event of an initial request for certification, each other ingredient used in making the batch, one package of each containing approximately 5 grams.

(d) Not less than in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fees for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (2) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsules and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.c.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany each request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.c.7 (d) of this chapter.

§ 146.c.208 Chlortetraycline powder (chlortetraycline hydrochloride powder) or tetracycline hydrochloride powder—(a) Standards of identity, strength, quality, and purity.

Chlortetraycline powder, tetracycline hydrochloride powder, and tetracycline powder are crystalline chlortetraycline hydrochloride, tetracycline hydrochloride, or tetracycline, with or without one or more suitable and harmless vitamin substances, their salts, and harmless buffer substances, preservatives, dyes, coloring, flavorings, and local anesthetics (if it is intended for use solely as a dusting powder).

The content of chlortetraycline or tetracycline hydrochloride is not less than 15 milligrams per gram of powder. The moisture content of chlortetraycline or tetracycline hydrochloride powder is not more than 2 percent. The moisture content of tetracycline powder is not more than 7.5 percent.

The chlortetraycline used conforms to the requirements of § 146.c.218 (a) (1) of this section.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as to change the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, handling, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label as hereafter indicated, the following:

(i) The number of milligrams of chlortetraycline or tetracycline hydrochloride powder or tetracycline (expressed in terms of equivalence of tetracycline hydrochloride) per gram; or, if it is intended for use solely as an ingredient in the drinking water of animals and is conspicuously so labeled, the number of grams of drug per pound in the immediate container;

(ii) The statement "Expiration date _______" the blank being filled in with the date that is 48 months after the closing month in which the batch was certified if it is chlortetraycline hydrochloride powder, or with the date that is 24 months after the month during which the batch was certified if it is tetracycline, or in the case of tetracycline powder or if it contains one or more vitamin substances: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iii) If it contains a preservative, a local anesthetic, or vitamin substances, the name and quantity of each such ingredient;

(iv) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it, or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(d) On the label and labeling. If it contains one or more vitamin substances, after the name "chlortetraycline powder," "tetracycline hydrochloride powder," or "tetracycline powder," wherever such name appears on the label, the words "with vitamins" (the blank being filled in with the name of the vitamin ingredient used) or "with vitamins" (if it contains more than one vitamin ingredient), in juxtaposition with such name.

On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinarians on the use of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(e) Request for certification; samples.

(i) In addition to complying with the requirements of § 146.c.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date during which the batch was made of tetracycline, tetracycline hydrochloride or tetracycline used in making such batch was completed, the number of grams of drug per pound in the immediate container, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(ii) Except as otherwise provided in subparagraph (d) of this paragraph, each person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The chlortetraycline, tetracycline hydrochloride, or tetracycline used in making the batch; potency, pH, crystallinity, and extinction coefficient if it is tetracycline hydrochloride or tetracycline.

(f) Inspection. As otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 containers in the batch, but in no case less than 5 or more than 12 immediate containers unless such batch contains more than 5,000 containers in which case the sample shall consist of 1 gram for each 5,000 immediate containers in the batch, but in any case less than five 1.0-gram portions or more than twelve 1.0-gram portions, except if it is intended for use as an ingredient in the drinking water of animals, each portion in the sample submitted shall consist of 1 ounce in lieu of 1.0 gram. Such sample shall be collected from the immediate containers, 1.0-gram portions, or 1-ounce portions at such intervals throughout the entire time the containers are being filled that the
(a) The chlortetracycline, tetracycline hydrochloride, or tetracycline used in making the batch; 10 packages, each containing approximately equal portions of not less than 10 milligrams, packaged in accordance with the requirements of §146c.201 (b).

(ii) In case of an initial request for certification, each of the ingredients used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (i) or (ii) of this paragraph, and no sample referred to in subparagraph (2) (d) or (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with §146c.201 (a) or (b) (3) (1), (ii) and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether such batch complies with the requirements of §146.3 of this chapter for the issuance of a certificate, the cost of such investigations shall be:

(i) $4.00 for each individual container or buffer or diluent used if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(ii) $4.00 for each individual container or buffer or diluent not so recognized.

(iii) $1.00 for each individual buffer or diluent, if it is prepared as directed in its labeling.

(iv) $0.50 for each individual buffer or diluent, if it is not prepared as directed in its labeling.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146c.201 (d) of this chapter.

(1) Exemption of chlortetracycline powder for veterinary use, tetracycline hydrochloride powder for veterinary use, and tetracycline powder for veterinary use from certification. Chlortetracycline powder, tetracycline hydrochloride powder, and tetracycline powder that conform to the requirements of paragraphs (a) (except that if they contain one or more of such substance and it is necessary to determine that all such substances are essential for nutritive purposes, and except that they may contain one or more added mineral substances essential for nutritive purposes); (b) and (c) and with the exception of those covered by the requirements of sections 502 (1) and 507 of the act, if they comply with all the following conditions:

(1) They are intended solely for veterinary use; and are conspicuously so labeled.

(2) If they contain added vitamins or minerals, the labels bear the name and quantity of such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The labels bear an expiration date that is not more than 48 months, or 24 months if it contains a vitamin substance or it is tetracycline hydrochloride powder or tetracycline powder, after the month during which the batch was last assayed and released by the manufacturer.

(4) The labels bear a statement that solutions prepared with such drugs are stable for not more than 24 hours.

(5) The circular or other labeling within or attached to the package bears information that only the antibiotics are intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Pinkeye and superficial cuts and abrasions.

(ii) Bacterial enteritis in swine.

(iii) Bacterial pneumonia in swine.

(iv) Chronic respiratory disease (arbo infection) in birds and (arbo fever) in swine.

(v) Infectious sinusitis in poultry.

b. §146.206 Chlortetracycline ophthalmic (chlortetracycline hydrochloride ophthalmic) tetracycline hydrochloride ophthalmic—(a) Standards of identity, strength, quality, and purity. Chlortetracycline ophthalmic and tetracycline hydrochloride ophthalmic is crystalline tetracycline or crystalline tetracycline hydrochloride, with or without one or more suitable and harmless preservatives, buffer substances, and diluents. It is sterile. Its moisture content is not more than 0.5 percent. The chlortetracycline or tetracycline hydrochloride is of such quantity that when dissolved as directed the potency of such solution is not less than 1,000 micrograms per milliliter and each bottle is labeled with a potency after it has been kept for 2 days at a temperature of 15° C. (59° F.) Such solution has a pH of 8.0, ± 0.2. The chlortetracycline used conforms to the requirements of §146c.201 (a) except subparagraphs (2) (4) and (5) of such paragraph.

(ii) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. The immediate container shall be a tight container as defined by the U. S. P., its closure shall be such that the container need not be opened through any means other than the means by which the contents are to be administered, and the container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any reasonably possible changes and except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 5 milligrams, and each may be packaged in combination with a container of the solvent, sterile distilled water U. S. P.

(c) Labeling. Each package shall bear on its labeling the date hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in the immediate container;

(iii) The statement “Expiration date ________,” the blank being filled in with the date which is 12 months if it is tetracycline hydrochloride ophthalmic or 36 months if it is chlortetracycline ophthalmic after the month during which the batch was certified: Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) If it is packaged in combination with a container of a solvent, the statement “Warning—Not for injection in the eye.”

(v) If it contains chlortetracycline, the name and quantity of each such substance.

(2) On the outside wrapper or container:

(i) The statement “Caution: Federal law prohibits dispensing without prescription,” unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available standard source of information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or if a reference is not available, a brief statement of the kind of matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that such statement may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the labeler.

(d) Request for certification; samples. (1) In addition to complying with the requirements of §146.2 of this chapter a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless previously submitted) the date on which the latest assay of the chlortetracycline or tetracycline hydrochloride used in making such batch was completed, the number of milligrams in each immediate container, the quantity of the drug comprising such batch was prepared as directed in its labeling.

(ii) If the statement that such solvent conforms to the requirements of §146c.201 (a) except subparagraphs (2) (4) and (5) of such paragraph.

(c) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(iii) Each other buffer and diluent, if it is prepared as directed in its labeling.

(b) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(c) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(iii) Each other buffer and diluent, if it is prepared as directed in its labeling.

(b) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(c) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(iii) Each other buffer and diluent, if it is prepared as directed in its labeling.

(b) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(c) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(iii) Each other buffer and diluent, if it is prepared as directed in its labeling.

(b) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(c) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(iii) Each other buffer and diluent, if it is prepared as directed in its labeling.

(b) Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.
(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request for such drug, the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:
   (a) For all tests except sterility: one immediate container for each of 5,000 immediate containers in the batch, but in case less than 5 immediate containers or more than 12 immediate containers, the person shall submit a representative sample of not less than 50 milligrams, in accordance with the requirements of § 146c.201 (b)

   (b) For sterility testing: 10 immediate containers.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; ten packages, each containing approximately equal portions of not less than 50 milligrams, in accordance with the requirements of § 146c.201 (b) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(iii) In case of an initial request for such drug, the person shall submit in connection with his request for such drug, a representative sample of not less than 50 milligrams, in accordance with the requirements of § 146c.201 (a) except § 146c.201 (b) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(iv) The statement "Warning: Not for injection"

(v) The statement "Expiration date: ________", the blank being filled in with the month during which the batch was certified:

   (i) The batch mark
   (ii) The number of milligrams in the immediate container.

(vi) The statement "Expiration date: ________", the blank being filled in with the month during which the batch was certified:

   (i) The batch mark
   (ii) The number of milligrams in the immediate container.

(vii) The statement "Warning—Not for injection".

(viii) On the outside wrapper or container and on the immediate container of the chlortetracycline or tetracycline hydrochloride:

   (i) The batch mark
   (ii) The number of milligrams in the immediate container.

(ix) If it is packaged for dispensing or other printed matter will be sent on request:

   (i) A brochure containing the following information:

   (1) The batch mark
   (2) The potency per milliliter after dissolving the chlortetracycline or tetracycline hydrochloride used in making the batch was completed, the quantity of each ingredient used in making the solution included in the packaged combination, and a statement that such solution conforms to the requirements prescribed therefor by this section.

   (2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request for the conditions hereinafter indicated, accurately representative samples of the following:

   (i) The batch; potency and moisture.

   (ii) The solution after the chlortetracycline or tetracycline hydrochloride has been dissolved therein:

   (iii) The chlortetracycline or tetracycline hydrochloride used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline hydrochloride.

   (3) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request for the conditions hereinafter indicated, accurately representative samples of the following:

   (i) The batch; one package for each of 2,500 packages in the batch, but in no case less than 5 packages or more than 12 packages, collected by taking a single package at each interval throughout the period of packaging the batch, and a statement that the quantities packaged during the intervals are approximately equal.

   (ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; 10 packages, each containing approximately equal portions of not less

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**FEDERAL REGISTER**

**Tuesday, December 20, 1955**

**§ 146c.201**

**Chlortetracycline tablets (chlortetracycline hydrochloride tablets)**

Tetracycline tablets (tetracycline hydrochloride tablets) Chlortetracycline tablets and tetracycline tablets are tablets than conform to all requirements and are subject to all procedures prescribed by § 146c.201 for chlortetracycline or tetracycline capsules, except that the average moisture content of the tablets is not more than 3.0 percent and its expiration date is not more than 48 months.

**§ 146c.202**

**Chlortetracycline otc (chlortetracycline hydrochloride otc, chlortetracycline hydrochloride for oral solution) tetracycline hydrochloride otc (tetracycline hydrochloride for oral solution)**

(a) Standards of identity, strength, quality, and purity. Chlortetracycline otc, tetracycline otc is a packaged combination of one immediately container of crystalline chlortetracycline or crystalline tetracycline hydrochloride and one immediate container of a suitable and harmless solution. The chlortetracycline tablets or tetracycline hydrochloride is of such quantity that when dissolved as directed the potency of such solution is not less than 5 milligrams per milliliter and it has been kept for 7 days at a temperature of 15° C. (59° F.). The chlortetracycline used conforms to the requirements of § 146c.201 (a) except § 146c.201 (b) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(b) The chlortetracycline or tetracycline hydrochloride used in making the batch; ten packages, each containing approximately equal portions of not less than 50 milligrams, in accordance with the requirements of § 146c.201 (b)

(c) The number of milligrams in the immediate container.

(d) The statement "Expiration date: ________", the blank being filled in with the month during which the batch was certified:

(i) The batch mark
(ii) The number of milligrams in the immediate container.

(e) The statement "Warning—Not for injection".

(f) On the outside wrapper or container and on the immediate container of the chlortetracycline or tetracycline hydrochloride:

(i) The batch mark
(ii) The number of milligrams in the immediate container.

(g) If it is packaged for dispensing or other printed matter will be sent on request:

(i) A brochure containing the following information:

(1) The batch mark
(2) The number of milligrams in the immediate container.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request for the conditions hereinafter indicated, accurately representative samples of the following:

(i) The batch; potency and moisture.

(ii) The solution after the chlortetracycline or tetracycline hydrochloride has been dissolved therein:

(iii) The chlortetracycline or tetracycline hydrochloride used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline hydrochloride.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request for the conditions hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each of 2,500 packages in the batch, but in no case less than 5 packages or more than 12 packages, collected by taking a single package at each interval throughout the period of packaging the batch, and a statement that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; 10 packages, each containing approximately equal portions of not less
RULES AND REGULATIONS

Chlortetracycline and Tetracycline Hydrochloride

1. Chlortetracycline and Tetracycline Hydrochloride—(a) Standards of identity, strength, quality, and purity. Chlortetracycline and tetracycline hydrochloride are crystalline chlortetracycline or crystalline tetracycline hydrochlorides, with or without suitable and harmless diluents, preservatives, and lubricants. The content of chlortetracycline or tetracycline hydrochloride is not less than 50 milligrams per gram of powder. It is sterile. Its moisture content is not more than 2 percent. The chlortetra-

cycle used conforms to the requirements of § 146c.201(a) except § 146c.201(c) (1) (ii) of this paragraph, and tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a), except § 146c.218 (a) (4) and (6). Each other substance used, if its name is recognized by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the original condition as will not cause any change in the strength, quality, or purity thereof beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

2. Labeling. Each package of surgical powder shall bear, on its label or labeling as hereinafter indicated, the following:

(i) The outside wrapper or container and the immediate container;

(ii) The batch mark;

(iii) The number of milligrams of chlortetracycline or tetracycline hydrochloride per gram of powder in the immediate container;

(iv) The statement "Expiration date __________", the blank being filled in with the date which is 24 months after the date during which the batch was certified: Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(v) If it contains a preservative, the name and quantity of each such ingredient.

3. On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription. This drug is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled."

(ii) If it is packaged for dispensing and is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that the tetracycline hydrochloride used in making such batch was completed, the number of milligrams of chlortetracycline or tetracycline hydrochloride in each immediate container, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(ii) Labeling. Each package of surgical powder shall bear, on its label or labeling as hereinafter indicated, the following:

(i) The outside wrapper or container and the immediate container;

(ii) The batch mark;

(iii) The number of milligrams of chlortetracycline or tetracycline hydrochloride per gram of powder in the immediate container;

(iv) The statement "Expiration date __________", the blank being filled in with the date which is 24 months after the date during which the batch was certified: Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(v) If it contains a preservative, the name and quantity of each such ingredient.

4. On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription. This drug is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled."

(ii) If it is packaged for dispensing and is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that the tetracycline hydrochloride used in making such batch was completed, the number of milligrams of chlortetracycline or tetracycline hydrochloride in each immediate container, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(ii) Labeling. Each package of surgical powder shall bear, on its label or labeling as hereinafter indicated, the following:

(i) The outside wrapper or container and the immediate container;

(ii) The batch mark;

(iii) The number of milligrams of chlortetracycline or tetracycline hydrochloride per gram of powder in the immediate container;

(iv) The statement "Expiration date __________", the blank being filled in with the date which is 24 months after the date during which the batch was certified: Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(v) If it contains a preservative, the name and quantity of each such ingredient.

5. On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription. This drug is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled."

(ii) If it is packaged for dispensing and is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that the tetracycline hydrochloride used in making such batch was completed, the number of milligrams of chlortetracycline or tetracycline hydrochloride in each immediate container, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.
(2) On the outside wrapper or container:
(i) The statement ‘Caution: Federal law prohibits dispensing without prescription,’ unless it is packaged for dispensing only for veterinary use and is conspicuously so labeled.
(ii) If it is packaged for dispensing and it is intended only for veterinary use, or if it is to be intended solely for veterinary use and is conspicuously so labeled.

(i) The batch; one suppository for each 5,000 suppositories in the batch, but in no case less than 20 or more than 103 suppositories, collected by taking single suppositories at such intervals throughout the entire time the suppositories are being made, that the quantities made during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; 10 packages, each containing approximately equal portions of not less than 0.5 milligrams, packaged in accordance with §146c.201 (b) (2) (i) of this paragraph, and no sample referred to in subparagraph (2) (ii) of this paragraph, is required if such package has been previously submitted.

(c) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be
(1) $1.00 for each suppository in the samples submitted in accordance with paragraph (d) (3) (i) of this section.
(2) $4.00 for each immediate container as defined by the U. S. P., and each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(2) If the Commissioner considers that investigations other than examinations of the samples submitted, as required by §146.3 of this chapter for the issuance of a certificate the cost of such investigations shall be
(1) $1.00 for each suppository in the samples submitted in accordance with paragraph (d) (3) (i) of this section, and $4.00 for each immediate container as defined by the U. S. P., and each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(3) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(d) Request for certification; samples. (1) In addition to complying with the requirements of §146c.218 (a) (2) (4) and (5) each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(2) Packaging. In all cases the immediate container shall be such as defined by the U. S. P., and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any change which are normal and unavoidable in good packaging, storage, and distribution practice as shall be disregarded.

(c) Labelling. Each package shall bear on its label or labeling, as hereinafter indicated, the following:
(1) On the outside wrapper or container and in the immediate container:
(i) The batch mark.
(ii) The number of milligrams of chlortetracycline or tetracycline hydrochloride in each suppository of the batch.
(iii) If it conforms to the standards, the name and quantity of each such ingredient.
(iv) The statement ‘Expiration date shall be nine months from the date which is 24 months after the month during which the batch was certified: Provided, however That such expiration date may be omitted from the immediate container with his request results of tests and any sample has been previously submitted.

(b) Labeling. Each package shall bear on its label or labeling, as hereinafter indicated, the following:
(1) On the outside wrapper or container:
(i) The statement ‘Caution: Federal law prohibits dispensing without prescription,’ unless it is packaged for dispensing only for veterinary use and is conspicuously so labeled.
(ii) If it is packaged for dispensing and it is intended only for veterinary use, or if it is to be intended solely for veterinary use and is conspicuously so labeled.

(i) The batch; one suppository for each 5,000 suppositories in the batch, but in no case less than 20 or more than 103 suppositories, collected by taking single suppositories at such intervals throughout the entire time the suppositories are being made, that the quantities made during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; 10 packages, each containing approximately equal portions of not less than 0.5 milligrams, packaged in accordance with paragraph (d) (3) (i) of this paragraph, and no sample referred to in subparagraph (2) (ii) of this paragraph, is required if such package has been previously submitted.

(c) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be
(1) $1.00 for each suppository in the samples submitted in accordance with paragraph (d) (3) (i) of this section, and $4.00 for each immediate container as defined by the U. S. P., and each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(2) If the Commissioner considers that investigations other than examinations of the samples submitted, as required by §146.3 of this chapter for the issuance of a certificate the cost of such investigations shall be
(1) $1.00 for each suppository in the samples submitted in accordance with paragraph (d) (3) (i) of this section, and $4.00 for each immediate container as defined by the U. S. P., and each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(3) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(d) Request for certification; samples. (1) In addition to complying with the requirements of §146c.218 (a) (2) (4) and (5) each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(2) Packaging. In all cases the immediate container shall be such as defined by the U. S. P., and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any change which are normal and unavoidable in good packaging, storage, and distribution practice as shall be disregarded.

(c) Labelling. Each package shall bear on its label or labeling, as hereinafter indicated, the following:
(1) On the outside wrapper or container:
(i) The statement ‘Caution: Federal law prohibits dispensing without prescription,’ unless it is packaged for dispensing only for veterinary use and is conspicuously so labeled.
(ii) If it is packaged for dispensing and it is intended only for veterinary use, or if it is intended solely for veterinary use and is conspicuously so labeled.

(i) The batch; one suppository for each 5,000 suppositories in the batch, but in no case less than 20 or more than 103 suppositories, collected by taking single suppositories at such intervals throughout the entire time the suppositories are being made, that the quantities made during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; 10 packages, each containing approximately equal portions of not less than 0.5 milligrams, packaged in accordance with paragraph (d) (3) (i) of this paragraph, and no sample referred to in subparagraph (2) (ii) of this paragraph, is required if such package has been previously submitted.

(c) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be
(1) $1.00 for each suppository in the samples submitted in accordance with paragraph (d) (3) (i) of this section, and $4.00 for each immediate container as defined by the U. S. P., and each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(2) If the Commissioner considers that investigations other than examinations of the samples submitted, as required by §146.3 of this chapter for the issuance of a certificate the cost of such investigations shall be
(1) $1.00 for each suppository in the samples submitted in accordance with paragraph (d) (3) (i) of this section, and $4.00 for each immediate container as defined by the U. S. P., and each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.
Labeling. Each package shall bear on its label or labeling, as herein-after indicated, the following:

(I) The batch mark.

(II) The number of milligrams of chlortetracycline per gram and per linear foot of gauze.

(iii) The length, width, and type of gauze contained in the package.

(iv) The statement "Expiration date ________," the blank being filled in with the date which is 24 months after the month during which the batch was certified: Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the immediate container, the statement "Sterility cannot be guaranteed if the package bears evidence of damage or has been previously opened."

(3) On the outside wrapper or container:

(I) The statement "Caution: Federal law prohibits dispensing without prescription and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(b) Packaging. In all cases the immediate container for each chlortetracycline dressing shall be a tight container as defined by the U. S. P and shall be of such composition as will not cause any change in the purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging practice and distribution shall be disregarded.

(c) Labeling. Each package shall bear on its label or labeling, as herein-after indicated, the following:

(I) The batch mark.

(ii) The number of grams of chlortetracycline ointment contained in each dressing and the number of milligrams of chlortetracycline per gram of ointment.

(iii) The length, width, and type of gauze contained in the dressing.

(iv) The statement "Expiration date ________," the blank being filled in with the date which is 24 months after the month during which the batch was certified: Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the immediate container, the statement "Sterility cannot be guaranteed if the package bears evidence of damage or has been previously opened."

(3) On the outside wrapper or container:

(I) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(II) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

§ 146c.201 Chlortetracycline dressing (chlortetracycline hydrochloride dressing)—(a) Standards of identity, strength, quality, and purity. Chlortetracycline dressing is absorbent gauze impregnated with chlortetracycline ointment. Such dressing shall contain not less than 2 milligrams of chlortetracycline. It is sterile. Its moisture content is not more than 5 percent. The chlortetracycline ointment used conforms to the standards prescribed for chlortetracycline ointment by § 146c.202 (a) except that its potency is not less than 20 milligrams per gram. The absorbent gauze used conforms to the standards prescribed therefor by the U. S. P.

§ 146c.202 Chlortetracycline ointment—(a) Standards of identity, strength, quality, and purity. Chlortetracycline ointment used in making such dressing shall meet the requirements of § 146c.201 (b) except as otherwise provided in subparagraph (d) (3) (i) of this paragraph, such person shall submit in connection with his request a statement showing the batch mark and the number of packages of each size in such batch, the batch mark and the number of packages, the potency of each gram and of each linear foot of gauze, and the date which is 24 months after the month during which the batch was certified: Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(3) On the outside wrapper or container:

(I) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(II) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(d) (3) (i) If the Commissioner considers that investigations other than examination of such chlortetracycline gauze packings and packages are necessary to determine whether the batch complies with the requirements of § 146c.3 of this chapter for the issuance of a certificate, the cost of such investigations, the fees, the fees shall be of such composition as will not cause any change in the purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging practice and distribution shall be disregarded.

(II) If the Commissioner considers that investigations other than examination of such chlortetracycline gauze packings and packages are necessary to determine whether the batch complies with the requirements of § 146c.3 of this chapter for the issuance of a certificate, the cost of such investigations, the fees, the fees shall be of such composition as will not cause any change in the purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging practice and distribution shall be disregarded.

(II) The chlortetracycline used in making the batch; potency, toxicity, moisture, and purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging practice and distribution shall be disregarded.

(III) The chlortetracycline used in making the batch; five packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(IV) The statement "Expiration date ________," the blank being filled in with the date which is 24 months after the month during which the batch was certified: Provided, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the immediate container, the statement "Sterility cannot be guaranteed if the package bears evidence of damage or has been previously opened."

(3) On the outside wrapper or container:

(I) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(II) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

§ 146c.214 Chlortetracycline dressing (chlortetracycline hydrochloride dressing)—(a) Standards of identity, strength, quality, and purity. Chlortetracycline dressing is absorbent gauze impregnated with chlortetracycline ointment. Such dressing shall contain not less than 2 milligrams of chlortetracycline. It is sterile. Its moisture content is not more than 5 percent. The chlortetracycline ointment used conforms to the standards prescribed for chlortetracycline ointment by § 146c.202 (a) except that its potency is not less than 20 milligrams per gram. The absorbent gauze used conforms to the standards prescribed therefor by the U. S. P.
The batch was completed, the number of grams of chlortetracycline ointment contained in each dressing of the batch and its potency per gram, the quantity of each ingredient used in making the batch, and its name shall be on request. The expiration date may be omitted from the label if it is 4 days without significant loss of potency. The expiration date may be omitted from the label if it is 4 days without significant loss of potency.

(3) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the label. Such circular or other labeling may also bear a statement that such circular or other labeling containing information for other veterinary use of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Request for certification; samples.

(1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chlortetracycline with vasconstrictor shall submit with his request a statement giving the method of dissolution of the chlortetracycline used in making such batch.

(2) Except as otherwise provided in subparagraph (d) of this paragraph, if the investigation is not less than 12 dressings.

(3) Except as otherwise provided in subparagraph (d) of this paragraph.
such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately equal quantities of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iv) In case of an initial request for certification of the packaged combination of chlortetracycline with vasoconstrictor, or when any change is made in the composition of such solution; five packages of the solution included in the combination.

§ 146c.217 Chlortetracycline calcium oral drops; chlortetracycline calcium syrup; tetracycline syrup—(a) Standards of identity, strength, quality, and purity. Chlortetracycline calcium oral drops, chlortetracycline calcium syrup, and tetracycline syrup are chlortetracycline calcium prepared from crystalline chlortetracycline hydrochloride or crystalline tetracycline, with or without one or more suitable sulfonamides and one or more suitable and harmless buffer substances, suspending and stabilizing agents, and preservatives, suspended in a suitable and harmless vehicle. Each milliliter shall contain a quantity of chlortetracycline calcium or tetracycline equivalent to not less than 25 milligrams of chlortetracycline hydrochloride or tetracycline hydrochloride. It is nontoxic. The pH is not less than 5.5 nor more than 9.0, except if it is tetracycline syrup the pH is not less than 4.5 nor more than 5.5. The crystalline chlortetracycline hydrochloride used to contain not less than 48.0% of U. S. P. or N. F. chlortetracycline hydrochloride conforming to the requirements of § 146c.520. Each other substance used, if any, to make the solution, conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or character of the contents beyond the limits therein applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label or labeling, as herein-after indicated, the following:

(i) The batch mark.

(ii) The potency per milliliter expressed in terms of its equivalency of crystalline chlortetracycline or tetracycline hydrochloride.

(iii) The name and quantity of each sulfonamide and preservative used in making the batch.

(d) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container or package in the samples submitted in accordance with paragraph (2) (i) (ii) (iii) and (iv) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146c.3 of this chapter for the issuance of a certificate, the cost of such investigations shall be charged to the applicant.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146c.201 (d) of this chapter.

§ 146c.218 Tetracycline hydrochloride or tetracycline used in making the batch; potency, toxicity, moisture, pH, and dissolution.

(a) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made on samples, each containing approximately representative sample of:

(i) The batch; average potency per milliliter, toxicity, pH, and dissolution.

(b) The chlortetracycline hydrochloride or tetracycline used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than 5 or more than 12 packages, collected by sampling the packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline hydrochloride or tetracycline used in making the batch; 10 packages each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iv) No result referred to in subparagraph (2) of this paragraph, and no sample referred to in subparagraph (3) (i) (ii) (iii) and (iv) of this section.

§ 146c.213 Test and certification of batches of chlortetracycline or tetracycline used in making the batch; potency, toxicity, moisture, pH, and assays.

(a) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made on samples, each containing approximately representative sample of:

(i) The batch; average potency per milliliter, toxicity, pH, and dissolution.

(b) The chlortetracycline hydrochloride or tetracycline used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline.

(c) Each ingredient used in making the batch; one package for each ingredient used, collected by sampling the packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(d) No result referred to in subparagraph (2) of this paragraph, and no sample referred to in subparagraph (3) (i) (ii) (iii) and (iv) of this section.

§ 146c.212 Request for certification, samples and charges.

(a) Request for certification, samples and charges. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement relative to each mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline hydrochloride or tetracycline used in making such batch was completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made on samples, each containing approximately representative sample of:

(i) The batch; average potency per milliliter, toxicity, pH, and dissolution.

(b) The chlortetracycline hydrochloride or tetracycline used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline.

(3) Each other substance used in making the batch; one package for each such substance, collected by sampling the packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.
tion of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.218 Tetracycline hydrochloride—(a) Standards of identity, strength, quality, and purity. Tetracycline hydrochloride is the crystalline hydrochloride salt of the deschloro derivative of a kind of chlortetracycline or a mixture of two or more such salts, with or without one or more suitable and harmless stabilizing agents. It is so purified and dried that:

(1) Its potency, and the potency of the tetracycline hydrochloride used in the manufacture of tetracycline hydrochloride forms, shall be not less than 900 micrograms per milligram.

(2) It is sterile.

(3) It is nontoxic.

(4) It is nonpyrogenic.

(5) It contains no harmful nor harmful-like substance.

(6) Its moisture content is not more than 2 percent.

(7) Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 1.8 and not more than 2.8, except if it is intended for use by injection its pH is not less than 2.0 and not more than 2.8.

(8) Its extinction coefficient $E_{1cm}^{1cm}$, and the extinction coefficient of the tetracycline hydrochloride used in the manufacture of tetracycline for intravenous use, is $372.15$ at $380$ μm.

(b) Packaging; labeling; request for certification; check tests and assays; samples; fees. Tetracycline hydrochloride conforms to all requirements and procedures prescribed for chlortetracycline hydrochloride by § 146c.201 (b) (c) (d) and (e) that:

(1) It shall be labeled with an expiration date that is 24 months after the month during which the batch was certified.

(2) The person who requests certification of a batch of tetracycline hydrochloride that contains stabilizing agents and is intended for intravenous use shall submit with his request (unless they were previously submitted) the results of the latest tests and assays made on the batch of the tetracycline hydrochloride used in making such batch for potency and extinction coefficient and a sample consisting of two packages each containing approximately 500 micrograms of the tetracycline hydrochloride used in making such batch for potency and extinction coefficient.

(3) The fee for the services rendered with respect to each immediate container of the tetracycline hydrochloride used in the manufacture of a batch of tetracycline hydrochloride for intravenous use submitted in accordance with the requirements prescribed therefor by subparagraph (2) of this paragraph shall be $4.00.

§ 146c.219 Crude chlortetracycline oral veterinary—(a) Standards of identity, strength, quality, and purity. Crude chlortetracycline is crude tetracycline with suitable and harmless diluents, buffer substances, and suspending or dispersing agents. It contains not less than 100 micrograms of tetracycline per pound. Its moisture content is not more than 6 percent.

(b) Packaging. In all cases the immediate container shall be a well-closed container not less than 12 ounces of the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any change which shall be within the limits prescribed in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not more than 100 pounds.

(c) Labeling. Each package shall bear on its label or labeling, as hereinafter provided, the following:

(1) On the outside of the container or container and the immediate container:

(i) The batch mark.

(ii) The number of grams of chlortetracycline used in each pound of the batch.

(iii) The statement "For oral veterinary use only."

(iv) The statement "Expiration date —

[Date 12 months after the expiration date that is 24 months after the month during which the batch was certified.]

The blank being filled in with the date which is 12 months after the date which the batch was certified: Provided, However, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for the use of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Request for certification; samples. (1) In addition to complying with § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of grams of chlortetracycline in each pound of the batch, and the quantity of each ingredient used in making the batch, and the date on which the latest assay of the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for average potency and average moisture.

(2) Such person shall submit in connection with his request a sample of the batch consisting of 1 ounce for each 3,000 pounds in the batch, but in no case less than five 1-ounce portions or more than twelve 1-ounce portions collected by taking single 1-ounce portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) of this section.

(2) If the Commissioner considers that investigations other than examination of such drug are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(d) Exemption of crude chlortetracycline oral veterinary from certification. Crude chlortetracycline oral veterinary is exempt from the requirements of paragraphs (a) (except that it may contain one or more essential vitamin and mineral substances for nutritive purposes) (b) and (c) of this section shall be exempt from the requirements of sections 502 (1) and 507 of act, if it complies with all the following conditions:

(1) If it contains added vitamins or minerals, its label bears the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(2) The label bears an expiration date that is not more than 12 months after the month during which the batch was last assayed and released by the manufacturer.

(3) The label bears a statement that solutions prepared with the drug are stable for not more than 24 hours.

(4) The circular or other labeling within or attached to the package bears information that only the antibiotic is intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

I. Bacterial enteritis in swine.

II. Bacterial pneumonia in swine.

III. Chronic respiratory disease (arsenic infection), hemamitosis, blue comb (mud fever, nonspecific infectious enteritis) in poultry.

IV. Infectious coryza in poultry.

§ 146c.220 Tetracycline—(a) Standards of identity, strength, quality, and purity. Tetracycline is the hydrated or anhydrous crystalline compound of the deschloro derivative of a kind of chlorotetracycline, or a mixture of two or more such compounds. It is so purified that:

(1) Its potency is not less than 975 micrograms per milligram on the anhydrous basis.

(2) It is nontoxic.

(3) Its moisture content is not more than 13 percent.

(4) Its pH in an aqueous suspension prepared by adding 10 milligrams per
milliliter is not less than 3.0 and not more than 7.0.

(5) Its extinction coefficient $E = 15 \, \text{cm}^{-1} \, \text{g}^{-1}$ is $0.42 \pm 0.15$ at 380 nm as calculated on the anhydrous basis.

(b) Packaging. In all cases the immediate container shall be tight containers as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of tetracycline shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(I) The batch mark.

(II) The number of milligrams of tetracycline hydrochloride, and the total number of grams in the immediate container.

(III) The name and quantity of each other ingredient in the immediate container.

(d) Request for certification, check tests and assays; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with its request a statement showing the batch mark, the number of packages of each size in the batch, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, pH, color, uniformity, and extinction coefficient.

(2) Such person shall submit with his request an accurately representative sample of the batch consisting of 10 packages, each containing approximately 60 milligrams taken from a different part of such batch and each packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which tetracycline is to be used, the manufacturer of the batch that is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the results required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer the results of such check tests and assays as are so requested.

(e) Fees. The fee for the service rendered with respect to each batch under the regulations in this part shall be:

(I) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) and (3) of this section.

(II) If the Commissioner considers that a fundamental examination of such immediate containers is necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.3 (d) of this chapter.

§ 146c.221 Tetracycline hydrochloride for intramuscular use—

(a) Standards of identity, strength, quality, and purity. Tetracycline hydrochloride for intramuscular use is a dry mixture of tetracycline hydrochloride and one or more suitable buffer substances, with or without one or more suitable preservatives and anesthetic agents. It is sterile. It is nonpyrogenic. Its moisture content is not more than 5 percent. Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 2.0 and not more than 3.0.

(b) Other substances. Each other substance used, if its identity, strength, quality, and purity are prescribed therefor by such official compendium.

(c) Packaging. In all cases the immediate containers shall be tight containers as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate containers shall be of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Each such container shall contain not less than 100 milligrams of tetracycline hydrochloride, and each may be packaged in combination with a container of a suitable and harmless diluent.

(d) Labeling. That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is not conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(I) If it is intended for use by man, adequate directions and warnings for its proper use with a veterinarian licensed by law to administer such drug.

(II) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the proper use of such drug by the veterinary practitioner licensed by law to administer such drug.

(III) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(I) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the proper use of such drug by the veterinary practitioner licensed by law to administer such drug.

(II) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the proper use of such drug by the veterinary practitioner licensed by law to administer such drug.

(III) A statement of the conditions under which such solutions prepared from the drug should be stored and the statement "Sterile solutions may be stored at room temperature for 24 hours without significant loss of potency."

(4) Request for certification, samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. The number of milligrams of tetracycline hydrochloride used in making such batch was completed, the number of milligrams of tetracycline hydrochloride in each package, the date on which the latest assay of the drug comprising the batch was completed, the quantity of each other ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit with his request the results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(I) The batch: Potency, sterility, pyrogenicity, moisture, pH.
The tetracycline hydrochloride used in making the batch: Potency, toxicity, habitability, extinction coefficient, and crystallinity.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch.

(a) For all tests except sterility: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 10 or more than 17 immediate containers.

(b) For sterility testing: 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The tetracycline hydrochloride used in making the batch: 10 packages containing approximately equal portions of not less than 250 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each, containing approximately 5 grams.

(iv) In case of an initial request for the certification of a batch which is to be packaged in combination with a diluent that is not recognized by the U. S. P. or when any change is made in the composition of such diluent: 5 packages of the diluent included in the combination.

(v) Each batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(a) For all tests except sterility: 10 packages, each containing approximately 0.25 gram.

(b) For sterility testing: 10 packages, each containing approximately 40 milligrams of tetracycline hydrochloride. Each such package shall be packaged in accordance with the requirements of paragraph (b) of this section.

(5) No request shall be entertained under subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such request or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) § 4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i), (ii), (iii), and (iv) of this section.

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146c.203 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit made in accordance with § 143.5 (d) of this chapter.

§ 146c.222 Tetracycline hydrochloride oral suspension; tetracycline hydrochloride oral solution; tetracycline calcium oral suspension—

(a) Standards of identity, strength, quality, and purity. Tetracycline hydrochloride oral suspension, tetracycline hydrochloride oral solution, and tetracycline calcium oral suspension are tetracycline hydrochloride, tetracycline hydrochloride or tetracycline calcium prepared from tetracycline hydrochloride, with one or more suitable and harmless suspending and dispersing agents (unless it is tetracycline hydrochloride oral solution) with or without one or more suitable sulfonamides; and with or without one or more suitable and harmless coloring agents, flavorings, buffer substances, and preservatives, and under such conditions as will not cause any change in the strength, quality, or purity of the contents beyond any limit prescribed therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(b) The batch mark and (unless it was previously submitted) the date on which the batch was certified: Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(c) The outside wrapper or container.

(i) The statement "Caution: Federal law prohibits dispensing without prescription" unless it is packaged for dispensing and it is intended for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and if such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling:

(i) If it is tetracycline hydrochloride oral suspension and it contains one or more sulfonamides, after the name "tetracycline hydrochloride oral suspension," wherever it appears, the words "with sulfonamide(s)", or "with sulfonamide(s)" will be placed in the blank being filled in with the name of the vitamin ingredient used, or "with vitamins," if it contains more than one vitamin ingredient, in juxtaposition with such name.

(ii) If it is tetracycline hydrochloride oral solution or tetracycline calcium oral suspension and it contains one or more sulfonamides, after the name "tetracycline hydrochloride oral solution" or "tetracycline calcium oral suspension," wherever it appears, the words "with sulfonamide(s)", in juxtaposition with such name.

(iii) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iv) If it is packaged for dispensing and is intended for veterinary use, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by veterinarians licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and if such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(v) On the label and labeling:

(i) If it is tetracycline hydrochloride oral suspension and it contains one or more sulfonamides, after the name "tetracycline hydrochloride oral suspension," wherever it appears, the words "with sulfonamide(s)", or "with sulfonamide(s)" will be placed in the blank being filled in with the name of the vitamin ingredient used, or "with vitamins," if it contains more than one vitamin ingredient, in juxtaposition with such name.

(ii) If it is tetracycline hydrochloride oral solution or tetracycline calcium oral suspension and it contains one or more sulfonamides, after the name "tetracycline hydrochloride oral solution" or "tetracycline calcium oral suspension," wherever it appears, the words "with sulfonamide(s)", in juxtaposition with such name.

(iii) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iv) If it is packaged for dispensing and is intended for veterinary use, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by veterinarians licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and if such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(5) If it is packaged for dispensing and is intended for veterinary use, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by veterinarians licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and if such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(6) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.
latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (d) of this paragraph, each person shall submit in connection with his request for results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Average potency per milliliter, average moisture if it is tetracycline hydrochloride oral suspension or tetracycline hydrochloride oral solution, and pH if it is tetracycline hydrochloride oral solution or tetracycline calcium oral suspension.

(ii) The tetracycline hydrochloride used in making the batch: Potency, toxicity, moisture, pH, crystallinity, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request for quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The tetracycline hydrochloride used in making the batch: 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In the case of an initial request for certification, each other ingredient used in making the batch: 1 package of each containing approximately 5.0 grams.

(4) No result referred to in subparagraph (a) (i) of this paragraph and no sample referred to in subparagraph (b) of this paragraph, is required if such result or sample has been previously submitted.

(f) Fee: The fee for the services rendered with respect to each batch under the regulations in this part shall be:

1. $4.00 for each package in the samples submitted in accordance with paragraph (d) (i) (ii), and (iii) of this section.

2. If the Commissioner considers that investigations other than the examination of the packages are necessary to determine whether or not such batch conforms to the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this chapter shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.223 Chlortetracycline - neomycin-streptomycin-pencillin ointment; tetracycline hydrochloride - neomycin-dihydrostreptomycin - penicillin ointment; tetracycline hydrochloride - neomycin-dihydrostreptomycin-pencillin ointment, chlorotetra-cycline-neomycin-dihydrostreptomycin-pencillin ointment, tetracycline hydrochloride-neomycin-streptomycin-pencillin ointment, and tetracycline hydrochloride - neomycin-dihydrostreptomycin-pencillin ointment conform to the requirements of § 146c.204 for tetracycline hydrochloride capsules, except:

1. The neomycin used in making the batch: 5 packages, each containing approximately equal portions of not less than 0.5 gram.

2. The streptomycin or dihydrostreptomycin used in making the batch: 5 packages, each containing approximately equal portions of not less than 0.5 gram.

3. The procaine penicillin G used in making the batch: 10 packages, each containing approximately equal portions of not less than 30 milligrams.

4. The fee for the services rendered with respect to each immediate container in the samples of neomycin, streptomycin or dihydrostreptomycin, and penicillin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146c.224 Tetracycline hydrochloride-nystatin capsules. Tetracycline hydrochloride-nystatin capsules are capsules that conform to all the requirements and procedures prescribed by § 146c.204 for tetracycline hydrochloride capsules, except that:

(a) Each capsule contains not less than 100,000 units of nystatin. The nystatin used is produced by the growth of Streptomyces noursei. It is a white to yellow to light-tan powder. It is very slightly soluble in water, moderately soluble in methanol, butanol, or ethanol. Its pH is not less than 3.0 percent. It exhibits absorption maxima at 231, 305, and 319 μ when dissolved in methanol, and its specific rotation in dimethyl formamide at 20° C. is not more than +23°.

(b) In addition to the labeling prescribed for tetracycline hydrochloride capsules, each package shall bear on its label or labeling the number of units of nystatin in each capsule of the batch.

(c) In addition to complying with the requirements of § 146c.204 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the results and the date of the latest tests and assays of the nystatin used in making the batch for potency, toxicity, moisture, pH, streptomycin content of the dihydrostreptomycin, crystallinity if it is crystalline dihydrostreptomycin, and crystallinity and penicillin G content of the procaine penicillin G. He shall also submit in connection with his request a sample consisting of not less than 10 capsules (unless it was previously submitted) a sample consisting of 10 packages, each containing approximately equal portions of not less than 300 milligrams of the nystatin used in making the batch.

(d) The fee for the services rendered with respect to each container in the sample of nystatin submitted in accordance with the requirements prescribed therefor by paragraph (g) of this section shall be $4.00.

§ 146c.225 Tetracycline hydrochloride-nystatin tablets. Tetracycline hydrochloride-nystatin tablets are tablets that conform to all the requirements and procedures prescribed by § 146c.224 for tetracycline hydrochloride-nystatin capsules except that the expira-
(III) In case of an initial request for certification, each other ingredient used in making the batch: One package of each composition is to be submitted, except that if cortisone, or a derivative of cortisone is used, such package shall contain approximately 100 milligrams.

(4) No result referred to in subparagraph (c) (1) or (c) (2) of this paragraph (c) (1) or (c) (2) of this paragraph, shall be submitted if such result or sample has been previously submitted.

(c) Fee. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (1) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch is to be certified, such request shall be decided upon by the Commissioner in such manner as he considers necessary.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit made in accordance with § 140.22 of this chapter for the issuance of a certificate, the cost of such investigation.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium. In all cases the immediate container shall contain not less than 3.75 milligrams of tetracycline hydrochloride. The pH is not less than 3.0 nor more than 5.0. The tetracycline used conforms to the requirements of § 146.229 (a) (i) Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(1) The batch mark:

(ii) The potency per milliliter expressed in terms of its equivalency of tetracycline hydrochloride:

(iii) If the batch contains, in addition to tetracycline, one or more other active ingredients specified in paragraph (a) of this section, after the name "Tetracycline and vasoconstrictor suspension," wherever such name appears, the words "with __________" in juxtaposition with such name, the blank being filled in with the common or usual name of each such other ingredient used.

(iv) If on a circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is consecutively so labeled, adequate directions for use, and warnings for the veterinary use of such batch as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(v) The statements "Caution: Federal statute makes dispensing without prescription a violation of law."

(vi) The name and address of the manufacturer, packer, or distributor.

(vii) The statement that a statement or other printed material containing information for other veterinary uses of such drug comprising such batch was completed, the date on which such batch was completed, the date on which the latest assay of the tetracycline used in making the batch was completed, the quantity of each ingredient used in making the batch, and a statement that such each ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit with his request results of the tests and analyses listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Average potency per milliliter, and pH.

(ii) The tetracycline used in making the batch: Potency, toxicity, moisture, pH, crystallinity, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit with his request results of the tests and analyses listed after each of the following, made by him on an accurately representative sample of the following:

(i) The batch: One package for each 5,000 packages in the batch, but in no case less than 5 nor more than 12 packages, collected at single locations, each location being selected at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The tetracycline used in making the batch: 10 packages, each containing approximately equal portions of not less than 3 milligrams, packaged in accordance with the requirements of § 146.229 (b) (ii) in case of an initial request for certification, each other ingredient used in making the batch: One package of each composition is to be submitted, except that if cortisone, or a derivative of cortisone is used, such package shall contain approximately 100 milligrams.

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tetracycline ointment and the number of grams of chlorotetracycline ointment that shall be ejected when used as directed on the container.

(iii) The statement "Expiration date ________," the blank being filled in with the date that is 24 months after the month during which the batch was certificated: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing a list of contraindications and possible sensativities adequate for the use of such drug by practitioners licensed by law to administer it, or a reference to a brochure or other printed matter containing such information and a statement that such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(iii) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) Request for certification, samples.

(1) In addition to complying with the requirements of §146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the date on which such packages were manufactured, and (unless it was previously submitted) the date on which the latest assay of the chlorotetracycline used in making the batch was completed, the quantity of each ingredient used in making such batch, the date on which the latest assay of the drug comprising such batch was completed, and that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request results of the tests and analyses listed after each of the following:

(i) The batch: Average potency per gram, sterility, and moisture.

(ii) The chlorotetracycline used in making the batch. Potency, toxicity, use by man, and identity.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request results of the tests and analyses listed after each of the following:

(i) The batch: For all tests except sterility 1 immediate container for each 5,000 milligrams of drug contained in the batch, but in no case less than 5 or more than 12 immediate containers.

(b) For sterility testing: 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlorotetracycline used in making the batch: 5 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of §146.c.201 (b)

(iii) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each component of the ointment base, each containing approximately 200 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no same reference for subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

$5.00 for each package in the samples submitted in accordance with paragraph (d) (1) (a), (d), and (iii) of this section.

$10.00 for each package in the samples submitted in accordance with §146.3 (d) of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with §146.8 (d) of this chapter.

PART 146d—CERTIFICATION OF CHLORAMPHENICOL AND CHLORAMPHENICOL-CONTAINING DRUGS

Sec. 146d.301 Chloramphenicol.

146d.302 Chloramphenicol capsules.

146d.303 Chloramphenicol ointment.

146d.304 Chloramphenicol ophthalmic.

146d.305 Chloramphenicol palmitate.

146d.306 Chloramphenicol palmitate oral suspension.

146d.307 Chloramphenicol solution; chloramphenicol for aqueous injections.

146d.308 Chloramphenicol otic; chloramphenicol topical.

146d.309 Chloramphenicol — streptomycin capsules; chloramphenicol-dihydrostreptomycin capsules.

146d.310 Chloramphenicol — streptomycin oral suspension.

146d.311 Chloramphenicol palmitate-streptomycin oral suspension; chloramphenicol palmitate-dihydrostreptomycin oral suspension.

veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions for use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions for use by veterinarians licensed by law to administer such drug.

(iii) If it is intended to comply with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such request is covered by an advance deposit: it maintained in accordance with § 146.3 of this chapter.

§ 146d.308 Chloramphenicol capsules

(a) Standards of identity, strength, purity, and quality. Chloramphenicol capsules are capsules composed of chloramphenicol, with or without the addition of one or more suitable and harmless diluents, lubricants, colorings, and stabilizers. Each capsule contains at least 50 milligrams of chloramphenicol. The chloramphenicol used conforms to the requirements prescribed therefor in the official compendium.

(b) Potency. Unless each chloramphenicol capsule is enclosed in a foil or plastic film and such enclosure is conspicuously so labeled, adequate directions and possible sensitization warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Request for certification, check tests and assays; samples. (1) In addition to complying with the requirements of § 146d.301 of this chapter, a person who requests certification of a batch of chloramphenicol shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of grams in each package, and the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied by a request for an advance deposit, the amount of which shall be calculated on the basis of the cost of such investigations. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than 8 immediate containers or more than 15 immediate containers.

(3) If such batch is not packaged for repackaging or for use as an ingredient in the manufacture of another drug, such person shall submit with his request a sample containing ten approximately equal portions of at least one million grams of the drug comprising such batch, each taken from different parts of such batch; each such portion shall be packaged in a separate container, and in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches of chloramphenicol or batches of another drug in which chloramphenicol is a component, such person shall submit with his request the number of milligrams in each capsule of the batch.

(c) Labeling. Each package of chloramphenicol capsules shall bear, on its label or packaging, such information as hereinafter indicated, the following: (i) The name of the drug; (ii) The batch mark; (iii) The number of milligrams in each capsule of the batch; and (iv) The statement: "Expiration date", the blank being filled in with the date within which the batch was completed, which shall not be more than 5 years after the expiration date, if any, furnished by the manufacturer.

(d) Requests for certification, check tests and assays; samples. (1) In addition to complying with the requirements of § 146d.301 of this chapter, a person who requests certification of a batch of chloramphenicol capsules shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark, the number of milligrams in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the chloramphenicol used in making such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided by subparagraph (2) of this paragraph, such person shall submit in connection with his request suitable tests and batches made after each of the following dates, whichever is later, in an accurately representative sample of:

(i) The batch; average potency per capsule.

(ii) The chloramphenicol used in making the batch; potency, toxicity, specificity, rotation, melting point, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (2) of this paragraph, such person shall submit in connection with his request suitable tests and batches made after each of the following:

(i) The batch; one capsule for each 5,000 capsules in the batch, in no case less than 20 capsules or more than 500 capsules, collected by selecting equal proportions of capsules at such intervals over the entire time of preparation that the quantities encapsulated during the intervals are approximately equal.

(ii) The chloramphenicol used in making the batch; ten packages, each containing approximately equal portions of

(e) Fees. The fee for the services rendered with respect to each batch under this section shall be:

(1) $10.00 for each immediate container in the sample submitted. Provided, however, that such fee shall be reduced to an amount proportionate to the size of such batch.

(2) In connection with contemplated requests for certification of a batch of chloramphenicol capsules, each package shall be accompanied by a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.
not less than 300 milligrams each, packaged in accordance with the requirements of § 146d.303 of this chapter.

(iii) In case of an initial request for certification, each diluent, lubricant, coloring, and flavoring used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch of chloramphenicol capsules under the regulations in this part shall be:

(1) $1.00 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsules and packages, are necessary to determine whether or not such batch complies with the requirements of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by a deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.303 Chloramphenicol ointment (chloramphenicol cream)—(a) Standards of identity, strength, quality, and purity. Chloramphenicol ointment is chloramphenicol in a suitable and harmless ointment base, with or without suitable and harmless buffer substances, dispersing and suspending agents. It may contain cortisone or a suitable derivative of cortisone. If such base is water-miscible, after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such ointment base is water-miscible issued in accordance with paragraph (d) (3) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(iii) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(d) Request for certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, each person who requests certification of a batch of chloramphenicol ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark; and (unless it was previously submitted) a certificate on which the latest assay of the chloramphenicol used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request the results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(1) The batch; average potency per gram.

(ii) The chloramphenicol used in making the batch; potency, toxicity, pH, specific rotation, melting point, and cistion coefficient.

(iii) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(a) The batch, 1 package for each 5,000 packages in the batch, but in no case less than 5 packages or more than 15 packages if it is packaged in immediate containers of 10 grams, or more than 20 immediate containers if it is packaged in immediate containers of 12.5 grams, except if cortisone or a derivative of cortisone is used, such package shall contain approximately 100 milligrams.

(b) Chloramphenicol ointment used in making the batch: 10 packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146d.301 (b) (1) (ii).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 10 grams, except if cortisone or a derivative of cortisone is used, such package shall contain approximately 100 milligrams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each multiple-dose package that $1.00 for each single-dose container in the sample submitted in accordance with paragraph (d) (3) (i) of this section, and $4.00 for each pack of the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance
of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such batch is covered by an advance deposit maintained in accordance with § 1463.2 (d) of this chapter.

§ 1463.304 Chloramphenicol ophthalmic—(a) Standards of identity, strength, quality, and purity. Chloramphenicol ophthalmic is chloramphenicol, with or without one or more suitable and harmless preservatives, buffer substances, and diluents. It may contain cortisone or hydrocortisone, or a suitable ester of cortisone or hydrocortisone. It is sterile.

The chloramphenicol is of such quantity that when prepared as directed in its labeling the potency of such solution or suspension is not less than 1.0 milligram per milliliter and maintains its labeled potency after it has been kept for 10 days at room temperature. Such solution or suspension has a pH of 7.3±0.2. The chloramphenicol used conforms to the requirements of § 1463.301 (a), except subparagraphs (4), (5), and (6) of the section. Each ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. The immediate container of chloramphenicol ophthalmic shall be a tight container as defined by the U. S. P. Its closure shall be such one through which a hypodermic needle cannot be introduced. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container may be packaged in combination with a container of the solvent, sterile distilled water U. S. P.

(c) Labeling. Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) The batch mark and the immediate container.

(2) The number of milligrams of chloramphenicol in the immediate container.

(i) The statement "Expiration date _______," the blank being filled in with the date which is 60 months after the month during which the batch was certified: Provided, however That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(ii) If it is packaged in combination with a container of a solvent the statement "Warning—Not for injection.

(iii) The number of milligrams of each such substance.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing only for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for veterinary use, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) for such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(2) On the circular or other labeling within or attached to the package, if it is intended for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the layman. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to each veterinarian on request.

(iii) On the label and labeling, if it contains one of the active ingredients specified in paragraph (a) of this section, after the name "chloramphenicol ophthalmic," wherever it appears, the name of the ingredient in juxtaposition with such name.

(d) Request for certification: samples. (1) In addition to complying with the requirements of § 1462 of this chapter, a person who requests certification of a batch of chloramphenicol ophthalmic shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the size of each package and the number (if any) submitted) the date on which the latest assay of the chloramphenicol used in making such batch was completed, the number of milligrams of chloramphenicol in each immediate container, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each other ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section. If the batch mark and the immediate container and closure conform to the requirements prescribed therefor by this section, the batch shall comply with the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit in connection with his request for such batch, such samples as otherwize provided by § 1463.801 immedic cow in the batch; such packages each containing approximately 5.0 grams, except if cortisone acetate is used, such packages shall contain approximately 100 milligrams.

(3) No result referred to in subparagraph (2) (i) of this paragraph, and no sample referred to in subparagraph (2) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) § 1463.305 Chloramphenicol ophthalmic—(a) Standards of identity, strength, quality, and purity. Chloramphenicol ophthalmic is the white to grayish, tasteless, crystalline palmitate of chloramphenicol. It is both purified and dried that:

(1) It contains not less than 555 micrograms of chloramphenicol per milligram.

(2) It is nontoxic.
The chloramphenicol used conforms to the requirements of § 146d.301 (a) except subparagraphs (2) (4) and (5) of that paragraph.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146d.305 (d) of that chapter.

§ 146d.306 Chloramphenicol palmitate oral suspension—(a) Standards of identity, strength, quality, and purity. Chloramphenicol palmitate oral suspension is chloramphenicol palmitate and one or more vitamin substances, suspending agents, preservatives, colorings, and flavorings, with or without one or more suitable and harmless vitamin substances, suspended in a suitable and harmless vehicle. It contains not less than 30 milligrams of chloramphenicol per milliliter. Its pH is not less than 4.5 and not more than 7.0. The chloramphenicol palmitate used conforms to the requirements of § 146d.305 (a) Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of chloramphenicol palmitate shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(i) The batch mark.
(ii) The number of milligrams of chloramphenicol per milliliter.
(iii) The expiration date of each ingredient used in making the batch.
(iv) The statement “Expiration date _________,” the blank being filled in with the date which is 48 months after the month during which the batch was certified: Provided, however, That such expiration dates may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(d) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $0.50 for each immediate container submitted in accordance with paragraphs (d) and (e) of this section.

(2) $1.00 if each immediate container contains 5,000 individual packages in the batch, but in no case less than 5 or more than 12 packages, and if the information contained in the label, labeling, and container conforms to the requirements prescribed therefor by such compendium.

§ 146d.307 Chloramphenicol palmitate oral suspension—(a) Standards of identity, strength, quality, and purity. Chloramphenicol palmitate oral suspension is chloramphenicol palmitate and one or more vitamin substances, suspending agents, preservatives, colorings, and flavorings, with or without one or more suitable and harmless vitamin substances, suspended in a suitable and harmless vehicle. It contains not less than 30 milligrams of chloramphenicol per milliliter. Its pH is not less than 4.5 and not more than 7.0. The chloramphenicol palmitate used conforms to the requirements of § 146d.305 (a) Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of chloramphenicol palmitate oral suspension shall bear on its label or labeling, as hereinafter indicated, the following:

(i) The batch mark.
(ii) The number of milligrams of chloramphenicol per milliliter.
(iii) The expiration date of each ingredient used in making the batch.
(iv) The statement “Expiration date _________,” the blank being filled in with the date which is 48 months after the month during which the batch was certified: Provided, however, That such expiration dates may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(d) Reinspection. In addition to complying with the requirements of §§ 146d.301 and 146d.305 of this chapter, a person who requests certification of a batch shall submit with his request results of the tests and assays made on the batch mark, the number of packages of each size in such batch, the batch mark, and unless it was previously submitted, the date on which the latest assay of the chloramphenicol palmitate used in making such batch was completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and the statement that such ingredient conforms to the requirements prescribed therefor by this section.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $0.50 for each immediate container submitted in accordance with paragraphs (d) and (e) of this section.

(2) $1.00 if each immediate container contains 5,000 individual packages in the batch, but in no case less than 5 or more than 12 packages, and if the information contained in the label, labeling, and container conforms to the requirements prescribed therefor by such compendium.

§ 146d.310 Chloramphenicol palmitate oral suspension—(a) Standards of identity, strength, quality, and purity. Chloramphenicol palmitate oral suspension is chloramphenicol palmitate and one or more vitamin substances, suspending agents, preservatives, colorings, and flavorings, with or without one or more suitable and harmless vitamin substances, suspended in a suitable and harmless vehicle. It contains not less than 30 milligrams of chloramphenicol per milliliter. Its pH is not less than 4.5 and not more than 7.0. The chloramphenicol palmitate used conforms to the requirements of § 146d.305 (a) Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of chloramphenicol palmitate oral suspension shall bear on its label or labeling, as hereinafter indicated, the following:

(i) The batch mark.
(ii) The number of milligrams of chloramphenicol per milliliter.
(iii) The expiration date of each ingredient used in making the batch.
(iv) The statement “Expiration date _________,” the blank being filled in with the date which is 48 months after the month during which the batch was certified: Provided, however, That such expiration dates may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(d) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $0.50 for each immediate container submitted in accordance with paragraphs (d) and (e) of this section.

(2) $1.00 if each immediate container contains 5,000 individual packages in the batch, but in no case less than 5 or more than 12 packages, and if the information contained in the label, labeling, and container conforms to the requirements prescribed therefor by such compendium.

§ 146d.312 Chloramphenicol palmitate oral suspension—(a) Standards of identity, strength, quality, and purity. Chloramphenicol palmitate oral suspension is chloramphenicol palmitate and one or more vitamin substances, suspending agents, preservatives, colorings, and flavorings, with or without one or more suitable and harmless vitamin substances, suspended in a suitable and harmless vehicle. It contains not less than 30 milligrams of chloramphenicol per milliliter. Its pH is not less than 4.5 and not more than 7.0. The chloramphenicol palmitate used conforms to the requirements of § 146d.305 (a) Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of chloramphenicol palmitate oral suspension shall bear on its label or labeling, as hereinafter indicated, the following:

(i) The batch mark.
(ii) The number of milligrams of chloramphenicol per milliliter.
(iii) The expiration date of each ingredient used in making the batch.
(iv) The statement “Expiration date _________,” the blank being filled in with the date which is 48 months after the month during which the batch was certified: Provided, however, That such expiration dates may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(d) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $0.50 for each immediate container submitted in accordance with paragraphs (d) and (e) of this section.

(2) $1.00 if each immediate container contains 5,000 individual packages in the batch, but in no case less than 5 or more than 12 packages, and if the information contained in the label, labeling, and container conforms to the requirements prescribed therefor by such compendium.
(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (2) (1) and (ii) of this section.

(2) If the Commissioner considers that investigations other than examination of samples are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.307 Chloramphenicol solution; chloramphenicol for aqueous injection—

(a) Standards of identity, strength, quality, and purity. Chloramphenicol solution is chloramphenicol, with or without one or more suitable and harmless buffer substances, dissolved in one or more suitable and harmless solvents. Chloramphenicol for aqueous injection is a dry mixture of chloramphenicol and one or more suitable and harmless suspending agents, buffer substances, and preservatives. It is so purified that:

(1) If it is the solution of the drug, its potency is 250 milligrams per milliliter.
(2) It is sterile.
(3) It is nontoxic.
(4) It is nonpyrogenic.
(5) It contains no histamine nor histamine-like substances.
(6) If it is chloramphenicol solution, its pH is not less than 4.7 and not more than 8.0. If it is the dry mixture of the drug, the pH of a suspension prepared as directed in its labeling is not less than 4.5 and not more than 7.5.

Chloramphenicol used conforms to the requirements of § 146d.301 (a) Each other ingredient used in making the batch, its labeling shall be in accordance with the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents can not be used without destroying the seal, and shall be of such composition as will prevent any change in the strength, quality, or purity of the contents beyond any limit thereunder in applicable standards, except that minor changes so caused which are normal and unavoidable, and which do not affect the dosage and dose and dilution practice shall be disregarded. In case it is packaged for dispensing and if it is the solution of the drug, it shall be in colorless, transparent glass ampuls, each of which shall contain 2.0 milliliters. If it is packaged for dispensing and it is the dry mixture of the drug, it shall be in colorless, transparent glass ampuls, each of which shall contain 2.0 milligrams of chloramphenicol.

(c) Labeling. Each package shall bear on its label or labeling as hereinafter indicated:

(1) On the outside wrapper or container and the immediate container:
(1) The batch mark.
(2) If it is the solution of the drug, the number of milligrams of chloramphenicol in each milliliter of the batch; and if it is the dry mixture of the drug, the number of grams of chloramphenicol in each immediate container.
(3) The statement "Expiration date ______," the blank being filled in with the date which is 12 months after the month during which the batch was certified if it is the solution of the drug, or 48 months after the month in which the batch was completed, the batch mark, the number of milligrams or grams in each of such immediate containers.

(2) In the case of an initial request for certification, each other ingredient used, if its name is recognized by the U. S. P. or N. F., conforms to the requirements prescribed therefor by such official compendium.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(4) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) (1) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.
(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations, other than examination of such immediate containers, is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.308 Chloramphenicol otic; chloramphenicol topical—(a) Standards of identity, strength, quality, and purity. Chloramphenicol otic and chloramphenicol topical is chloramphenicol, with or without ethylaminobenzoate, in a suitable and harmless vehicle. The potency of the solution is not less than 5 milligrams per milliliter. Its moisture content is not more than 2 percent. Its pH is not less than 4 and not more than 8.

The chloramphenicol used conforms to the requirements of § 146d.301 (a) except subparagraphs (2) (d) and (3) of that paragraph. Each ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Each immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The name of the batch.

(ii) The milligrams of chloramphenicol, and if it contains ethylaminobenzoate, the quantity of such ingredient in each milliliter of the batch.

(iii) The statement "Expiration date----------." The blank being filled in with the date which is 12 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is a single immediate container or more than 100 immediate containers or more than 2 immediate containers and more than 100 immediate containers collected in an individual wrapper or container.

(iv) The statement "Warning—For external use only." (2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information concerning contraindications and possible sensitization adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(iii) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) Request for certification, samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the date on which the latest assay of the chloramphenicol used in making the batch was completed, the specific rotation, melting point, and expiration date of the solution is not less than 125 milligrams of chloramphenicol, unRussian.

(ii) Per capsule contains not less than 125 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standard prescribed therefor by § 146b.101 (a) of this chapter, except subparagraphs (2) and (4) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103 of this chapter, except for standards for sterility and pyrogens.

(3) Its moisture content is not more than 5 percent.

(4) The sale of the labeling prescribed for chloramphenicol capsules by § 146d.302 (c) (1) (ii) and (iii) each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of chloramphenicol and the number of milligrams of streptomycin or dihydrostreptomycin in each capsule and the statement of expiration date of the batch shall bear on the outside wrapper or container the date which is 24 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is a single immediate container or more than 100 immediate containers collected in an individual wrapper or container.

(5) In addition to complying with the requirements of § 146d.302, each person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the date on which the latest tests and the date of the latest tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, moisture, and pH.

(ii) The chloramphenicol used in making the batch; potency, toxicity, pH, specific rotation, melting point, and expiration date.

(iii) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(a) Chloramphenicol capsules; chloramphenicol-dihydrostreptomycin capsules. (b) Chloramphenicol capsules; chloramphenicol-dihydrostreptomycin capsules conform to all requirements prescribed by § 146d.302 for chloramphenicol capsules, and are subject to all procedures prescribed by § 146d.302 for chloramphenicol capsules, except that:

(1) Each capsule contains not less than 125 milligrams of chloramphenicol, unRussian.

(ii) Per capsule contains not less than 125 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standard prescribed therefor by § 146b.101 (a) of this chapter, except subparagraphs (2) and (4) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103 of this chapter, except for standards for sterility and pyrogens.

(3) Its moisture content is not more than 5 percent.

(4) The sale of the labeling prescribed for chloramphenicol capsules by § 146d.302 (c) (1) (ii) and (iii) each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of chloramphenicol and the number of milligrams of streptomycin or dihydrostreptomycin in each capsule and the statement of expiration date of the batch shall bear on the outside wrapper or container the date which is 24 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is a single immediate container or more than 100 immediate containers collected in an individual wrapper or container.

(5) In addition to complying with the requirements of § 146d.302, each person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the date on which the latest tests and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch.
for potency, toxicity, histamine content, moisture, pH, streptomycin content, if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate. He shall also submit in connection with his request a sample consisting of not less than 5 packages each containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(d) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed therefor by this section shall be $10.00.

§ 146d.310 Chloramphenicol tablets.
Chloramphenicol tablets are tablets that conform to all requirements and are subject to all procedures prescribed by § 146d.305 for chloramphenicol capsules, except that the expiration date of such tablets shall be 24 months after the month during which the batch was certified.

§ 146d.311 Chloramphenicol palmitate-streptomycin oral suspension. Chloramphenicol palmitate-streptomycin oral suspension and chloramphenicol palmitate-dihydrostreptomycin suspension conform to all requirements and are subject to all procedures prescribed by § 146d.306 for chloramphenicol palmitate oral suspension, except that:

(a) It contains not less than 30 milligrams of streptomycin or dihydrostreptomycin per milliliter. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except § 146b.101 (a) (3) and (6).

(b) The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.105 of this chapter, except that the expiration date of the batch shall be 24 months after the month during which the batch was certified.

(c) In addition to complying with the requirements of § 146d.306 (d) a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the results and date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, histamine content, pH, streptomycin if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin. He shall also submit in connection with his request a second sample consisting of not less than 6 packages of the batch and (unless it was previously submitted) a sample consisting of not less than 5 packages each containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements prescribed therefor by this section.

Part 146e—Certification of Bacitracin and Bacitracin-Containing Drugs

Sec. 146e.401 Bacitracin.
146e.402 Bacitracin ointment; zinc bacitracin ointment.
146e.403 Bacitracin tablets; zinc bacitracin tablets.
146e.404 Bacitracin troches; zinc bacitracin troches.
146e.405 Bacitracin with vasoconstrictor; bacitracin-vasoconstrictor troches.
146e.406 Bacitracin-tyrothricin troches; zinc bacitracin-tyrothricin troches.
146e.407 Bacitracin-tyrothricin ointment; zinc bacitracin-tyrothricin ointment.
146e.408 Bacitracin neomycin ointment.
146e.409 Bacitracin-polymyxin ointment.
146e.410 Bacitracin-neomycin tablets; zinc bacitracin-neomycin tablets.
146e.411 Bacitracin-acneymycin ointment; zinc bacitracin-acneymycin ointment.
146e.412 Bacitracin-polymyxin tablets.
146e.413 Bacitracin-acneymycin troches; zinc bacitracin-acneymycin troches.
146e.414 Bacitracin-acneymycin with vasoconstrictor; bacitracin-acneymycin with vasoconstrictor.
146e.415 Bacitracin-polymyxin troches; zinc bacitracin-polymyxin troches.
146e.416 Bacitracin-methylene dicaffeate.
146e.417 Powder bacitracin methylene dicaffeate and polymyxin sulfate oral veterinary.
146e.418 Zinc bacitracin.
146e.419 Bacitracin-acneymycin—polymyxin troches; zinc bacitracin-acneymycin—polymyxin troches.
146e.420 Bacitracin—tyrothricin—neomycin troches; zinc bacitracin—tyrothricin—neomycin troches.
146e.421 Bacitracin—neomycin—polymyxin troches.
146e.422 Bacitracin—polymyxin ointment.
146e.423 Soluble bacitracin methylene dicaffeate.
146e.424 Bacitracin—neomycin—polymyxin with vasoconstrictor; bacitracin—neomycin—polymyxin with vasoconstrictor.
146e.425 Bacitracin powder.
146e.426 Bacitracin-methylene dicaffeate and streptomycin sulfate oral veterinary.


§ 146e.401 Bacitracin—(a) Standards of identity, strength, quality, and purity. Bacitracin is a white to brown, neutral, water-soluble polypeptide. It is so purified and dried that:

(1) Its potency is not less than 50 units per milligram, except that if it is packaged for dispensing and it is intended for systemic medication its potency is not less than 50 units per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) Its moisture content is not more than 10 percent;

(6) Its pH in aqueous solution of 10,000 units per milliliter is not less than 5.5 and not more than 7.5.

§ 146e.402 Bacitracin ointment; zinc bacitracin ointment. All cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be tampered with, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefore in applicable standards, except that minor changes caused by normal and unavoidable in good packaging, storage, and distribution practices shall be disregarded.

In case it is packaged for dispensing, it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain not more than 60,000 units (unless it is intended solely for veterinary use and is conspicuously so labeled) and may be packaged in combination with a container of the solvent, water for injection U. S. P., physiological saline U. S. P., or with a container of an aqueous solution of a suitable local anesthetic.

(c) Labeling. Each package shall bear on its label or labeling as hereafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) If it is intended for systemic medication, the statement "For intramuscular use only".

The statement "Expiration date ————", the blank being filled in with the date which is 18 months after the month during which the batch was certified, except that it is labeled for repackaging or for use as an ingredient in the manufacture of another drug.

(2) On the outside wrapper or container:

(a) If it is intended for use by man, the statement "Caution: Federal law prohibits dispensing without prescription."

(b) If it is intended solely for veterinary use, and is conspicuously so labeled, the statement "Caution: Federal law restricts this drug to sale by
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or on the order of a licensed veterinarian.

(iii) If it is packaged for dispensing and it is intended for systematic medication the statement "Store in refrigerator not above 19° C. (66° F.)" or "Store below 15° C. (59° F.)"

(ii) On the outside wrapper or container, if it is packaged for dispensing, adequate directions for its use by practitioners licensed by law to administer such drug; the conditions under which such solutions should be stored, including a reference to their instability when stored out of the refrigerator, and the statement "Sterile solution may be kept in refrigerator for 1 week without significant loss of potency.

(d) Request for certification, check tests and assays; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of bacitracin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of units per container, and the date if it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by a description and sample made by him on the batch mark, potency, purity, pyrogens, moisture, and pH. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(a) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 6 or more than 10 immediate containers of each size and strength. If it is a powder, the statement "Expiration date and strength, quality, or purity of the container" shall be indicated, the following:

(b) Packaging. If it is bacitracin or zinc bacitracin, one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient per gram of the batch.

(c) Labelling. Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(1) The batch mark;

(2) The number of units per gram of the batch, or if it is a powder, the number of units per gram after the addition of the quantity of water recommended in this section.

(ii) For sterility testing;

(1) On the outside wrapper or container; and

(2) On the outside wrapper or container, if it is only for hospital use or otherwise.

(iii) If the batch contains, in addition to bacitracin or zinc bacitracin, one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient per gram of the batch.

(iv) The statement "Expiration date ___________," the blank being filled in with the date which is not more than 30 months after the month during which the batch was certified, except if it is zinc bacitracin ointment the blank is filled in with the date that is 24 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such ointment is packaged in an individual wrapper or container.

(v) If it is a powder, the statement "After the addition of water the ointment may be stored in refrigerator for 1 week without significant loss of potency."

(2) On the outside wrapper or container, if it is packaged for ophthalmic use by humans and it contains cortisone or a suitable derivative of cortisone, or one or more suitable sulfonamides, and, if it is intended solely for veterinary use and is conspicuously so labeled, one or more suitable antifungal agents or rotenone. Its potency is not less than 500 units per gram. Its moisture content is not more than 1 percent, except if it is a powder its moisture content is not more than 6 percent. The zinc bacitracin used conforms to the requirements of § 146e. 418 (a) The bacitracin used conforms to the requirements of § 146. 401 (a) except § 146e. 401 (a) (1) and (2), but its potency is not less than 500 units per milligram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) For sterility testing; 10 immediate containers.

Each such package shall contain approximately 100,000 units and shall be packaged in collapsible tubes, the batch shall be with closed containers as defined by the U. S. P. and which shall not be larger than the 2-ounce size, except if it is labeled solely for hospital use; but in no case shall such ointment be packaged in individual wrappers less than collapsible tubes. If it is labeled for ophthalmic use, and such tubes shall not be larger than the ½-ounce size. If it is a powder, it shall be packaged in individual containers of glass which meet the applicable standards for tight containers as defined by the U. S. P. The composition of the immediate container and closure shall be such as not to cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Fee. The fee for the services rendered with respect to each batch under the regulations in this part, shall be:

(1) $400 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (1) (2) and (4) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146e. 402 Bacitracin ointment; zinc bacitracin ointment.—(a) Standards of identity, strength, quality, and purity.

Bacitracin ointment and zinc bacitracin ointment are composed of bacitracin or zinc bacitracin in an unsensitizing base with one or more indigenous and harmless ointment base, or they are a powder composed of bacitracin or zinc bacitracin and one or more suitable and harmless diluents, dispersing agents, and preservatives. The statement "Expiration date ___________," the blank being filled in with the date which is not more than 30 months after the month during which the batch was certified; Provided, however, That such expiration date may be omitted from the immediate container if such ointment is packaged in an individual wrapper or container.

(1) If it is a powder, the statement "After the addition of water the ointment may be stored in refrigerator for 1 week without significant loss of potency."

(2) On the outside wrapper or container, if it is packaged for ophthalmic use by humans or if it is intended for use by humans and it contains cortisone or a suitable derivative of cortisone, or one or more suitable sulfonamides, the statement "Caution: Federal law prohibits dispensing without prescription" and reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such ointment by practitioners licensed by law to administer such drug; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or printed matter will be sent on request: Provided, however, That such reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.
(3) On the outside wrapper or container, if it is intended solely for veterinary use and it contains fluorocorticosteroids (9α-fluorohydrocortisone) the statement, "Veterinarian or Federal Law requires this drug to be sold by or on the order of a licensed veterinarian" and a reference specifically identifying a readily available point of sale within or attached to the package, containing information (including contraindications and possible sensitization) adequate for the use of such ointment by practitioners licensed by law to administer such drug; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or printed matter will be sent on request: Provided, however, that this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the label or labeling, if it contains, in addition to bacitracin or zinc bacitracin, one or more other active ingredients specified in paragraph (a) of this section, after the name "bacitracin ointment" or "zinc bacitracin," wherever such name appears, the words "contains cortisone or a derivative of cortisone," if it contains cortisone or one or more sulfonamides, or if it is intended solely for veterinary use, or unless it contains an anti-fungal agent, rotenone, cortisone or one or more sulfonamides, or if it contains cortisone or a derivative of cortisone, appropriate directions and warnings for prophylactic use in humans or for the veterinary use of such ointment.

(5) On a circular or other labeling within or attached to the package, unless it is packaged for ophthalmic use in humans or is intended for human use and contains cortisone or a derivative of cortisone or one or more sulfonamides, or if it is intended for veterinary use and it contains fluorocorticosteroids (9α-fluorohydrocortisone), adequate directions and warnings for prophylactic use in humans or for the veterinary use of such ointment. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other uses of such ointment by practitioners licensed by law to administer such drug will be sent to such practitioner on request.

(d) Requests for certification; samples.

(1) In addition to complying with the requirements of § 146.401 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the exact name, the number of packages of each size in such batch, the batch number and, unless it was previously submitted, the date on which the latest assay of the batch was completed, the quantity of each ingredient used in making such batch and, if applicable, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (d) of this paragraph, each package shall contain in connection with his request, the quantity, character and description of each active ingredient, and a statement identifying the batch, the quantities packaged during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less than 500 milligrams, packaged in accordance with the requirements of § 146.401(b).

(iii) The zinc bacitracin used in making the batch; five packages, each containing approximately equal portions of not less than 1.0 gram, packaged in accordance with the requirements of § 146.418(b).

(iv) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing not less than 500 grams, except if cortisone or a derivative of cortisone is used, such package shall contain approximately 100 milligrams.

(4) No request referred to in subparagraph (2)(ii) of this paragraph, and no sample referred to in subparagraphs (3)(i)(ii) or (iii) of this paragraph, is required if such result or sample has been previously submitted.

(f) Fees. The fee for the certificates rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3)(i)(ii), (iii), and (iv) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for license of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (d) of this paragraph shall accompany the request for certification unless such fee is covered by advance deposit maintained in accordance with § 146.5(d) of this chapter.

(5) Exemption of bacitracin ointment from certification. Bacitracin ointments that conform to the requirements of paragraphs (a) and (b) of this section, except paragraph (c) (1)(iv) of this section, shall be exempt unless it contains one or more active ingredients as defined in paragraph (a) or it contains an anti-fungal agent, rotenone, cortisone or a derivative of cortisone from the requirements of sections 502(1) and 507 of this act, if it complies with the following conditions:

(1) The outside wrapper or container and the immediate container bear an expiration date not more than 36 months after the month during which the batch was last assayed and released by the manufacturer; and

(2) It is intended for use by man and is packaged for ophthalmic use, or it contains one or more sulfonamides and the brochure, printed matter, and circular referred to in paragraph (2) of this section bear information for use of such drug only in the local treatment of superinfections caused by bacitracin-sensitive organisms; and further, that such brochure, printed material and circular be directions and warnings adequate for such use by practitioners licensed by law to administer such drug; or

(3) It is intended for use by man and it is not packaged for ophthalmic use nor contains one or more sulfonamides, or it is intended solely for veterinary use and is conspicuously so labeled; and its labeling bears information that the drug is for use only in the prevention of infection in minor cuts and abrasions and, further, bears directions adequate for such use by the laity and a statement that use of the drug shall be continued and a physician (if it is for human use) or a veterinarian (if it is for veterinary use) consulted if signs of irritation or infection appear.

146.401 Bacitracin tablets; zinc bacitracin tablets; bacitracin implanta- tions; zinc bacitracin suppositories (if they are represented for vaginal use) bacitracin implantation pellets; zinc bacitracin implantation pellets (if they are represented for use by implantation under the skin of animals)—(a) Standards of identity, strength, quality, and purity. Bacitracin tablets and zinc bacitracin tablets (if they are represented for use by implantation under the skin of animals) shall be tablets containing bacitracin or zinc bacitracin, with or without the addition of one or more suitable and harmless buffer substances, dyes, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 1,000 units nor more than 10,000 units. Its moisture content is not more than 5 percent. Unless it is represented to be used for inhalation therapy, the bacitracin used in making such tablets shall conform to the requirements of § 146.401(a) except subparagraphs (1) (2) and (4) of that paragraph. The zinc bacitracin used in making such impression shall conform to the requirements of § 146.418(a) except subparagraphs (2) and (4) of that paragraph. The zinc bacitracin used in making such impression shall conform to the requirements of § 146.418(a) except subparagraphs (2) and (4) of that paragraph.

(b) Packaging. Unless each tablet is enclosed in a foil or plastic film and such enclosures are marked on the outside wrapper or container by the U.S. P. to conform to the standards prescribed therefor by such official compendium.

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strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package shall bear, on its label or labeling as hereafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) The statement “Expiration date—,” the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If it is implantation pellets, the statement “For veterinary use only.”

(2) On the outside wrapper or container:

(i) The statement “Caution: Federal law prohibits dispensing without prescription,” unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible adverse reactions) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(iii) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by practitioners licensed by law to administer it.

(iv) On the outside wrapper or container, the quantity is recognized in the National Formulary or other official compendium.

(b) Packaging. Unless each troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of troches shall bear, on its label or labeling as hereafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units of bacitracin or zinc bacitracin in the immediate container when such container is a plug or a film, or both, with the statement “For veterinary use only.”

(iii) The statement “Expiration date—,” the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: Provided, however, That this reference may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.3 (a) of this chapter.

§ 146.e.404 Bacitracin troches; zinc bacitracin troches—(a) Standards of identity, strength, quality, and purity. Bacitracin troches and zinc bacitracin troches are troches composed of bacitracin or zinc bacitracin and such other substance as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(b) Packaging. Unless each troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Labeling. Each package of troches shall bear, on its label or labeling as hereafter indicated, the following:

(i) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units of bacitracin or zinc bacitracin in the immediate container when such container is a plug or a film, or both, with the statement “For veterinary use only.”

(iii) The statement “Expiration date—,” the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: Provided, however, That this reference may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.3 (a) of this chapter.
(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the use of such troches. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other uses of such troches by practitioners licensed by law to administer such drug will be sent to such practitioner upon request.

(3) Certification; samples. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin or zinc bacitracin used in making such batch was completed, the number of units in each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of the troches comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (d) of this paragraph, each immediate container shall be labeled with an immediate container of a packaged combination, a statement that distilled water U.S.P. should be used;

(ii) The potency for milliliter after the bacitracin has been dissolved therefrom;

(iii) The statement "Expiration Date ________ (the blank being filled in with the common or usual name of the bacitracin)" (a) Standards of identity, strength, quality, and purity. Bacitracin with vasoconstrictor is a dry mixture of bacitracin and a suitable vasoconstrictor, with or without suitable buffer substances, preservatives, colorings, and flavorings, or it is a packaged combination of one immediate container of bacitracin and one immediate container of a solution of a suitable vasoconstrictor, with or without suitable and harmless buffer substances, preservatives, colorings, and flavorings. The bacitracin is of such quality that directed the potency of such solution is not less than 200 units per milliliter, and maintains its labeled potency after it has been kept at room temperature. Such solution is isotonic, and has a pH of 6.0 ± 0.5. The moisture content of the dry mixture of bacitracin with vasoconstrictor is not more than 5 percent. The bacitracin used conforms to the requirements of § 146.401 (a) except subparagraphs (2) and (d) of that paragraph. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Each immediate container shall be a tight, airtight container as defined by the U.S.P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit thereof in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate container of the dry mixture of bacitracin with vasoconstrictor may be packaged in combination with an immediate container of a suitable diluent.

(c) Labeling. Each package of bacitracin with vasoconstrictor shall bear on its label or labeling, as hereinafter indicated:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) If it is a packaged combination of one immediate container of bacitracin and one immediate container of a vasoconstrictor, the statement "Expiration date ________" (the blank being filled in with the date which is 12 months after the month during which the batch was certified. If it is the dry mixture of bacitracin with vasoconstrictor, the statement "Expiration date ________" (the blank being filled in with the date which is 12 months after the month during which the batch was certified. Such expiration dates may be omitted when the immediate container is a combination of one immediate container of bacitracin and one immediate container of a solution of a suitable vasoconstrictor, if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container and on the immediate container of the solution in the packaged combination:

(i) A statement giving the method of dissolving the bacitracin and, if it is not a packaged combination, a statement that distilled water U.S.P. should be used;

(ii) The potency for milliliter after the bacitracin has been dissolved therefrom;

(iii) The statement "Expiration Date ________ (the blank being filled in with the common or usual name of the bacitracin)" (a) Standards of identity, strength, quality, and purity. Bacitracin with vasoconstrictor is a dry mixture of bacitracin and a suitable vasoconstrictor, with or without suitable buffer substances, preservatives, colorings, and flavorings, or it is a packaged combination of one immediate container of bacitracin and one immediate container of a solution of a suitable vasoconstrictor, with or without suitable and harmless buffer substances, preservatives, colorings, and flavorings. The bacitracin is of such quality that directed the potency of such solution is not less than 200 units per milliliter, and maintains its labeled potency after it has been kept at room temperature. Such solution is isotonic, and has a pH of 6.0 ± 0.5. The moisture content of the dry mixture of bacitracin with vasoconstrictor is not more than 5 percent. The bacitracin used conforms to the requirements of § 146.401 (a) except subparagraphs (2) and (d) of that paragraph. Each other substance used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging. Each immediate container shall be a tight, airtight container as defined by the U.S.P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit thereof in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate container of the dry mixture of bacitracin with vasoconstrictor may be packaged in combination with an immediate container of a suitable diluent.

(c) Labeling. Each package of bacitracin with vasoconstrictor shall bear on its label or labeling, as hereinafter indicated:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) If it is a packaged combination of one immediate container of bacitracin and one immediate container of a vasoconstrictor, the statement "Expiration date ________" (the blank being filled in with the date which is 12 months after the month during which the batch was certified. If it is the dry mixture of bacitracin with vasoconstrictor, the statement "Expiration date ________" (the blank being filled in with the date which is 12 months after the month during which the batch was certified. Such expiration dates may be omitted when the immediate container is a combination of one immediate container of bacitracin and one immediate container of a solution of a suitable vasoconstrictor, if such immediate container is packaged in an individual wrapper or container.
request a statement showing the
batch mark, the number of pack-
ages in each batch, the number of units
in each immediate container, and (unless it was previously submitted) the date on
which the latest assay of the bacitracin
included in each batch was completed,
the quantity of each ingredient used in
making the batch of the dry mixture of bacitracin with vasoconstrictor, the
quantity of each ingredient used in mak-
ing the solution included in the pack-
aged combination, and a statement that
such solution conforms to the require-
ments prescribed therefor by this sec-
tion.
(ii) When any change is made in the
com-
position of such package, are necessary to
determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such in-
vestigations.

The fee prescribed by subparagraph (1)
of this paragraph shall accompany the
request for certification unless such fee is
covered by an advance deposit maint-
ained in accordance with § 146.8 (d) of
this chapter.

§ 146e.406 Bacitracin-tyrothricin troches; zinc bacitracin-tyrothricin troches. (a) Bacitracin-tyrothricin troches and zinc bacitracin-
trachel roches conform to all requirements and are subject to all procedures prescribed by § 146e.404 for bacitracin troches and zinc bacitracin troches, except that:
 each troche contains not less than 5 milligrams of bacitracin or zinc bacitracin.
 Each troche contains not less than
1 milligram of tyrothricin.
 Each troche may be tabletted with
or without ethyl ammoniumzoate.

(b) In lieu of the directions prescribed for bacitracin troches and zinc bacitracin troches by § 146e.404 (a) (i), (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of bac-
itracin or zinc bacitracin and the number
of milligrams of tyrothricin and ethyl ammoniumzoate in each troche of the batch.

§ 146e.407 Bacitracin-tyrothricin ointment. (a) Bacitracin-tyrothricin ointment conforms to all requirements prescribed by § 146e.402 for bacitracin ointment, and is subject to all procedures prescribed by § 146e.402 for bacitracin ointment, except paragraph (1) of that section, and except that:
 (1) It contains not less than 0.5 mill-
gram of tyrothricin per gram of oint-
ment.

(b) In lieu of the directions prescribed for bacitracin ointment by § 146e.402 (a) (i), (ii) each package shall bear on the outside wrapper or container and on the immediate container the number of units of bacitracin and the number of milligrams of tyrothricin in each gram of the batch.

§ 146e.408 Bacitracin ophthalmic—
(a) Standards of identity, strength,
quality, and purity. Bacitracin ophthal-
mic is bacitracin, with or without one or
more suitable and harmless preserva-
tives, local anesthetics, buffer substances,
and diluents. It is sterile. Its moisture
content is not more than 5 percent. The
bacitracin is of such quantity that when
dissolved as directed in its labeling the
potency of such solution is not less than
500 units per milliliter and maintains its
labeled potency after it has been kept for
7 days at room temperature. Such solu-
tion must have a pH of 6.6±0.5. The
bacitracin used conforms to the require-
ments of § 146e.401 (a), except subparagraphs (2) and (4) of that paragraph.

Fees. The fee for the services rendered with respect to each batch of bacitracin with vasoconstrictor under the regulations in this part shall be:

(1) $25 for each immediate container
submitted in accordance with paragraph (d) (1), (ii), (ii), (iii), and (iv) of this section.

(2) If the Commissioner considers
that investigations other than examina-
tion of such packages, are necessary
to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such in-
vestigations.

The fee prescribed by subparagraph (1)
of this paragraph shall accompany the
request for certification unless such fee is
covered by an advance deposit maint-
ained in accordance with § 146.8 (d) of
this chapter.
(3) On the label or labeling, if a local anesthetic is prescribed, the name of the local anesthetic—"bacitracin-neomycin.-" wherever it appears, the words "with ________" (the blank being filled in with the common or usual name of the local anesthetic), in juxtaposition to the name, is conspicuous so labeled.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement of the name of a brochure or other printed matter containing information for other veterinary uses of such drug by the veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) Requests for certification; samples. (1) In addition to complying with the requirements of § 146e.402 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of each immediate container, the date on which the batch was completed, the number of units made up in each immediate container, the date on which the latest assay of the bacitracin used in making such batch was completed, the number of each other ingredient used in making the batch, and a statement that such batch was made up in accordance with the requirements prescribed therefor by this section. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request the results of the tests and assays listed after each of the following, made by him on an accurately representative sample:

(i) The batch; potency, sterility, moisture, and pH of the solution prepared as directed in its labeling.

(ii) The bacitracin used in making the batch; potency, toxicity, moisture, and pH of the solution prepared as directed in its labeling.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request the results of the tests and assays listed after each of the following, made by him on an accurately representative sample:

(i) The batch: potency, sterility, moisture, and pH.

(ii) The bacitracin used in making the batch: potency, toxicity, moisture, and pH.

(4) In lieu of the labeling prescribed by § 146e.402 (c) (1) (ii) and (iv), each package shall bear on the outside wrapper or container and on the immediate container the number of units of bacitracin and the number of units of polymyxin B in each gram of the batch and the statement "Expiration date: ________", the name and title of the individual who certifies that the batch was made in accordance with the standards of identity, strength, quality, and purity prescribed for the drug, the batch shall be filled in with the date on which the batch was completed, 36 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(5) In addition to complying with the requirements of § 146e.402 (c) (1) (ii) and (iv), each package shall bear on the outside wrapper or container and the immediate container, the statement "Shake well" and "For injection."

(6) In addition to complying with the requirements of § 146e.402 (d), a person who requests certification of a batch of the Bacitracin-neomycin tablets and zinc bacitracin-neomycin tablets, shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays of the polymyxin used in making the batch for potency and toxicity. He shall also submit in connection with his request a sample consisting of not less than 5 packages of the drug conforming to all requirements prescribed therefor by this section, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146e.403 of this chapter.

§ 146e.403 Bacitracin-polymyxin ointment. (a) Bacitracin-polymyxin ointment conforms to all requirements prescribed by § 146e.402 for bacitracin ointment, and is subject to all procedures prescribed by § 146e.402 for bacitracin ointment, except paragraph (4) of that section, and except that:

(1) Its content of bacitracin is not less than 200 units per gram.

(2) It contains not less than 4,000 units of polymyxin B. The polymyxin B used conforms to the requirements prescribed for polymyxin B by § 146b.107 of this chapter.

(3) Its moisture content is not more than 0.5 percent.

(4) If it is in liquid form, it shall be packaged in transparent containers of not less than 33 milligrams of neomycin. The neomycin used is produced by the growth of Streptomyces fradiae, has a potency of not less than 330 micrograms (one Waksman unit is equivalent to 3.3 micrograms of the base) per milligram, is non-toxic, has a moisture content of not more than 5 percent, and its pH in an aqueous solution 33 milligrams per milliliter is not less than 5.0 and not more than 7.5.

(5) In lieu of the labeling prescribed by § 146e.403 (c) (1) (ii) and (iv), each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin and the number of units of polymyxin B in each gram of the batch and the statement "Expiration date: ________", the name and title of the individual who certifies that the batch was made in accordance with the standards of identity, strength, quality, and purity prescribed for the drug, the batch shall be filled in with the date on which the batch was completed, 36 months after the month during which the batch was certified: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(6) In addition to complying with the requirements of § 146e.403 (c) (1) (ii) and (iv), each package shall bear on the outside wrapper or container and the immediate container, the statement "Shake well" and "For injection."

(7) In addition to complying with the requirements of § 146e.403 (d), a person who requests certification of a batch of Bacitracin-polymyxin ointment, shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays.
of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a statement showing the number of units of bacitracin used in each package and the immediate container the number of units of polymyxin B in each package of the batch.

(b) The fee for the services rendered with respect to each package of the sample submitted in accordance with paragraph (c) of this section shall be $4.00.

§ 146e.412 Bacitracin-polymyxin tablets. (a) Bacitracin-polymyxin tablets conform to all requirements prescribed by § 146e.403 for bacitracin tablets, and are subject to all procedures prescribed by § 146e.403 for bacitracin tablets except that:

(1) Each tablet contains not less than 400 units of bacitracin.

(2) Each tablet contains not less than 8,000 units of polymyxin B sulfate. The polymyxin B used conforms to the requirements prescribed for polymyxin by § 146e.107 (a) of this chapter.

(3) In lieu of the labeling prescribed for bacitracin tablets by § 146e.403 (c) (1) and (ii), each package shall bear on the outside wrapper or container the statement "Expiration date ______," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time.

(4) In addition to the labeling prescribed by § 146e.403 (d) a person who requests certification of a batch shall submit with his request a sample consisting of not less than 30 tablets of such batch, and (unless it was previously submitted) the results and the date of the latest tests and assays of the polymyxin B used in making the batch for potency and toxicity.

He shall also submit in connection with his request a sample consisting of not less than 5 packages containing approximately equal portions of not less than 0.5 gram each of the neomycin used in making such batch.

(b) The fee for the services rendered with respect to each immediate container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.413 Bacitracin-neomycin troches, zinc bacitracin-neomycin troches. Bacitracin-neomycin troches and zinc bacitracin-neomycin troches conform to all requirements and are subject to all procedures prescribed by § 146e.410 for bacitracin tablets, except that:

(a) Each troche contains not less than 200 units of bacitracin or zinc bacitracin. The zinc bacitracin used conforms to the requirements prescribed by § 146e.118 (a), (b) and (c).

(b) Each troche contains not less than 2.5 milligrams of neomycin.

(c) Each troche may be tableted with or without one or more suitable and harmless local anesthetics, preservatives, and chemical antimicrobial agents.

(d) In addition to the labeling prescribed for bacitracin-neomycin tablets, if it contains one or more of the ingredients specified in paragraph (c) of this section, each package shall bear on the outside wrapper or container the number of units of polymyxin B in each package of the batch.

(e) If zinc bacitracin is used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than 6 packages of the bacitra-
bacitracin-polymyxin troches conform to the standards prescribed therefor by this section shall be $4.00.

§ 146e.415 Bacitracin-polymyxin troches; zinc bacitracin-polymyxin troches (a) Bacitracin-polymyxin troches and zinc bacitracin-polymyxin troches conform to all requirements and are subject to all procedures prescribed by § 146e.404 for bacitracin troches and zinc bacitracin troches, except that:

(a) Each troche contains not less than 50 units of bacitracin or zinc bacitracin.

(b) Each troche contains not less than 1,000 units of polymyxin B sulfate. The polymyxin B used conforms to the requirements prescribed for polymyxin by § 146b.107 (a) of this chapter.

(c) Each troche shall be labeled with or without one or more suitable and harmless local anesthetics, the name and quantity of each such ingredient in each troche of the batch.

(d) In addition to the labeling prescribed for troches and bacitracin troches, each package shall bear on its label or labeling the number of units of polymyxin B; and if it contains one or more local anesthetics, the name and quantity of each such ingredient in each troche of the batch.

(e) In addition to complying with the requirements of § 146e.404 (d) a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the polymyxin B used in making the batch for potency and toxicity. He shall also submit in connection with his request a sample consisting of not less than 50 troches and (unless it was previously submitted) a sample consisting of 5 packages, each containing approximately equal portions of not less than 500 million units of the polymyxin used in making the batch.

(f) The fee for the services rendered with respect to each container in the sample of polymyxin submitted in accordance with the requirements prescribed therefore by this section shall be $4.00.

§ 146e.416 Bacitracin methylene disalicylate—(a) Standards of identity, strength, quality, and purity. Bacitracin methylene disalicylate is a salt of bacitracin and methylenedisalicylate known as a mixture of bacitracin methylene disalicylate and streptomycin sulfate oral veterinary—(a) Standards of identity, strength, quality, and purity. Powder bacitracin methylene disalicylate and streptomycin sulfate oral veterinary—(a) is a mixture of bacitracin methylene disalicylate and streptomycin sulfate oral veterinary, with or without one or more suitable and harmless local anesthetics, the name of each, and the name and quantity of each such ingredient in each troche of the batch.

(b) Each troche contains not less than 20 milligrams of Streptomycin activity per gram; and the weight of the drug in the immediate container shall be tight containers shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(d) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(e) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(f) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(f) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(g) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(h) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(h) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(i) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(j) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(k) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(l) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(m) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(n) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(n) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(o) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(p) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(q) Late-t tests, the date of the late-t tests, and the weight of the drug in the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.
the latest assays of the bacitracin methylene disalicylate and streptomycin sulfate oral veterinary used in making such batch were completed, the quantity of each ingredient used in making the batch, the date on which the last assay of the drug comprising such batch was completed, and a statement that each other ingredient used conforms to the standards prescribed therefor by this chapter.

(2) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request results of the tests and analyses specified in subparagraph (4) of this paragraph, made by him on an accurately representative sample of:

(i) The batch; units of bacitracin activity per gram, milligram of streptomycin activity per gram, and moisture.

(ii) The bacitracin methylene disalicylate and the streptomycin sulfate oral veterinary used in making the batch; potency, toxicity moisture, and pH.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request results of the tests and analyses in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers or more than 12 immediate containers, unless each such container is packaged to contain more than 30 grams, in which case the sample shall consist of 30 grams for each 5,000 immediate containers in the batch, but in no case less than 6 30-gram portions or more than 1230-gram portions. Such samples shall be collected by taking single immediate containers or 30-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The bacitracin methylene disalicylate used in making the batch; 5 5.0 gram containers containing equal portions of not less than 5 grams each, packaged in accordance with the requirements of § 146e.410 (b).

(iii) The streptomycin sulfate oral veterinary used in making the batch; 5 packages containing approximately equal portions of not less than 1.6 gram each, packaged in accordance with the requirements of § 146e.114 (b) of this chapter.

(iv) In case of an initial request for certification, the other ingredients used in making the batch; 1 package of each contained in 100 0.1 gram containers of each size in the batch.

(4) No result referred to in subparagraph (2)(i) and (ii) of this paragraph, and no sample referred to in subparagraph (3)(i) and (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this chapter shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraphs (1)(i), (ii), (iii) and (iv) of this section.

(2) Such person shall also submit with his request an accurately representative sample of each package, consisting of 5 packages each containing approximately 1.0 gram taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(f) Packaging. The fee for the services rendered with respect to each batch under the regulations in this chapter shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) of this section.

4.00 per package. Such person shall submit in connection with his request results of the tests and analyses specified in subparagraph (4) of this paragraph, made by him on an accurately representative sample of:

(i) The batch; units of bacitracin activity per gram, milligram of streptomycin activity per gram, and moisture.

(ii) The bacitracin methylene disalicylate and the streptomycin sulfate oral veterinary used in making the batch; potency, toxicity moisture, and pH.

(3) Except as otherwise provided by subparagraph (d) of this paragraph, such person shall submit in connection with his request results of the tests and analyses in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers or more than 12 immediate containers, unless each such container is packaged to contain more than 30 grams, in which case the sample shall consist of 30 grams for each 5,000 immediate containers in the batch, but in no case less than 6 30-gram portions or more than 1230-gram portions. Such samples shall be collected by taking single immediate containers or 30-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The bacitracin methylene disalicylate used in making the batch; 5 5.0 gram containers containing equal portions of not less than 5 grams each, packaged in accordance with the requirements of § 146e.410 (b).

(iii) The streptomycin sulfate oral veterinary used in making the batch; 5 packages containing approximately equal portions of not less than 1.6 gram each, packaged in accordance with the requirements of § 146e.114 (b) of this chapter.

(iv) In case of an initial request for certification, the other ingredients used in making the batch; 1 package of each contained in 100 0.1 gram containers of each size in the batch.

(4) No result referred to in subparagraph (2)(i) and (ii) of this paragraph, and no sample referred to in subparagraph (3)(i) and (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this chapter shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraphs (1)(i), (ii), (iii) and (iv) of this section.

(2) Such person shall also submit with his request an accurately representative sample of each package, consisting of 5 packages each containing approximately 1.0 gram taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(f) Packaging. The fee for the services rendered with respect to each batch under the regulations in this chapter shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) of this section.
or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed therefor by paragraph (a) of this section: Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription."

(ii) If it is packaged for dispensing, a reference specifically identifying a readily available medical publication containing information (including contra-indications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: Provided, however, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(d) Request for certification; samples.

(1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless they were previously submitted) the dates on which the latest assays of the bacitracin or zinc bacitracin, neomycin, and polymyxin B used in making such batch were completed, the potency of the drug, and the quantity and concentration of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on or accurately representative sample of:

(i) The batch; average potency of bacitracin or zinc bacitracin, neomycin, and polymyxin per troche, and average moisture.

(ii) The bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(iii) The zinc bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(iv) The neomycin used in making the batch; potency, toxicity, moisture, and pH.

(v) The polymyxin used in making the batch; potency and toxicity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, each person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 troche for each 5,000 troches in the batch, but in no case less than 50 troches, selected and collected by taking single troches at such intervals throughout the entire time of tabulating that the quantities tabulated during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; 5 packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146.610 (b).

(iii) The zinc bacitracin used in making the batch; 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(iv) The neomycin used in making the batch; 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(v) The polymyxin used in making the batch; 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(vi) In case of an initial request for certification, each other ingredient used in making the batch, 1 package of each, containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (i), (ii), (iv) and (v) of this paragraph, and no sample referred to in subparagraph (3) (i), (ii), (iv) and (v) of this paragraph, is required if such result or sample has been previously submitted.

(e) Fees. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each troche in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii), (iv), and (vi) of this section.

(2) The fee for the services rendered with respect to each immediate container shall be $4.00.

(3) In addition to complying with the requirements of § 146.410 (a) (4), a person who requests certification of a batch shall submit with his request a sample showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the neomycin used in making such batch.

(4) The fee for the services rendered with respect to each immediate container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.421 Bacitracin-neomycin-polymyxin tablets. (a) Bacitracin-neomycin-polymyxin tablets conform to all requirements and are subject to all procedures prescribed by § 146e.412 for bacitracin-polymyxin tablets, except that:

(i) Each tablet contains not less than 500 milligrams of neomycin.

(ii) The neomycin used conforms to the requirements prescribed therefor by § 146e.410 (a) (5).

(iii) In lieu of the requirements of § 146e.412 (a) (3), each package shall bear the name of the immediate container and the number of units of bacitracin-polymyxin tablets conforming to all requirements and are subject to all procedures prescribed by § 146e.410 (a) (3), the number of units of polymyxin B, and the number of milligrams of neomycin in each tablet of the batch.

(b) In addition to complying with the requirements of § 146e.410 (a) (4), each package shall bear the name of the immediate container and the number of units of each such substance.

§ 146e.422 Bacitracin-polymyxin-neomycin ointment. (a) Bacitracin-polymyxin-neomycin ointment conforms to all requirements prescribed by § 146e.409 for bacitracin-polymyxin tablets, and is subject to all procedures prescribed by § 146e.409 for bacitracin-polymyxin ointment, except that:

(i) Each tube of neomycin is not less than 3 milligrams per gram. The neomycin used conforms to the standards prescribed by § 146e.410 (a) (2).

(ii) It may contain one or more suitable and harmless chemical antimicrobial agents.

(3) In addition to the labeling prescribed by § 146e.409 (a) (5) each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of bacitracin in each troche of the batch, and if it contains cortisone or a derivative of cortisone, the name and quantity of each such substance.

§ 146e.413 Bacitracin-polymyxin tablets.

(a) Bacitracin-polymyxin tablets conform to all requirements and are subject to all procedures prescribed by § 146e.412 for bacitracin-polymyxin tablets, except that:

(i) Each tablet contains not less than 1 milligram of tyrothricin.

(ii) They may contain cortisone or a suitable derivative of cortisone.

(iii) In addition to the labeling prescribed for bacitracin-neomycin troches and zinc bacitracin-neomycin troches, each package shall bear on the outside wrapper or container and the immediate container the name of the number of milligrams of polymyxin B contained in each troche of the batch, and if it contains cortisone or a derivative of cortisone, the name and quantity of each such substance.
oointment shall be submitted with his request a statement showing the batch mark and (unless they were previously submitted) the results of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of 5 packages of bacitracin-polymyxin-neomycin ointment and (unless it was previously submitted) a sample consisting of 5 packages of the neomycin used in making the batch, each containing approximately 0.5 gram.

(b) The fee for the services rendered with respect to each immediate container in the sample of neomycin tests submitted in accordance with the requirements prescribed therefor by paragraph (a) (4) of this section shall be $4.00.

§ 146e.423 Soluble bacitracin methylene disalicylate—(a) Standards of identity, strength, quality, and purity. Soluble bacitracin methylene disalicylate is a mixture of bacitracin methylene disalicylate, sodium carbonate, and sodium bicarbonate, or with or without suitable and harmless diluents, and contains the equivalent of not less than 25 grams of the bacitracin master standard per pound. Its moisture content is not more than 8.5 percent. Its pH in an aqueous solution containing 200 units per milliliter is not less than 8.5 and not more than 9.5. The bacitracin methylene disalicylate used conforms to the requirements of § 146e.416 (a). Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) Packaging; labeling; request for certification, samples; fees. Soluble bacitracin methylene disalicylate conforms to all requirements and procedures prescribed for bacitracin methylene disalicylate by § 146e.416 (b), (c), (d), and (e) except that the person who requests certification of a batch shall submit with his request (unless previously submitted) a sample consisting of 5 packages of the immediate container, each containing approximately 5 grams, of the bacitracin methylene disalicylate used in making the batch.

(c) Exemptable bacitracin methylene disalicylate from certification. Soluble bacitracin methylene disalicylate that conforms to the requirements of paragraphs (a) (except that it may contain one or more essential vitamin and mineral substances for nutritive purposes) and (b) of this section shall be exempt from the requirements of sections 502 and 510 (a) of this chapter if it complies with all the following conditions:

(1) Its label bears an expiration date that is not more than 24 months after the month during which the batch was last assayed and released by the manufacturer.

(2) If it contains added vitamins or minerals, its label bears the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The label bears a statement that solutions prepared with the drug are stable for not more than 24 hours.

(4) The circular or other labeling within or attached to the package bears information that only the antibiotic is used in the preparation for external use, in connection with the following conditions, and further, bears directions and warnings adequate for such use:

(i) Chronic respiratory disease (aracnic infections) in chickens.

(ii) Blue comb (mud fever, nonspecific infectious enteritis) in poultry.

(iii) Infectious anemia in poultry.

(iv) Bacterial enteritis in swine.

§ 146e.424 Bacitracin-neomycin-polymyxin B ointment with vasoconstrictor (the blank being filled in with the common or usual name of the vasoconstrictor).

(a) Bacitracin-neomycin-polymyxin B ointment with vasoconstrictor conforms to all requirements and is subject to all procedures prescribed by § 146e.414 for bacitracin-neomycin with vasoconstrictor, except that:

(1) When prepared as directed in its labeling, each milliliter shall contain not less than 50 units of bacitracin 3.5 milligrams of neomycin, and 1,000 units of polymyxin B in an aqueous solution of the packaged immediate container that conforms to the requirements prescribed for polymyxin B by § 146b.107 (a) of this chapter.

(2) It may contain the enzyme hyaluronidase.

(3) It may be a packaged combination of one immediate container of dry components of the drug and one immediate container of solution of components of the drug; but in no case shall bacitracin or hyaluronidase be a component of such solution of the packaged combination.

(4) The moisture content of the dry components of the drug is not more than 2.5 percent.

In addition to the labeling prescribed by § 146e.414 (a) (2) each package shall bear on the outside wrapper or container or the immediate container the number of units of polymyxin B in each container, and if it contains hyaluronidase the quantity of such ingredient in each container.

(6) On the label or labeling, if it contains hyaluronidase, after the name "bacitracin-neomycin-polymyxin B with vasoconstrictor" wherever it appears, "and hyaluronidase, after the name" shall appear in juxtaposition with such name.

(7) In addition to complying with the requirements of § 146e.414 (a) (3), a person who requests certification of a batch shall submit with his request a statement showing the number of units of polymyxin B in each immediate container, the batch mark, and (unless it was previously submitted) the date on which the latest test of the batch was completed.

(a) Providing, however, that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(b) The statement "For oral veterinary use only."

(c) The label or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the latly.

(d) Request for certification, samples, etc. In addition to complying with the requirements of § 146b.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of the drug comprised by the batch, the batch mark and (unless it was previously submitted) the date on which the latest test of the batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest test of the drug comprised by such batch was completed, and a statement that each ingredient used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and
The batch: Units of bacitracin per gram, and moisture.

(ii) The bacitracin used in making the batch: Potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, each immediate container shall contain not less than 30 grams of bacitracin powder. A concentrated solution of insulin or insulin injection, in labeled packages, of amorphous or crystalline form, derived from one or more such solutions.

(4) The circular or other labeling referred to in paragraph (2) of this section bears information that only the antibiotic is intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Chronic respiratory disease (air-sac infection) in chickens.

(ii) Blue comb (mud fever, non-specific infectious enteritis) in poultry.

(iv) Bacterial enteritis in swine.

§ 146e.417 Tablets bacitracin methylene disalicylate and streptomycin sulfate are tablets that conform to all requirements and are subject to all procedures prescribed by § 146e.417 for powder bacitracin methylene disalicylate and streptomycin sulfate oral veterinary, except that:

(a) Each tablet contains not less than 200 units of bacitracin activity and not less than 20 milligrams of streptomycin activity.

(b) In lieu of the directions for labeling prescribed by § 146e.417 (a) (i), each package shall bear on the outside wrapper or container and the immediate container the quantity of each antibiotic in each tablet.

(c) In lieu of the directions for sampling prescribed by § 146e.417 (d) (3) (D), the sample shall consist of not less than 30 tablets and not more than 100 tablets.

(d) The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) §4.00 for each immediate container in the samples submitted in accordance with paragraphs (2), (i) (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with the requirements of § 146.6 of this chapter.

(1) Exemption of bacitracin powder from certification. Bacitracin powder that conforms to the requirements of paragraphs (a) (except that it may contain one or more essential vitamin and mineral substances for nutritive purposes) (b) and (c) of this section, except paragraph (1) (iii), shall be exempt from the requirements of paragraphs 502 (1) and 507 of the act if it complies with all the following conditions:

(i) Its label bears an expiration date that is not more than 18 months after the month during which the batch was last assayed and released by the manufacturer.

(ii) If it contains additions or minerals, its label bears the name and quantity of each such substance and a statement that such substances are present to be homogeneous.

(iii) If it contains vitamins and minerals while animals are eating less feed.

(3) The label bears a statement that solutions prepared with the drug are stable for not more than 24 hours.

(iv) Bacterial enteritis in swine.

§ 146e.417 Tablets bacitracin methylene disalicylate and streptomycin sulfate oral veterinary. Tablets bacitracin methylene disalicylate and streptomycin sulfate oral veterinary are tablets that conform to all requirements and are subject to all procedures prescribed by § 146e.417 for powder bacitracin methylene disalicylate and streptomycin sulfate oral veterinary, except that:

(a) Each tablet contains not less than 200 units of bacitracin activity and not less than 20 milligrams of streptomycin activity.

(b) In lieu of the directions for labeling prescribed by § 146e.417 (a) (i), each package shall bear on the outside wrapper or container and the immediate container the quantity of each antibiotic in each tablet.

(c) In lieu of the directions for sampling prescribed by § 146e.417 (d) (3) (D), the sample shall consist of not less than 30 tablets and not more than 100 tablets.

(d) The fee for the services rendered with respect to each tablet in the sample submitted in accordance with the requirements prescribed by paragraphs of this section shall be §1.00.
RULES AND REGULATIONS

this part may be exercised by such other responsible officials of the Food and Drug Administration as the Commissioner may designate for that purpose.

(n) The term "act" means the Federal Food, Drug, and Cosmetic Act, as amended.

(a) The definitions and interpretations of terms contained in section 921 of the act shall be applicable to such terms when used in the regulations in this part.

§ 164.2 Requests for certification, samples; storage; approvals preliminary to certification. (a) A request for certification of a batch shall be addressed to the Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D.C. A request for certification shall be signed by the manufacturer and accompanied by a full statement of such facilities and controls used in maintaining the identity, strength, quality, and purity of master lots and dilutions therefrom; the equipment, methods, and processes used in diluting master lots and mixtures thereof, on dilutions and batches therefrom, and on ingredients used in such dilutions and batches; and the laboratory facilities used in such controls.

Such initial request shall also be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of master lots and dilutions therefrom; the equipment, methods, and processes used in diluting master lots and mixtures thereof, on dilutions and batches therefrom, and on ingredients used in such dilutions and batches; and the laboratory facilities used in such controls.

(b) The master lot mark and batch marks used by such person. When any change is made in any of such facilities or controls, or in any initial request for certification thereto shall be accompanied by a full statement of such change.

(c) A person who requests certification of a batch shall submit in connection with his request statements showing:

(1) The master lot mark of each master lot used or to be used wholly or partly as an ingredient or component of such material;

(2) The quantity of each such master lot so used;

(3) The original quantity of each such master lot (unless such information has been previously submitted);

(4) The quantity of the batch; and

(5) The batch mark.

(d) Except as otherwise provided in paragraphs (g) and (h) of this section, a person who requests certification of a batch shall submit in connection with his request results of the tests and assays listed after paragraphs (g) and (h) of this section, a person who requests certification shall submit in connection with his request results of the tests and assays listed after paragraphs (g) and (h) of this section.

(1) The master lot mark or mixture referred to in subparagraph (f) of this paragraph; in a quantity containing approximately 2,000 U. S. P. Units of insulin.

(2) If the batch is to be protamine zinc insulin, a trial mixture which is intended to be accurately representative of the mixture which will constitute the finished batch; in a quantity containing approximately 2,000 U. S. P. Units of insulin.

(3) If the batch is to be globulin zinc insulin, a trial mixture which is intended to be accurately representative of the mixture which will constitute the finished batch; in a quantity containing approximately 2,000 U. S. P. Units of insulin.

(4) If the batch is to be protamine zinc insulin or isophane insulin, the lot of each such master lot or mixture referred to in subparagraph (f) of this paragraph; in quantity containing approximately 2 grams.

(5) If the batch is to be globulin zinc insulin, a trial mixture made from the master lot or mixture referred to in subparagraph (f) of this paragraph; in a quantity containing approximately 5 grams.

(6) If the batch is to be lente insulin, the mixture referred to in paragraph (d) (6) of this section: Nitrogen, moisture, chloride, and ash.

(7) If the mixture referred to in paragraph (d) (7) of this section: Nitrogen, reaction, zinc, isophane ratio of the protamine to the master lot or mixture (by the test prescribed in § 164.14 (a)), and biological activity of the supernatant liquid (by the test prescribed in the official United States Pharmacopoeia, including supplements thereto).

(8) If the batch is to be isophane insulin, the trial mixture referred to in paragraph (d) (7) of this section: Moisture, nitrogen, chloride, and ash.

(9) If the batch is to be lente insulin, the trial mixture referred to in paragraph (d) (6) of this section: Nitrogen, reaction, zinc, isophane ratio of the protamine to the master lot or mixture prepared to be an ingredient of the trial mixture referred to in paragraph (d) (5) of this section: Nitrogen, reaction, zinc, and biological activity of the supernatant liquid, and proportion of crystalline component (by the test prescribed in § 164.14 (e)).

(10) The finished batch: Nitrogen, reaction, sterility, and if the batch is protamine zinc insulin, globin zinc insulin, isophane insulin, or lente insulin, zinc.

(11) The results of tests and assays for the following shall be reported in the terms indicated:

(a) Ash (except globulin hydrochloride)—milligrams per 1,000 U. S. P. Units of insulin.

(2) Ash in globulin hydrochloride—percentage by weight.

(3) Chloride—percentage by weight as HCl.

(4) Isophane ratio—milligrams of protamine per 100 U. S. P. Units of insulin.

(5) Moisture—percentage by weight.

(6) Nitrogen (except in globulin hydrochloride and protamine)—milligrams per milliliter in the cases of solutions and suspensions, and percentage by weight in the case of solids.

(7) Nitrogen in globulin hydrochloride—percentage by weight, calculated to a moisture-free, ash-free, chloride-free basis.

(8) Nitrogen in protamine—percentage by weight, calculated to a moisture-free basis.


(10) Proportion of crystalline component—percentage of total nitrogen of the preparation present in the crystalline component.

(11) Reaction—hydrogen ion concentration (pH).

(12) Sulfate—percentage by weight, as SO4, calculated to a moisture-free basis.

(13) Zinc—milligrams per milliliter in the cases of solutions and suspensions, and percentage by weight in the case of solids.
(g) (1) No sample referred to in paragraph (d) (1) to (3) inclusive, of this section, and no result referred to in paragraph (e) (1) to (3) inclusive, of this section, is required if such sample or result has been submitted in connection with a previous request for certification.

(2) If a request for certification of a batch of 80-unit strength insulin, or lente insulin, or protamine zinc insulin, or lente insulin, or insulin purified for use in insulin therapy, as such batch of 80-unit strength insulin, or lente insulin, or protamine zinc insulin, or lente insulin, and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (3) of this section, and no result referred to in paragraph (e) (3) of this section, is required if the batch is to be protamine zinc insulin of 80-unit strength, and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (3) of this section, and no result referred to in paragraph (e) (3) of this section, is required if such sample or result has been submitted in connection with a previous request for certification.

(3) The value for nitrogen submitted pursuant to paragraph (e) (1) and (2) of this section may be calculated from the result of a test therefor submitted pursuant to paragraph (c) (1) or (2) of this section, and no result referred to in paragraph (e) (1) or (2) of this section, is required if the batch is to be protamine zinc insulin of 80-unit strength, and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (3) of this section, and no result referred to in paragraph (e) (3) of this section, is required if such sample or result has been submitted in connection with a previous request for certification.

(4) The value for nitrogen submitted pursuant to paragraph (e) (1) and (2) of this section may be calculated from the result of a test therefor submitted pursuant to paragraph (c) (1) or (2) of this section, and no result referred to in paragraph (e) (1) or (2) of this section, is required if such sample or result has been submitted in connection with a previous request for certification.

(5) The value for nitrogen submitted pursuant to paragraph (e) (1) and (2) of this section may be calculated from the result of a test therefor submitted pursuant to paragraph (c) (1) or (2) of this section, and no result referred to in paragraph (e) (1) or (2) of this section, is required if such sample or result has been submitted in connection with a previous request for certification.

(6) No sample referred to in paragraph (d) (1) to (3) inclusive, of this section, and no result referred to in paragraph (e) (1) to (3) inclusive, of this section, is required if such sample or result has been submitted in connection with a previous request for certification.

(j) As promptly as practicable after the samples submitted pursuant to paragraph (d) (1) and (2) of this section, and the results of any other material or information relative thereto that may be required under this section, are received by the Commissioner, he shall notify the person who requested certification, stating the reasons for refusal. In case of a refusal to approve, the Commissioner shall state his reasons therefor.

(b) In like manner, the Commissioner shall notify the person who submits samples pursuant to paragraph (d) (3) inclusive, of this section, is required if such sample or result has been submitted in connection with a previous request for certification.

§ 164.3 Certifications.

(a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and the samples required by or pursuant to § 164.2 have been submitted, and such information contains no untrue statement of a material fact;

(2) The batch complies with these regulations and conforms to the standards of identity, strength, quality, and purity for insulin U. S. P., protamine zinc insulin, globin zinc insulin, isophane insulin, or lente insulin;

the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of such certifications as are set forth in § 164.4, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to § 164.2, or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) For the purposes of his investigations under the authority of this section, the Commissioner may cause the sample, or a portion thereof, to be analyzed, at a temperature above freezing but not above 15° C. (59° F.), and under such other conditions as prevent, to the extent practicable, any change in composition; except that master lots and parts thereof, which are solids may be stored at ordinary room temperatures.

FEDERAL REGISTER

Tuesday, December 20, 1955

9803
of the Insulin Committee of the University of Tokyo.

§ 164.4 Conditions on the effectiveness of certificates. (a) A certificate shall not become effective:

(1) If it is obtained through fraud, or through misrepresentation or concealment of a material fact;

(2) With respect to any package, unless its immediate container complies with the requirements of § 164.5 and such package or such immediate container has been so sealed that its contents cannot be used without destroying such package or seal; and

(3) With respect to any package, unless its label and labeling bear all words, statements, and other information, and are distinguished by the color or colors, required by §§ 164.6 and 164.7.

(b) A certificate shall cease to be effective:

(1) With respect to any package of insulin U. S. P., protamine zinc insulin, or isophane insulin, on the expiration date specified in the official United States Pharmacopoeia, including supplements thereof;

(2) With respect to any package of lente insulin, 18 months after the immediate container therein was filled; and

(3) With respect to any package, when such package or the seal thereof or the immediate container therein or the seal of the immediate container is broken, or when its label or labeling ceases to conform to any requirement of § 164.6 or § 164.7.

(4) With respect to any package, when the drug therein so changes that it fails to meet the standards of identity, strength, quality, and purity upon the basis of which the batch was certified; except that those minor changes in potency (not exceeding 10 percent from the potency stated on the label, in the case of insulin U. S. P. which occur before the expiration date, and which are normal and unavoidable in good storage and distribution practice, shall be disregarded.

§ 164.5 Packaging. Each batch shall be packaged in immediate containers of colorless transparent glass. Such containers shall be closed with a substance through which successive doses may be withdrawn by hypodermic needle without removing the closure or destroying its effectiveness. The containers and closures shall be sterile at the time the containers are filled and closed. The composition of the containers and closures shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor prescribed in applicable standards of strength, quality, and purity. The shape of the containers shall be cylindrical, except that the cross-section of the container of the insulin shall be a rounded square and the shape of the containers for lente insulin shall be hexagonal.

§ 164.6 Labeling. Each package from a batch that has been certified in accordance with the regulations in this part shall bear, on its label or labeling as hereinafter indicated, the following:

(a) On the outside wrapper or container and the immediate container of the retail package:

(1) The product mark of such batch;

(2) The strength of the drug in terms of the U. S. P. Units of insulin per milliliter; and

(3) If the seal required by § 164.4 (b) in the immediate container only, the statement required by paragraph (b) (1) of this section.

(b) On the outside container or wrapper of the retail package:

(1) The statement "Expiration date _______", the blank being filled in with the date on which the certificate applicable to such batch expires with respect to such package, as provided in § 164.4 (b) (1) or (2) and

(2) The statement "Keep in a cold place, avoid freezing;"

(3) If one batch contains 40, 80, or 100 U. S. P. Units of insulin per milliliter, on the circular or other labeling of the retail package:

(1) A statement that the treatment of diabetes is an individual problem and that the use of the drug, the time of its administration, and the number of daily doses and the quantity of each, as well as diet and exercise, are problems which require the skill and continuous medical supervision;

(2) A statement explaining that the potency of the drug in terms of units of insulin per milliliter stated on the label, and that the patient should understand the meaning of the volume markings on the syringe;

(3) A description of a practicable method for cleansing, and the use of an antiseptic on, the site of injection;

(4) A description of the technique of withdrawal from the vial and the use of an antiseptic for the syringe and the needle and syringe before use;

(5) A description of the technique for cleansing, and the use of an antiseptic on, the site of injection;

(6) A statement that failure to comply with the techniques described in subparagraphs (3) (4) and (5) of this paragraph may lead to infection of the patient;

(7) A statement that injection should be subcutaneous, at a different site from that of the preceding injection, and a caution against intravenous or intrauterine use;

(8) An explanation of hypoglycemia and its relation to overdosage, omission of meals, illness, and infection;

(9) A statement of the significance of sugar urine and of the necessity of tests thereof; and

(10) A caution against use after the expiration date shown on the outside wrapper or container.

(b) On the circular or other labeling of the retail package, if the batch is insulin zinc insulin, isophane insulin, or lente insulin (in addition to the information required by paragraphs (a), (b), (c), and (e) of this section):

(1) An explanation of the difference, as compared with other insulin-containing drugs, in onset of action, duration, and the time and frequency of administration;

(2) A caution that it is not to be substituted for any other insulin-containing drug except on the advice and direction of a physician;

(3) A statement that a uniform suspension of the preparation is necessary and is brought about by careful shaking before use; and

(4) A caution against use when the precipitate has become turbid or granular in appearance, has formed or deposit of solid particles on the wall of the container.

(g) On the circular or other labeling of the retail package, if the batch is globulin zinc insulin, or isophane insulin, the expiration date shown on the outside wrapper or container, if the batch is insulin U. S. P. which occurs before the expiration date shown on the outside wrapper or container. Each package from a batch of Insulin Committee of the University of Tokyo:

(1) That the expiration date shown on the outside wrapper or container:

(2) A statement explaining that the potency of the drug in terms of units of insulin per milliliter, in addition to the information required by paragraphs (a), (b), (c), and (e) of this section:

(3) An explanation of hypoglycemia and its relation to overdosage, omission of meals, illness, and infection;

(4) A statement of the significance of sugar urine and of the necessity of tests thereof; and

(5) A caution against use after the expiration date shown on the outside wrapper or container.

(b) On the circular or other labeling of the retail package, if the batch is protamine zinc insulin, isophane insulin, or lente insulin (in addition to the information required by paragraphs (a), (b), (c), and (e) of this section):

(1) An explanation of the difference, as compared with other insulin-containing drugs, in onset of action, duration, and the time and frequency of administration;

(2) A caution that it is not to be substituted for any other insulin-containing drug except on the advice and direction of a physician;

(3) A caution against use if any turbidity or precipitate has developed in the solution.

(1) If the batch contains 800 U. S. P. Units of insulin per milliliter, on the outside container or wrapper and the immediate container of the retail package:

(1) The statement "Warning—Federal law prohibits dispensing without prescription"; and

(2) The statement "Warning—High potency—Use for ordinary use."

(1) If the batch contains 500 U. S. P. Units of insulin per milliliter, on the circular or other labeling of the retail package:

(1) Information adequate for the safe and effective use of the drug, by practitioners licensed by law to administer it, in insulin shock therapy and for the treatment of diabetic patients with high insulin resistance (daily requirement more than 200 units).

(2) A prominently placed and conspicuous statement: "Warning—This insulin preparation contains 500 units of insulin in each cubic centimeter. Extreme caution must be observed in measurement of dosage because inadvertent overdose may result in irreversible insulin shock. Severe consequences may result if it is used other than under constant medical supervision";

(3) A caution against intravenous use; and

(4) A caution against use after the expiration date shown on the outside wrapper or container.
§ 164.7 Distinguishing colors on packages. (a) The outside containers or wrappers of the packages, and the labels on the immediate containers, of each strength of insulin U.S.P. shall be distinguished by the following colors:

Red, if it contains 40 U. S. P. Units of insulin per milliliter.
Green, if it contains 80 U. S. P. Units of insulin per milliliter.
Orange, if it contains 100 U. S. P. Units of insulin per milliliter.

Marrow (a deep but not more than 20 to each inch) brown and white diagonal stripes, if it contains 500 U. S. P. Units of insulin per milliliter.

But if the master lot used was in crystalline form, the distinguishing colors, instead of those prescribed above, may be the following:

Red and gray, if it contains 40 U. S. P. Units of insulin per milliliter.
Green and gray, if it contains 80 U. S. P. Units of insulin per milliliter.

(b) The outside containers or wrappers of the packages, and the labels on the immediate containers of each amount of protamine zinc insulin shall be distinguished by the following colors:

Red and white, if it contains 40 U. S. P. Units of insulin per milliliter.
Green and red, if it contains 80 U. S. P. Units of insulin per milliliter.

(c) The outside containers or wrappers of the packages, and the labels of the immediate containers, of each strength of isophane insulin shall be distinguished by the following colors:

Red and brown, if it contains 40 U. S. P. Units of insulin per milliliter.
Green and brown, if it contains 80 U. S. P. Units of insulin per milliliter.

(d) The outside containers or wrappers of the packages, and the labels of the immediate containers, of each strength of globin zinc insulin shall be distinguished by the following colors:

Red and blue, if it contains 40 U. S. P. Units of insulin per milliliter.
Green and blue, if it contains 80 U. S. P. Units of insulin per milliliter.

(e) The outside containers or wrappers of the packages, and the labels of the immediate containers, of each strength of isophane insulin shall be distinguished by the following colors:

Red and lavender, if it contains 40 U. S. P. Units of insulin per milliliter.
Green and lavender, if it contains 80 U. S. P. Units of insulin per milliliter.

§ 164.8 Records of distribution. (a) The person to whom a certificate is issued shall keep complete records showing each shipment and other delivery (including exports) of each batch or part thereof, by the person requesting such certificate and showing each such shipment and delivery into, or from any place in, any State or Territory, made by any person subject to his control, including records showing the date and quantity of each such shipment and delivery and the name and post office address of the person to whom such shipment or delivery was made.

(b) Upon request of any officer or employee of the Food and Drug Administration or of any other officer or employee of the United States, acting on behalf of the Secretary, the person to whom a certificate is issued, at all reasonable hours within 3 years after disposal of the batch covered by such certificate, shall make such records available to any such officer or employee, and shall accord such officer or employee full opportunity to make inventory of such batch on hand and otherwise to check the correctness of such records.

§ 164.9 Authority to refuse certification service. When the Secretary finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;
(b) Failed to keep the records required to be kept by § 164.8; or
(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of such batch on hand and otherwise to check the correctness of such records, as required by such section, the Secretary may immediately suspend service to such person under the regulations in this part, and may continue such suspension until the person shows adequate cause why such suspension should be terminated.

§ 164.10 Fees. (a) (1) Fees for the services rendered under the regulations in this part shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(2) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and conditions, warrants a refund from the fund collected during such period, he shall make such refund to the depositor.

(b) (1) $25 if the master lot or mixture of two or more master lots or parts thereof, as follows:

(1) $50 if the master lot or mixture has not been previously approved by the Commissioner.

(2) $25 if the master lot or mixture has been previously approved by the Commissioner in accordance with § 164.3.

(2) For each trial dilution, as follows:

(1) $25 if the results of an assay for purity for protamine, when protamine chloride is used, isophane insulin, or lente insulin.

(3) $50 for each lot of globin hydrochloride.

(4) $10 for each package in the sample of the finished batch.

(c) A.A.E. (b) (1) of this paragraph shall not be submitted.

§ 164.11 Standards of quality and purity for protamine. When protamine is dried to constant weight at 100° C., its total nitrogen content is not more than 22.5 percent and not more than 25 percent, and its sulfate content, calculated as SO₃, is not less than 16 percent and not more than 19 percent.

§ 164.12 Standards of quality and purity for globin hydrochloride.
ash content of globin hydrochloride is not more than 0.3 percent; its nitrogen content, calculated to moisture, ash, and hydrochloric acid free base, is not less than 18.0 percent and not more than 17.5 percent.

§ 164.13 Standards of identity, strength, quality, and purity for lente insulin. Lente insulin is a sterile suspension, in a buffered water medium, of insulin modified by treatment with zinc chloride. Of the insulin contained in the preparation not more than 1 U. S. P. Unit of insulin per milliliter is in solution, approximately 25 percent is crystalline line, and the remainder is amorphous. Zinc-insulin crystals are used in such quantity that each milliliter of the preparation, when the precipitate therein is brought into uniform suspension, contains either 40 or 80 U. S. P. Units of insulin. The preparation contains, for each 100 U. S. P. Units of insulin, not less than 0.20 milligram and not more than 0.25 milligram of zinc (not less than 40 percent nor more than 65 percent is in the supernatant liquid) and not more than 0.65 milligram nitrogen. The preparation contains not less than 0.10 percent and not more than 0.17 percent (w/v) sodium acetate, not less than 0.55 percent and not more than 0.75 percent (w/v) sodium chloride, and not more than 0.11 percent (w/v) methyl-p-hydroxybenzoate. The pH of the finished product is not less than 7.1 nor more than 7.5.

§ 164.14 Tests and methods of assay. The following tests and methods of assay are prescribed for the purposes of the regulations in this part. (All reagents specified in this section shall be of U. S. P. quality or better.)

(a) Tests and methods of assay for insulin U. S. P., protamine zinc insulin, globin zinc insulin, and isophane insulin. The tests and methods of assay for insulin U. S. P., protamine zinc insulin, globin zinc insulin, and isophane insulin shall be those set forth therefor in the official United States Pharmacopoeia, including supplements thereto.

(b) Identification of lente insulin. Acidify lente insulin to a pH between 2.5 and 3.5. The precipitate dissolves, giving a clear, colorless liquid which conforms to the requirements of the identification test for insulin U. S. P. in the official United States Pharmacopoeia, including supplements thereto.

(c) Isoxane ratio. The isophane ratio shall be expressed as milligrams of protamine per 100 U. S. P. Units of insulin. Dissolve the crystals in 15 milliliters of 0.1 percent hydrochloric acid. The resulting solution must be clear. Add 6 to 25 milliliters of stock buffer solution (subdivision (1) of this subparagraph) Dilute with water to approximately 200 milliliters. Adjust the pH to 7.2 using hydrochloric acid or sodium hydroxide. Dilute with water to 1000 milliliters. The pH must be between 7.1 and 7.4. (ii) The protamine solution. Weigh 500 milligrams of the protamine to be used in making the batch and dissolve in 10 milliliters of the stock buffer solution (subdivision (1) of this subparagraph) If sodium chloride is to be used in preparing the batch add 25 milliliters of 4.2 percent (w/v) sodium chloride solution. Dilute to 250 milliliters with water. The pH must be between 7.1 and 7.4.

(ii) Conduct of the test. Measure six 25-milliliter samples of the insulin solution (subparagraph (a) of this paragraph) into six test tubes. To the first tube add 0.60 milliliter of the protamine solution (subparagraph (1) (iii) of this paragraph) to the second add 0.72 milliliter, to the third add 0.84 milliliter, to the fourth add 0.96 milliliter, to the fifth add 1.08 milliliters, and to the sixth add 1.20 milliliters. Mix the contents of each tube and let stand for at least 30 minutes. Centrifuge. (Do not filter.) From each supernatant fluid remove two 10-milliliter samples, thus creating two series of samples. To each of one series add 1 milliliter of the insulin solution (subparagraph (1) (ii) of this paragraph). To each of the other series add 1 milliliter of the protamine solution (subparagraph (1) (iii) of this paragraph) and let stand for the same approximate time. Measure the turbidity of each sample by means of a photometer or nephelometer. Plot the readings of the turbidity against the amount of protamine originally added in milligrams per 100 U. S. P. Units of insulin as abscessus, and the photometer or nephelometer readings as ordinates. The abscissa of the intersection of the two curves indicates the isophane ratio of the protamine to the zinc-insulin crystals. In order to increase the precision of the test, when the isophane isophane ratio is known, the quantities of protamine solution to be added to the six test tubes may be so chosen that the range (0.60 to 1.20 milliliters) is reduced, and the approximate isophane ratio is near the middle of the range.

The isophane ratio found is not more than 100 percent nor less than 90 percent of the ratio of protamine to insulin used in the trial mixture referred to in § 164.12 (d) (7).

(b) Proportion of crystalline component in lente insulin. The proportion of crystalline component is expressed as percent of the total nitrogen of the preparation which is present in the crystalline component.

(1) Reagent. Dissolve in water 0.15 grams of granulated sodium bicarbonate and 20 grams of sodium chloride. Add 68 milliliters of tenth-normal hydrochloric acid, 150 milliliters of acetic acid, and sufficient water to make 500 milliliters.

(ii) Conduct of the test. Take 15 milliliters of lente insulin and carefully pour on the supernatant liquid. Re-suspend the solid phase in 5 milliliters of water and 10 milliliters of tenth-normal silver nitrate reagent (subparagraph (1) of this paragraph) and again centrifuge. Discard the supernatant liquid and repeat the washing with the same quantities of water and wash reagent and again discard the supernatant liquid. Dissolve the crystalline residue in sufficient dilute hydrochloric acid to make the volume 15 milliliters. Determine the nitrogen content of this solution by the method specified in paragraph (b) of this section. The nitrogen found must be not less than 55 percent nor more than 67 percent of the total nitrogen of the solution.

(e) Sterility of lente insulin. Use the method described in the official United States Pharmacopeia, including supplements thereto, for insulin U. S. P. for solution in globin hydrochloride—

(1) Conduct of the test. Weigh accurately about 0.5 gram of globin hydrochloride into a small beaker and dissolve in 10-15 milliliters of distilled water. Add 10 milliliters of tenth-normal silver nitrate, 5 milliliters of nitric acid, and 6 milliliters of a saturated solution of potassium permanganate. Heat and place in a water bath for approximately 1 hour. If any brown color remains, stir again, rinse the sides of the beaker with distilled water and place on the steam bath until the brown color disappears. Transfer quantitatively to a 50-milliliter volumetric flask and fill the flask to the mark with distilled water. Mix and filter through a dry filter paper into a dry vessel. Transfer exactly 40 milliliters of the filtrate into a 250-milliliter of ferric ammonium sulfate test solution and titrate with tenth-normal ammonium thiocyanate. To obtain the amount of ferric ammonium sulfate in the test solution, deduct 1.25 times the number of milliliters of ammonium thiocyanate used from 10; multiply this difference by 0.365 and divide by the weight of the sample in grams.

(c) Reagents. The reagents used are those described in the official United States Pharmacopeia, including supplements thereto.

(1) Identification of protamine—(1) Conduct of the test. Weigh accurately about 250 milligrams of protamine and dissolve it in about 100 milliliters of approximately tenth-normal hydrochloric acid. Heat to boiling add 20 milliliters of barium chloride test solution. Digest on a steam bath for 1 hour; allow to cool. Filter through an ignited and washed Gooch crucible; wash free of chloride. Dry, ignite, and weigh. The weight of barium sulfate thus obtained multiplied by 41.15 and divided by the weight of sample is the percent sulfate of the sample. Calculate the results to a moisture-free basis.
(2) Reagents. The reagents used are those described in the official United States Pharmacopeia, including supplements thereto.

(h) Nitrogen. Determine total nitrogen by the method described in the official United States Pharmacopeia, including supplements thereto, for insulin U. S. P.

(i) Zinc in insulin-containing solutions or suspensions. Use the method described in the official United States Pharmacopeia, including supplements thereto, for insulin U. S. P.

(j) Zinc in insulin-containing solids. Dissolve 10 to 20 milligrams, accurately weighed, of insulin-containing solids in 5 to 10 milliliters of distilled water containing 1 drop of five-normal hydrochloric acid, and proceed as directed in the official United States Pharmacopeia, including supplements thereto, under the test for zinc in insulin U. S. P.

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### Table: Chemical Derivatives

<table>
<thead>
<tr>
<th>Substance</th>
<th>Chemical Derivative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barbituric Acid</td>
<td>(a) 3,5-dichloro-3,5-dinitro-2-hydroxybenzoic acid</td>
</tr>
<tr>
<td>Cannabis</td>
<td>(c) 2-(trifluoromethyl)benzoic acid</td>
</tr>
<tr>
<td>Carboxyl</td>
<td>(e) 2-(trifluoromethyl)benzoic acid</td>
</tr>
<tr>
<td>Chloral</td>
<td>(g) 2-(trifluoromethyl)benzoic acid</td>
</tr>
<tr>
<td>Concomere</td>
<td>(i) 2-(trifluoromethyl)benzoic acid</td>
</tr>
<tr>
<td>Codone</td>
<td>(k) 2-(trifluoromethyl)benzoic acid</td>
</tr>
<tr>
<td>Dihydroxy</td>
<td>(m) 2-(trifluoromethyl)benzoic acid</td>
</tr>
<tr>
<td>Eudrazone</td>
<td>(o) 2-(trifluoromethyl)benzoic acid</td>
</tr>
<tr>
<td>Heterocyclon</td>
<td>(q) 2-(trifluoromethyl)benzoic acid</td>
</tr>
<tr>
<td>Morphene</td>
<td>(s) 2-(trifluoromethyl)benzoic acid</td>
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<tr>
<td>Opium</td>
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<tr>
<td>Paraldehyde</td>
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<tr>
<td>Sulphite</td>
<td>(y) 2-(trifluoromethyl)benzoic acid</td>
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(Received... Interprets or applies... 9398)
§ 281.3 Method of storing in warehouse. (a) When tea under examination is stored in any warehouse it must be so placed as to be separate from other merchandise and to be under convenient supervision by customs officers and the Department of Health, Education, and Welfare. At ports where there are no bonded warehouses or in class 2 or 3, the chief customs officer of the port will, when necessary, procure suitable premises for the temporary storage of any tea reaching his port. The repacking of tea in warehouse for export purposes is not allowed.

(b) All expenses of storage, cartage, and labor must be paid by the importer.

§ 281.5 Examination of packages. Chief officers of customs may order such an examination of each package or string of packages as will satisfy them that no dutiable goods are packed therein. For this purpose the customary designation should be made of packages for examination in public stores.

§ 281.8 Tea blended, mixed and re-packaged for export. The importer or dealer string to import teas into the United States to be blended, mixed, and repacked for export can do so by bonding a warehouse under the provisions of section 311 of the Tariff Act of 1930 (46 Stat. 691, 18 U.S.C. 1311) as an exception to the provisions of § 281.15, inclusive, of the Customs Regulation of 1943 (19 CFR 19.13–19.15) giving bond on Customs Form No. 3553. All teas placed in bonded duplicate trade warehouses must be exported.

Cross Reference: For customs regulations governing manufacturing warehouses, see 19 CFR 19.12–19.15.

§ 281.14 Taking of samples at ports where tea examiner is stationed. The examination of teas at ports where a duly qualified tea examiner is stationed shall be made by means of samples drawn by the examiner from packages designated by the tea examiner. The importer, when his teas are ready for sampling, shall submit in duplicate to the chief officer of the port a tea list and release permit (T. I. S., Cat. No. 1) of the several lines included in the invoice, and the tea examiner shall select for examination packages representing the different lines.

§ 281.15 Result of examination, form of report. (a) The examination and report upon such samples shall be made in accordance with the provisions of section 7 of the Tea Importation Act (29 Stat. 666; 21 U.S.C. 48) and the result of such examination shall be noted on the invoice by the tea examiner before he returns the invoice to the collector of customs. The tea examiner at the same time shall mark his returns on the original copy of the chop list and release permit (T. I. S., Cat. No. 1), which, after being duly signed by him, should be forwarded to the chief officer of customs.

(b) In case the tea coverings are not fit for either exportation or sale, the tea examiner shall make a report to the chief officer of customs on the original copy of the chop list and release permit (T. I. S., Cat. No. 1) and such report shall constitute a unit.

(1) In case a properly released sample is desired the importer shall furnish an additional chop and release permit (T. I. S., Cat. No. 1) of the goods that he desires, the original chop list and release permit being retained by the tea examiner until action on all the teas in the entry has been taken.

§ 281.16 Taking of samples at ports where there is no tea examiner. (a) In case an entry of imported tea shall be made at a port or subport where no tea examiner is stationed the importer should prepare the chop list and release permit (T. I. S., Cat. No. 1) of the goods that he desires, the original chop list and release permit being retained by the tea examiner until action on all the teas in the entry has been taken.

§ 281.17 Chop list. (a) In all cases the importer shall indicate on the chop list and release permit where the goods are to be sampled, whether on the dock or in warehouse. If the consulor invoice has not been received the importer may prepare an additional copy of the chop list and release permit as a pro forma invoice covering several lots of teas each being properly labeled "Pro Forma Invoice." (b) Importers may print their chop list and release permit forms, provided...
§ 281.18 Surplus samples. (a) Surplus samples drawn from importations for purposes of examination, and which represent pure tea as declared by the examiner, shall be returned to the importer after examination, if so requested by the importer, but if no request is made for the return of samples they shall be disposed of as provided in § 281.22 for unused standard samples.

(b) Surplus samples representing tea which has been finally rejected should be destroyed, or, after being denatured, should be sold for manufacturing purposes under the Tea Importation Act (29 Stat. 163; 21 U.S. C. 41).

§ 281.19 Tea standards. (a) Samples for standards of the following teas, prepared, identified, and submitted by the Board of Tea Experts on February 16, 1955, are hereby fixed and established as the standards of purity, quality, and fitness for consumption under the Tea Importation Act for the year beginning May 1, 1955, and ending April 30, 1956:

1. Formosa Oolong.
2. Formosa Black (Formosa Black and Congou type).
3. Japan Black.
4. Japan Green.
5. Scented Canton type.
6. Canton Oolong type.

These standards apply to tea shipped from abroad on or after May 1, 1955, which is governed by the standards which became effective May 1, 1954 (19 F.R. 1141).

(b) The Board of Tea Experts shall prepare duplicate samples of the standards for teas.

(See 2, 29 Stat. 665, as amended; 21 U.S. C. 42)

§ 281.20 Effective date of tea standards. The standards prepared and submitted to the Secretary of Health, Education, and Welfare by the Board of Tea Experts, approved by him on or before February 15 of each year, shall be fixed and established as standards under the act and shall be in effect from the first day of the calendar year until April 30, inclusive, of the following year, except that tea shipped from abroad prior to May 1 of any year shall be governed by the standards in effect at the time of shipment. Any standards for each year will be published in the Federal Register.

§ 281.21 To whom standards will be furnished. (a) A quantity of tea of the approved standards will be packed in half-pound tin containers by competent tea packers under the constant supervision of an officer of the Food and Drug Administration and full sets will be furnished the Board of Tea Appeals, the supervising tea examiner, and the examiners of tea at all the tea examining stations.

(b) Standards will be furnished to actual importers and regular tea brokers on application to the supervising tea examiner, at the actual cost of the same.

§ 281.22 Disposition of obsolete standards. All standards for teas which have served their purpose and new season samples have been submitted, the old samples may be included in quarterly sales of unclaimed goods, and the proceeds paid into the Treasury. After deducting expenses of advertisement and sale, the designation on the packages showing such teas to have been used as Government standards to be obliterated before delivery to purchasers.

§ 281.23 Instructions to examiners. (a) Examiners are instructed not to pass upon samples representing importations of tea imported separately from the importation; neither shall they give nonofficial opinions on samples.

(b) The examination of tea in comparison with the standards under this act shall be made according to the usual practice of the Board of Tea Experts, including the testing of an infusion in boiling water, and, if necessary, chemical analyses; and examiners are advised, inasmuch as they must not under the law admit any tea inferior to the standards in purity, quality, and fitness for consumption, to employ the present methods of determining the presence of artificial coloring or facing other teas. With the use of paste or gum, separate, made to imitate gunpowder or other teas, the greyy substance, if any, will appear on the paper, and if not equal to the standard the tea would justly be rejected.

§ 281.24 Testing of teas. (a) In comparing with standards, examiners are to test all the teas for quality, for impurity consisting of artificial coloring or facing matter, and other impurity, and for quality of infused leaf. Quality shall be ascertained by drawing, according to the custom of the tea trade, with the weight of a silver half dime to the cup. The quality must be equal to standard, but the flavor may be different in different districts, as long as it is equally fit for consumption. As an illustration, a Téchuan may be equal to a Aloyune, but a different district, as long as it is equally fit for consumption.

(b) Tea dust, fannings, and offgrades, including broken tea (ET), broken mix (BM), and Bohcha when so marked and for which there is no specific standard, should be tested for quality, purity, and fitness for consumption in comparison with their respective leaf standards.

§ 281.25 Testing quality of infused leaf. In order to test the quality of the infused leaf in comparison with the standard, a second drawing should be made of double weight. Before pouring off the water, examine for an excess of "floaters" (woody stems which remain floating after the leaf is thoroughly infused) to determine whether they are in sufficient quantity to reduce the quality of the tea below the standard.

After pouring off the water the infused leaf should be taken out so as to exhibit the lower side which rested against the cup. Should the mass show a larger quantity of exhausted or decayed leaf than the standard it affords sufficient evidence to be judged inferior in quality and consequently to be rejected.

§ 281.26 Macao or Canton congou and brick tea standards. Macao or Canton congou and brick tea should be compared with the standard for China congou. The mustiness or damaged flavor exhibited in certain Canton teas would be just cause for rejection.

§ 281.27 Teas imitating China green teas. Whenever Japan, Ceylon, India, or any other teas are made up to resemble the green teas of China, they are to be examined in comparison with the China green standards.

§ 281.28 Pouchong Formosa oolong teas. All Pouchong (scented) Formosa oolong teas should be examined in comparison with the Formosa standard.

§ 281.29 Tea dust. Tea dust or broken leaf mixed with other teas or separate, made to imitate gunpowder or other teas, with the use of paste or gum, or any other substance, would justly be rejected.

§ 281.30 Test for paraffin and similar substances. If the examiner suspects the presence of paraffin or similar substances, he should make the following test in comparison with the standard: Spread the tea between two sheets of unplastered white paper. Place thereon a hot iron. The greasy substance, if any, will appear on the paper, and if not equal to the standard the tea would justly be rejected.

§ 281.31 Tests for impurities. (a) To examine for impurities the following tests may be used in comparison with the standard:

1. Read test, with additions and modifications, and the cup test, double-weight. Place 2 ounces of tea in a sieve 5 or 6 inches in diameter, having 60 meshes to the inch and provided with a top. Silt a small quantity of the dust onto a camphorized white paper about 8 inches in diameter. The amount of dust placed on the paper should be approximately 1 grain. To get the requisite amount of dust it is sometimes necessary to rub the leaf gently against the bottom of the sieve, but this must not be done until the sieve has been well shaken over the test paper. Pour the dust thus collected from the paper into the scales, weigh out 1 grain, and return this quantity to the same paper, distributing it evenly over the surface of the paper. Then place the paper on a plain, firm surface, preferably glass or marble, and crush the dust by pressing over it with considerable pressure, a flat steel spatula about 5 inches long. Do this repeatedly until the tea dust is ground almost to a powder and the particles of coloring matter and the particles of coloring matter and other impurities, if any, will come more apparent. Brush off the loose dust and examine the paper by means of a simple lens magnifying 1½ times. In distinguishing these particles and streaks bright light is essential.

(2) The crushed leaf in either black or green tea appears in such quantity that there is no chance of missing the...
leaf for artificial coloring, facing material, or other impurities.

(3) The test is performed in comparison with the standard, and, if the tea is clearly equal to the standard with respect to artificial coloring, facing matter, or other impurities, the operation need not be repeated. If particles of artificial coloring, facing, or other impurities are found in the sample under comparison, whether or not the tea contains impurities, the presence of facing and other impurities, such as talc, gypsum, barium sulfate, clay, and kaolin.

(4) Repetition, using semiglazed black paper instead of the white paper. This black-paper test shows the presence of facing and other impurities, such as talc, gypsum, barium sulfate, clay, and kaolin.

(5) If the tea under examination is found, by the foregoing tests, to contain more impurities than the standard, draw samples from packages representing at least 5 percent of the lot in question, and subject each sample to the tests to ascertain whether or not the majority contain impurities in excess of the standard.

(6) The foregoing tests may be applied to tea of all varieties.

(b) Should the examination of the sample by the cup test, double-weight, for scum, sediment, etc., on the Road test, or both, disclose the presence of more impurities than the standard, a pound sample should be sent to the nearest district of the Food and Drug Administration and an analysis made in comparison with the standard to determine whether it contains more impurities than the standard. If the tea in question is found to contain more impurities than the standard, it would properly be rejected, notwithstanding the fact that it may be superior to the standard in some other respects or that it may be equal to the standard in purity.

(c) All extraneous substances are impurities, and the presence of any may be detected as the case may found efficient.

§ 281.34 Tolerance for fine tea particles. Except for teas listed under § 281.24 (b) the amount by weight of fine tea particles that will pass through a wire sieve having 30 openings per linear inch in diameter and made of a wire with a diameter of 0.01 inch, must not exceed 4 percent. Before condemning any tea for fine particles in excess of 4 percent, examiners shall seize at least 4 representative samples, each taken from a different package in a shipment containing four or more packages, or where a lesser number of packages is involved, seize a representative sample from each package.

§ 281.35 Tea inferior to the standard in any requisite is justly rejected. Should a tea prove on examination to be inferior to the standard in any one of the requisites—namely, quality, quality of Infused leaf, or purity—it would justly be rejected, notwithstanding the fact that it may be superior to the standards in some of the qualifications. No consideration shall be given due to the appearance or so-called style of the dry leaf.

§ 281.36 Action based on result of examination. (a) If, after examination, the tea is found not to be prohibited under the act, a release permit shall at once be granted to the importer, declaring that the tea is not within the prohibition of the Tea Importation Act; but if, on examination, such tea, or merchandise described as tea, is found in the opinion of the examiner, to come within the prohibitions of that act, the examiner shall immediately notify the Tea Board of the merchandise described as tea, and a reexamination called for by the importer the return of the examiner shall be found erroneous. Should a portion only of the invoice be passed by the examiner as correct, a permit of delivery shall be granted for that portion and the remainder held as provided in section 6 of the act (20 Stat. 698; 21 U.S.C. 47).

(b) If in all cases of reexamination by examiners, the importers should be notified of the reason for rejection; that is, whether it be on the ground of quality character of Infused leaf, dust, or admixture with foreign substances.

§ 281.37 Procedure for protest against findings. In case of customs, importer, or consignee shall protest against the finding of the examiner, the matter in dispute shall be referred for decision to the United States Board of Tea Appeals, designated by the Secretary of Health, Education, and Welfare, and if such board shall, after due examination, find the tea in question to be equal in purity, quality, and fitness for consumption as compared with the same kind of tea within the proper standards, a permit shall be issued by the collector of customs for its release and delivery to the importer; but if, upon such final re-examination by such board, the tea shall be found to be inferior in purity, quality, and fitness for consumption, as compared with the said standards, the importer or consignee shall be required to have the tea, or merchandise described as tea, reimported for double the value of the tea, or merchandise described as tea, as heretofore, and the remaining half pound, if the tea be rejected by said board, shall be distributed among the various examiners for their information and guidance.

(c) Teas rejected by tea examiners and rejections affirmed by the United States Board of Tea Appeals cannot be re-examined.

§ 281.39 Rejected tea. Rejected tea may be released or withdrawn for examination, for transportation, for reimportation, or for manufacturing purposes under the Tea Importation Act (35 Stat. 163; 21 U.S.C. 47), as the case may be.

§ 281.40 Exportation of rejected teas. (a) Teas to be exported for the reason that they are within the prohibition of the statute will be entered for exportation on Customs Form No. 7551, and bond on Customs Form No. 7557 shall be given for their exportation in a penal sum equal to double the value of the tea, described as tea, or merchandise described as tea, as hereinafore, and the remaining half pound, if the tea be rejected by said board, shall be distributed among the various examiners for their information and guidance.

(b) Whenever a bond is given to export any condemned tea in pursuance of the act, it will be canceled upon the filing of an outward bill of lading and a duly authenticated certificate of clearance from the customs officer superseding the lading for export, as the case may be, in a penal sum equal to double the value of the tea, described as tea, or merchandise described as tea, as hereinafore, and all accrued charges must be paid before issuance of permit for exportation.

(c) An outward bill of lading shall be made for transportation and immediate exportation in bond.

§ 281.41 Reimportation of exported teas forbidden. (a) No imported teas which have been rejected by an examiner, or by the United States Board of Tea Appeals, and exported under the provisions of this act, shall be reimported into the United States under the penalty of forfeiture for a violation of this prohibition.

(b) Customs officers will make seizure of any tea so imported.

§ 281.42 Destruction of condemned tea. Whenever condemned tea is to be destroyed it must be conveyed to some suitable place, and proper means, to be prescribed by the examiner, must be used for its effectual destruction, which shall be effected in the presence of an officer of customs, detailed by the collector for the purpose. Before the tea is destroyed, a particular description or statement of the same must be prepared containing the name of the Importer or owner, the
When letters of not less than 24-point size are required on a label in stating the word “Poison,” they must not be smaller than those above set forth.

§ 285.7 Directions for treatment. Except as provided in §285.8, the container shall bear in all cases upon the label or sticker thereof, immediately following the word “Poison,” directions for treatment in the case of internal personal injury; in addition, if the substance may cause external injury, directions for appropriate treatment shall be given.

The directions shall prescribe such treatment for personal injury as are sanctioned by competent medical authority, and the materials called for by such directions shall be, whenever practicable, such as are usually available in the household.

§ 285.8 Directions for treatment: exemption. Manufacturers and wholesalers; only, at the time of shipment or delivery for shipment, are exempted from placing directions for treatment on the label or sticker of any container for other than household use, but in any event the information required by section 2 (b) (1), (2) and (3) of the act (44 Stat. 1407; 15 U. S. C. 402) and the regulations in this part shall be given.

§ 285.9 Directions for treatment must be placed on container by person offering such container for general sale or exchange. A person who receives from a manufacturer or wholesaler any container which may be used for household purposes which is rendered dangerous for household use shall place such directions on the label or sticker if he offers such container for general sale or exchange.

§ 285.10 Specific guaranty. If a guaranty in respect to any specific lot of dangerous caustic or corrosive substances be given, it shall be incorporated in or attached to the bill of sale, invoice, or other schedule bearing the date and the name and quantity of the substance sold, and shall appear on the label or package. The following are forms of specific guaranties:

(a) Substances for both household use and other than household use:

The undersigned guarantees that the retail parcels, packages, or containers of the dangerous caustic or corrosive substances listed hereinafter (or specifying the substances) are not miscarried within the meaning of the Federal Caustic Poison Act (Signature and address of guarantor)
**RUL﻿S AND REGULATIONS**

by a manufacturer or wholesaler (§ 285.8, 285.9)

The dangerous caustic or corrosive substance or substances listed herein (or specifying the substances) in retail parcels, packages, or containers suitable for household use are for other than household use and are guaranteed, conditioned, and labeled within the meaning of the Federal Caustic Poison Act. 

(Name and address of manufacturer or wholesaler)

§ 285.11 General guaranty. In lieu of a particular guaranty for each lot of dangerous caustic or corrosive substances, a general continuing guaranty may be furnished by the guarantor to actual or prospective purchasers. The following are forms of continuing guaranties:

(a) Substances for both household use and other than household use:

The undersigned guarantees that the retail parcels, packages, or containers of the dangerous caustic or corrosive substance or substances to be sold to __________________ are not misrepresented by the meaning of the Federal Caustic Poison Act.

(Date) (Signature and address of guarantor)

(b) Substances for other than household use (this form may be issued only by a manufacturer or wholesaler (§§ 285.8, 285.9))

The dangerous caustic or corrosive substance or substances in retail parcels, packages, or containers suitable for household use to be sold to __________________ are for other than household use, and guaranteed not to be misrepresented by the meaning of the Federal Caustic Poison Act.

(Date) (Signature and address of manufacturer or wholesaler)

**SAMPLES**

§ 285.12 Collection of samples. Samples for examination by or under the direction and supervision of the Food and Drug Administration shall be collected by:

(a) An authorized agent in the employ of the Department of Health, Education, and Welfare. 

(b) Any officer of any State, Territory, or possession, or of the District of Columbia, authorized by the Secretary of Health, Education, and Welfare.

§ 285.13 Where samples may be collected. Caustic or corrosive substances within the scope of this Act (44 Stat. 1407; 15 U.S.C. 401-411) may be sampled wherever found.

§ 285.14 Analyzing of samples. Samples collected by an authorized agent shall be analyzed at the laboratory designated by the Food and Drug Administration. Only such samples as are collected in accordance with §§ 285.12, 285.13 may be analyzed by or under the direction and supervision of the Food and Drug Administration. Upon request one subdivision of the sample, if available, shall be delivered to the party or parties interested.

**MISCELLANEOUS**

§ 285.15 Investigations. Authorized agents in the employ of the Department of Health, Education, and Welfare shall make investigations, including the inspection of premises where dangerous caustic and corrosive substances subject to the act are manufactured, packed, stored, or held for sale or distribution, and make examinations of freight and other transportation records.

§ 285.16 Analysis. (a) The methods of examination of any employed shall be those prescribed by the Association of Official Agricultural Chemists, when applicable, provided, however, that any method of analysis or examination not satisfactory to the Food and Drug Administration may be employed.

(b) All percentages stated in the definitions in section 3 (a) of the Caustic Poison Act shall be determined by weight.

§ 285.17 Hearings. Whenever it appears from the inspection, analysis, or test of any container that the provisions of section 3 or 6 of the Caustic Poison Act (44 Stat. 1407, 1409; 15 U.S.C. 405, 406) have been violated and criminal proceedings are contemplated, notice shall be given to the party or parties against whom prosecution is under consideration and to other interested parties, and a date shall be fixed at which such party or parties may be heard. The hearing shall be held at the office of the Food and Drug Administration designated by the Secretary of Health, Education, and Welfare, and shall be private and confined to questions of fact. The parties notified may present evidence, either oral or written, in person or by attorney, to show cause why the matter should not be referred for prosecution as a violation of the Federal Caustic Poison Act.

§ 285.18 Hearings; when not provided for. No hearing is provided for when the health, medical, or drug officer or agent of any State, Territory, or possession, or of the District of Columbia, acts under the authority contained in section 8 of the Federal Caustic Poison Act (44 Stat. 1407; 15 U.S.C. 406) in reporting a violation direct to the United States attorney.

§ 285.19 Publication. (a) After judgment of the court in any proceeding under the Federal Caustic Poison Act, notice shall be given by publication. Such notice shall include the findings of the court and may include the findings of the analyst and such explanatory statements of fact as the Secretary of Health, Education, and Welfare may deem appropriate.

(b) This publication may be made in the form of a circular, notice, or bulletin, as the Secretary of Health, Education, and Welfare may direct.

(c) If an appeal be taken from the judgment of the court before such publication, that fact shall appear.

**IMPORTS**

§ 285.20 Required label information. Containers which are offered for import in all cases bear labels or stickers having thereon the information required by section 2 (b) (1) (2) and (3) of the Federal Caustic Poison Act and the directions for treatment in the case of personal injury, except such directions may not appear on the sticker at the time of shipment by a wholesaler or manufacturer for other than household use.

§ 285.21 Enforcement of provisions. The enforcement of the provisions of the Federal Caustic Poison Act as they relate to imported dangerous caustic or corrosive substances, in all cases except those referred to the court and may include the findings of the analyst and such explanatory statements of fact as the Secretary of Health, Education, and Welfare may deem appropriate.

§ 285.22 Delivery of containers. Contain- ers shall not be delivered to the consignee prior to report of examination, unless a bond has been given on the appropriate form for the amount of the full invoice value of such containers, together with the duty thereon, and on refusal of the consignee to return such containers for any cause to the custody of the collector when demanded, for the purpose of excluding them from the country or for any other purpose, the consignee shall pay an amount equal to the sum named in the bond and, and a copy of the bond, to the person in charge of the bonded entry for the pay of such charge for bonded entry, pending further order of the court and may include the findings of the analyst and such explanatory statements of fact as the Secretary of Health, Education, and Welfare may deem appropriate.

§ 285.23 Invoices. As soon as the importer makes entry, the invoices covering containers and the public stores packages shall be made available, with the least possible delay, for inspection by the representative of the district. When no sample is desired the invoice shall be stamped by the district "No sample desired, Food and Drug Administration, Department of Health, Education, and Welfare, per (initials of inspecting officer)."

§ 285.24 Samples. On the same day that samples are requested by the district, the collector or appraiser shall notify the importer that samples will be taken, that the containers must be held intact pending a notice of inspection and analysis, and that in case the containers do not comply with the requirements of the Federal Caustic Poison Act, they must be returned to the collector for disposition. This notification may be given by the collector or appraiser through individual notices to the importer or by suitable bulletin notices posted daily in the customhouse.

§ 285.25 No violation, release. As soon as examination of the act is completed, if no violation of the act is detected, the chief of the district shall send a notice of release to the importer and signee prior to report of examination, unless a bond has been given on the appropriate form for the amount of the full invoice value of such containers, together with the duty thereon, and on refusal of the consignee to return such containers for any cause to the custody of the collector when demanded, for the purpose of excluding them from the country or for any other purpose, the consignee shall pay an amount equal to the sum named in the bond and, and a copy of the bond, to the person in charge of the bonded entry for the pay of such charge for bonded entry, pending further order of the court and may include the findings of the analyst and such explanatory statements of fact as the Secretary of Health, Education, and Welfare may deem appropriate.

§ 285.26 Violation. (a) If a violation of the Federal Caustic Poison Act is disclosed, the chief of the district shall send to the importer due notice of the nature of the violation and of the time and place of hearing, and such notice may include the finding of the collector that the containers should not be refused admission. At the same time similar notice regarding detention of the containers shall be sent to the collector,
return his notice to the collector, prop-
port to the importer that the containers must
ported within
notice, a second notice, marked "second
the notice of hearing in person or
reasonable period to permit him to
shipment may be extended at his request
requesting him to refuse delivery thereof
ion at the place named.
notice to the collector or chief of district,
thereunder. The notice will also state
all regulations and instructions issued
performance thereof under the pro-
§ 285.27 Rejected containers. (a) In all cases where the containers are to be
refused admission, the chief of the dist-
within 1 day after hearing, or, if the
importer does not appear or reply
within 3 days after second notice,
the collector in duplicate
(b) Not later than 1 day after receipt
of this notice the collector shall sign and
transmit a certified copy of the notice,
which shall serve as notification to the
importer that the containers must be exported under customs supervision
within 3 months from such date, as pro-
vided for in § 285.22. The copy shall be
retained as office record and later
performed under the provisions of bond
or other containers of a similar nature.
(l) When containers are shipped to
another port for relabeling or expo-
tion, they must be shipped under customs
carrier's manifest, the same manner as shipments in bond.
§ 285.28 Relabeling of containers. (a) If containers are to be released after
relabeling, a notice shall be sent by the
of district direct to the importer, a
carbon copy being sent to the collector.
This notice must state specifically the
conditions to be performed, so as to bring
the performance thereof under the pro-
visions of the bond or other containers
ship to the chief of the
district. In all cases the importer
shall return his notice to the collector, prop-
ty certified as to the information re-
quired, as the form provides.
§ 285.29 Penalties. (a) In case of failure to comply with the instructions
of district to the chief or district as to conditions under which con-
tainers may be disposed of, the collector
shall notify the chief of district in all
cases coming to his attention within 3
days after inspection of the 3 months allowed by law
if no action is taken.
(b) The chief of district, upon receipt
of the above-described notice, and in
all cases of failure to meet the condi-
tions imposed in order to comply with the
provisions of the Federal Caustic Poison Act
himself, shall notify the chief
of customs such evidence
supervision, shall transmit to the col-
ector of customs such evidence
section shall furnish to collector
the chief of district as to conditions under which con-
tainers may be disposed of, and in all cases when
the act or other disposition
(b) VWhenrelabeling
im-
§ 285.30 Nonlaboratory ports. (a) At
the ports of entry where there is no dis-
trict the collector or deputy, on the day
when the first notice of expected ship-
ment of containers is received, either by
the collector or deputy, shall notify the chief
of district in whose territory the port
located.
(b) On the day of receipt of such no-
tice the chief of district shall mail to the
importer appropriate notice, if no
sample is desired. This notice serves as
an equivalent to stamping the invoices
at district ports with the legend "No sam-
ple desired, Food and Drug Administra-
Department of Health, Education, and Welfare, per (initials of inspecting
officer)"
(c) If samples are desired, the chief
of district shall immediately notify the
 collector.
(d) The collector at once shall for-
ward samples, accompanied by descrip-
tion of shipment.
§ 285.31 Chief of district as customs
officer. The chief of district shall be
deemed a customs officer of enforcing
import regulations.
§ 285.32 Enforcement agency. The
Federal Caustic Poison Act shall be en-
forced by the Food and Drug Adminis-
Department of Health, Education, and Welfare.

PART 289—REGULATIONS FOR THE ENFORCE-
MENT OF THE FEDERAL IMPORT MILK ACT
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§ 290.53 Judicial notice.

§ 290.54 Copies of exhibits.

§ 290.55 Affidavits.

§ 290.56 Copies of affidavits.

§ 290.57 Hearings before prosecution.

Short title of the act. § 290.1 Short title of the act. For the purposes of the regulations in this part the act (44 Stat. 1101; 21 U.S.C. 141-149) "To regulate the importation of milk and cream into the United States for the purpose of promoting the dairy industry of the United States and protecting the public health" shall be known and referred to as "the Federal Import Milk Act." § 290.2 Scope of the act. The provisions of the act apply to all milk and cream offered for import into the continental United States.

DEFINITIONS

§ 290.3 Milk. For the purposes of the act and of the regulations in this part:

Milk is the whole, fresh, clean, lactic secretion obtained by the complete milking of one or more healthy cows, properly fed and kept, excluding that obtained within 15 days before and 5 days after calving, or such longer period as may be necessary to render the milk practically coagulum free.

§ 290.4 Cream. Cream is that portion of the milk, rich in milk fat, which rises to the surface of milk on standing or is separated from it by centrifugal force. (See §§ 18.500 to 18.515 of this chapter.)

§ 290.5 Condensed milk. Condensed milk, as the term is used in section 3, paragraph 2, of the Import Milk Act, includes evaporated milk in the manufacture of which sterilization of the milk and cream is necessary and usual processes; it includes sweetened condensed milk only if it is prepared by a process which insures sterilization of the milk and cream. Condensed milk, as the term is used in paragraph 8, of the Import Milk Act, means sweetened condensed milk.

§ 290.6 Evaporated milk. Evaporated milk conforms to the definition and standard of identity for such food as set out in § 18.540 of this chapter.

§ 290.7 Sweetened condensed milk. Sweetened condensed milk conforms to the definition and standard of identity for such food as set out in § 18.530 of this chapter.

§ 290.8 Pasteurization. Pasteurization is the process of heating every particle of milk or cream to at least 143°F, and holding it at such temperature continuously for at least 30 minutes, or to at least 161°F, and holding it at such temperature continuously for at least 15 seconds.

§ 290.9 Shipper. A shipper is anyone, other than a common carrier, who ships, transports, or causes to be shipped or transported into the United States milk or cream owned by him.

§ 290.10 Secretary. Secretary means the Secretary of Health, Education, and Welfare.

§ 290.11 Commissioner of Food and Drugs. § 290.11 Commissioner of Food and Drugs. (a) Physical examination of any and all cows in herds producing milk or cream which is to be shipped or transported into the United States shall be made by an authorized veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced to determine whether such cow or cows are in a healthy condition. Such examination shall be made as often as the Secretary may deem necessary, and in any event, shall have been made within one year previous to the time of the importation.

(b) The results of the tuberculin test and all facts concerning the disposal of reacting or suspected animals shall be set forth in the form prescribed by the Secretary.

§ 290.14 Sanitary inspection of dairy farms. The sanitary conditions of any dairy farm producing milk or cream to be shipped or transported into the United States or to a plant from which milk or cream is to be shipped or transported into the United States must score at least 50 points out of 100 points, according to the methods for scoring as provided by the score card for sanitary inspection of dairy farms used by the Dairy Husbandry Branch, Agricultural Research Service of the United States Department of Agriculture at the time of scoring.

§ 290.15 Sanitary inspection of plants. The sanitary conditions of any plant handling milk or cream any part of which is to be shipped or transported into the United States shall score at least 50 points out of 100 points, according to the methods for scoring as provided by the score card for sanitary inspection of such plants used by the Dairy Husbandry Branch, Agricultural Research Service of the United States Department of Agriculture at the time of scoring.

§ 290.16 Scoring. Scoring of sanitary conditions required by §§ 290.14, 290.15 shall be done by an official inspector of the United States or of any State or municipality thereof or of the country in which the dairy farm or plant is located.

§ 290.17 Pasteurization; equipment and methods. All dairy farms and plants at which any milk or cream is pasteurized for shipment or transportation into the United States shall employ adequate pasteurizing machinery of a type easily cleaned and of sanitary construction capable of holding every portion of the milk or cream at the required temperature for the required time. Such pasteurizing machinery shall be properly equipped with accurate temperature recording devices, which shall be kept in good working order. The temperature at the time of heating and holding must invariably be recorded on thermograph charts, initialed, numbered, and dated by the official having jurisdiction over such farms and plants. All thermograph charts shall be held for a period of 1 year unless within that period they have been examined and released by such authorized agents as are designated by the Secretary.

§ 290.18 Method of bacterial count. The bacterial count of milk and cream refers to the number of viable bacteria as determined by the standard plate method of the American Public Health Association in use at the time of the examination.

§ 290.19 Authority to sample and inspect. Inspectors engaged in the enforcement of the Import Milk Act are empowered to test for temperature, to take samples of milk or cream, and to use such means as may be necessary for these purposes.
¶ 290.20 Permits for pasteurized milk or cream. A permit to ship or transport pasteurized milk or cream into the United States will be granted only upon compliance with the requirements of clauses 1 and 3 of section 2 of the Import Milk Act. §§ 290.12, 290.14, 290.15, as applicable.

¶ 290.21 Permits for raw milk or cream. Except as provided in § 185.24, permits to ship or transport raw milk or cream into the United States will be granted only when the milk or cream comes from dairy farms or plants where pasteurization is not carried on and then only upon compliance with the requirements of clauses 2 and 3 of section 2 of the Import Milk Act. §§ 290.12 to 290.15, as applicable.

¶ 290.22 Permits granted on certificates. In the discretion of the Secretary, a permit may be granted on a duly certified statement signed by a duly accredited official of an authorized department of any foreign government or of any State of the United States or any municipality thereof. Such statement shall be in the form of a certificate prescribed by the Secretary, and have attached thereto, as a part thereof, signed copies of reports prescribed by §§ 290.12, 290.13, and also by §§ 290.14, 290.15, as applicable. The necessary inspections shall be upon request of a producer shipping or transporting milk or cream into the United States by such permit shall have firmly attached thereto a tag in the following form, bearing the required information in clear and legible type:

<table>
<thead>
<tr>
<th>Product</th>
<th>(State where milk, pasteurized milk, raw cream, or pasteurized cream was produced)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employer</td>
<td>Address of shipper.</td>
</tr>
</tbody>
</table>

¶ 290.23 Permits waiving clause 4, section 2 of the Import Milk Act. The Secretary, in his discretion, will issue to a shipper or producer of a condensary a permit waiving the requirements of clause 4, section 2 of the Import Milk Act and allowing milk and cream containing not to exceed 1,200,000 bacteria per cubic centimeter to be shipped or transported into the United States if the condensary is located within a radius of 20 miles of the point of production of such milk and cream and the milk and cream are to be sterilized in the manufacture of condensed milk.

¶ 290.24 Permits waiving clauses 2 and 5, section 2 of the Import Milk Act. A permit to ship or transport raw milk into the United States will contain a waiver of clauses 2 and 5 of section 2 of the Import Milk Act when the shipper or producer of a condensary is located within a radius of 20 miles of the point of production of such milk, and the milk, prior to its sale, consumption, pasteurization, condensed, or evaporated.

¶ 290.25 Temporary permits. A temporary permit will be granted only upon a satisfactory showing that the applicant therefor has been unable to obtain the necessary inspections required by the applicable provisions of section 2 of the Import Milk Act. Temporary permits shall be valid until the Secretary shall provide for inspection to ascertain that clauses 1, 2, and 3 of section 2 of the Import Milk Act have been complied with.

¶ 290.26 Examination and inspection must be allowed. Milk and plants from which milk or cream is shipped or transported into the United States shall be open at all reasonable times to authorized agents for necessary examinations and inspections. Failure to permit such examinations and inspections may be considered cause for the suspension or revocation of the permit.

¶ 290.27 Application for permit. Application for a permit to ship or transport milk or cream into the United States shall be made by the actual shipper upon forms prescribed by the Secretary. The request for forms of applications for permits shall be addressed to Commissioner of Foods and Drugs, Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D. C.

¶ 290.28 Permit number. Each permit issued under the Import Milk Act, including each temporary permit, shall bear an individual number. The right to the use of such number is restricted solely to the permittee.

¶ 290.29 Form of tag. Each container of milk or cream shipped or transported into the United States by such permit shall have firmly attached thereto a tag in the following form, bearing the required information in clear and legible type:

| Provided, that in case of unit shipments consisting of milk only or cream only under one permit number, in lieu of each container being so marked, the vehicle of transportation, if unincorporated, may be tagged with the above tag, which should, in addition, show the number of containers and quantity of contents of each. |

¶ 290.30 Suspension and revocation of permit. A permit to ship or transport milk or cream into the United States may be suspended for cause at any time. A permit may be revoked for cause after notice to the permittee, who may appear in person, by attorney, or by letter and show cause why the permit should not be revoked.

¶ 290.31 Order to show cause why permit should not be revoked and temporary suspension of permit pending hearing. When the Secretary has reason to believe that the holder of any permit for the shipment of milk or cream into the United States has failed to comply with the provisions of or has violated sections 141-149 of Title 21, United States Code, or any of the regulations in this part, or that the milk or cream shipped by the holder of the permit into the United States is not produced and handled in conformity with, or that the quality thereof does not conform to, all of the provisions of section 122 of Title 21, United States Code, the Secretary shall serve upon the permittee an order to show cause why such permit should not be revoked, and, upon the hearing upon such order, the Secretary may temporarily suspend such permit.

¶ 290.32 Docket or file number. The order to show cause shall be assigned a docket or file number and the proceedings had thereon shall thereafter be referred to by such number.

¶ 290.33 Service of order to show cause. The order to show cause shall be addressed to the permittee, who shall be designated as the respondent, and shall be served upon the permittee by an employee of the Department of Health, Education, and Welfare or by registered mail, return receipt requested. If the respondent is a corporation, service shall be had upon the president, treasurer or statutory agent of the corporation.

¶ 290.34 Time and place of hearing. The Secretary shall set a time and place for a hearing upon the order to show cause.

¶ 290.35 Disqualification of examiner. The Secretary shall designate an employee of the Department of Health, Education, and Welfare as examiner to conduct the hearing, and such examiner may, in accordance with the rules of evidence applicable to administrative proceedings, admit or exclude any evidence presented and may limit the scope of any evidence admitted.

¶ 290.36 Appearance of respondent. The respondent may appear in person or by counsel. All persons who appear at the hearing must conform to the standards of ethical conduct required of practitioners before the courts of the United States.

¶ 290.37 Testimony of witnesses. The testimony of witnesses at the hearing shall be upon oath or affirmation administered by the examiner.

¶ 290.38 Admissibility of records. Copies of the records of the Department of Health, Education, and Welfare, certified under the seal of the Department, shall be admissible to the same extent that the original records would be admissible.

¶ 290.39 Depositions. The deposition of any witness, taken after reasonable notice to the opposite party and at a time and place and before a person designated for the purpose by the Secretary, shall be admitted if the evidence is otherwise admissible.

¶ 290.40 Affidavits. Affidavits, if relevant and material, may, in the discretion of the examiner, be admitted, but the Secretary will consider the lack of opportunity for cross-examination in determining the weight that shall be given to such evidence.

¶ 290.41 Hearsay evidence. Hearsay evidence may, in the discretion of the examiner, be admitted even though it...
§ 290.42 Form of introduction of evidence. The form of the introduction of evidence shall not be a ground of objecting to such evidence.

§ 290.43 Copies of exhibits. When practicable to do so, a copy of each exhibit shall be furnished to the opposing party either before or at the time of its introduction.

§ 290.44 Judicial notice. Judicial notice, on request, will be taken of such matters as are noticed by the courts of the United States.

§ 290.45 Objection to evidence. If the respondent objects to the admission of any evidence offered against him or the rejection of any evidence offered by him, or to the limitation of the scope of any evidence introduced by him, he shall state the grounds of such objection. If the objection is overruled, he may take an exception.

§ 290.46 Attorney representing the Department of Health, Education, and Welfare. At the hearing, the Secretary shall be represented by an attorney designated by the General Counsel of the Department of Health, Education, and Welfare.

§ 290.47 Filing of briefs. At the conclusion of the hearing, the examiner shall announce the period of time within which briefs may be filed following the receipt by the respondent of the tentative findings of fact and the tentative order, as set out in § 290.48.

§ 290.48 Tentative findings of fact. The examiner, within a reasonable time after the conclusion of the hearing, shall prepare tentative findings of fact and a tentative order, which shall be served upon the respondent or sent to him by registered mail.

§ 290.49 Exceptions by the respondent. Within 20 days after the receipt of the tentative findings of fact and the tentative order, the respondent, if he wishes to take exceptions to any matters set out therein, shall transmit such exceptions to the General Counsel of the Department of Health, Education, and Welfare. At the same time, the respondent shall transmit a brief statement concerning each of the exceptions to the actions of the examiner at the hearing, as set out in §§ 290.35–290.45, upon which he wishes to rely. If exception is taken to any proposed finding of fact, reference must be made to the pages or parts of the record relied upon and a corrected finding of fact must be submitted. The respondent, if he files exceptions, shall state in writing whether he desires to make an oral argument on the exceptions before the Secretary.

§ 290.50 Oral argument before the Secretary. In the event that an oral argument before the Secretary is requested, a date for such argument shall be fixed by the Secretary or by the Under Secretary, if designated to act in his stead.

§ 290.51 Issuance of final order. If oral argument is heard in any proceeding by the Secretary or Under Secretary, the final order in the proceeding shall be issued by the person who heard the argument.

§ 290.52 Hearing before prosecution. Before violation of the act is referred to the Department of Justice for prosecution under section 5 of the Federal Import Milk Act, an opportunity to be heard will be given to the party against whom prosecution is under consideration. The hearing will be private and confined to questions of fact. The party notified may present evidence, either oral or written, in person or by attorney, to show cause why he should not be prosecuted. After a hearing is held, if it appears that the law has been violated, the facts will be reported to the Department of Justice.

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