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LOANS TO INDIAN TRIBES AND TRIBAL CORPORATIONS  
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USDA/FNS limits the eligibility of children in schools and child care institutions which participate in National School Lunch, School Breakfast or Child Care Food Programs for free milk

USDA/FNS gives rate of reimbursement per half pint of milk for period 7-1-77 thru 6-30-78

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). This is a voluntary program. (See OFR notice 41 FR 32914, August 6, 1976.)

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Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

ATTENTION: For questions, corrections, or requests for information please see the list of telephone numbers appearing on opposite page.
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Questions and requests for specific information may be directed to the following numbers. General inquiries may be made by dialing 202-523-5240.

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A Cumulative List of CFR Sections Affected is published separately at the end of each month. The guide lists the parts and sections affected by documents published since the revision date of each title.

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### Reminders

(The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.)

**Rules Going Into Effect Today**

- **NRC**—Operational use of small quantities of source material; general license for Government agencies. 61853; 12-7-77
- **Treasury/CS**—Nogales, Ariz.: Extension of port limits. 61860; 12-7-77
- **DOT/FAA**—McDonnell Douglas Model DC-10 Series Airplanes; airworthiness directives. 61036; 12-1-77

**List of Public Laws**

*(Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.)*

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Hiller Model UH-12: C, D, E (4-place), L, EL and L-4s Converted from E-46; airworthiness directives. 61034; 12-1-77
SUMMARY: Special Milk Program regulations are amended to limit the eligibility of children in schools and child care institutions which participate in the National School Lunch, School Breakfast, or Child Care Food Programs for free milk under the Special Milk Program. No Special Milk Program reimbursement at the free rate may be claimed for milk served to a child during the meal service period, if the child receives a reimbursable meal under another program. The regulations are also amended to provide for annual adjustment of the Special Milk Program reimbursement rate on a "school year" rather than "fiscal year" basis; to define "school year"; Minor changes are also made for purposes of clarification and conformity. These regulatory changes are required by Pub. L. 95-165 which amends the National School Lunch Act and the Child Nutrition Act of 1966.

EFFECTIVE DATE: February 1, 1978 for all provisions except the announced rate and provisions (i) and (ii) under §215.8(b)(1) which shall be effective July 1, 1977.


SUPPLEMENTARY INFORMATION: Section 3 of the Child Nutrition Act of 1966, as amended by Pub. L. 95-166, provides that children who qualify for free lunches under guidelines set forth by the Secretary shall also be eligible for free milk, when milk is made available at times other than the periods of meal service in outlets that operate the National School Lunch, School Breakfast or Child Care Food Programs. The language of this amendment has been construed not "to deny any child in the lunchroom from receiving the milk that the child was entitled to." (Congressional Record F 11672) Therefore, in order to ensure that all qualified children receive free milk at meal times either as a component of free meals or as a separate beverage item, the Special Milk Program regulations are amended to require participating schools and institutions to make free milk available to all eligible children when the Program is operated at times other than meal service periods, and to furnish free milk during meal service periods to children determined eligible for free meals and milk, but who elect not to take the free meal under another program. This means that needy children who do not participate in the school lunch program (such as children who bring a bag lunch from home) will continue to be eligible for free milk during the lunch period.

This regulatory change does not affect the milk served to children as part of their National School Lunch, School Breakfast, or Child Care Food Program meals. It permits schools and institutions, at meal service periods, to make free milk available to eligible needy children who do not choose to take a free meal, and to make low cost milk available to all other children during such periods. Further, it encourages the availability of free milk to all needy children at times other than the meal service periods.

Pub. L. 95-166 also amended the Child Nutrition Act of 1966 to delete certain references to "fiscal year" and to substitute therefor "school year". Implementing changes are made in this amendment.

Since these regulatory changes implement nonsecretary provisions of Pub. L. 95-166, it is determined that proposed rule making and public participation procedures thereon are unnecessary and contrary to the public interest.

Accordingly, Part 215 is amended as follows:

1. In §215.1, the fifth and sixth sentences of the quoted statute are revised to read as follows:

§215.1 General purpose and scope.

Children who qualify for free lunches under guidelines set forth by the Secretary shall also be eligible for free milk, when milk is made available at times other than the periods of meal service in outlets that operate a food service program authorized under sections 4 and 17 of the National School Lunch Act and section 4 of this Act. For the fiscal year ending June 30, 1975, and for subsequent school years, the minimum rate of reimbursement for a half pint of milk served in schools and other eligible institutions shall not be less than 5 cents per half pint served to eligible children, and such minimum rate of reimbursement shall be adjusted on an annual basis each school year thereafter to reflect changes in the series of food away from home of the Consumer Price Index published by the Bureau of Labor Statistics of the Department of Labor.

2. In §215.2, paragraphs (k) and (l) are revised; and paragraphs (e-2) and (k-1) are added, as follows:

§215.2 Definitions.

(e-2) "CND" means the Child Nutrition Division of the Food and Nutrition Service of the Department.

(k-1) "Fiscal year" means the period of 12 calendar months beginning October 1, 1977, and each October 1 of any calendar year thereafter and ending September 30 of the following calendar year.

(k) "School year" means the period of 12 calendar months beginning July 1, 1977, and each July 1 of any calendar year thereafter and ending June 30 of the following calendar year.

3. In §215.7, paragraphs (d) (1) and (2) are revised as follows:

§215.7 Requirements for participation.

(d) (1) Operate a nonprofit milk service or, if food service is also maintained, operate a nonprofit food and milk service.

(2) (i) Make free milk available to all needy children whenever milk is made available under the Program at times other than during a meal service period;

(ii) Make free milk available to needy children who elect not to take a free meal reimbursable under the Act or under the National School Lunch Act, when milk is made available under the Program during a meal service period; and

(iii) Make no discrimination...
against any needy child because of inability to pay for the milk.

4. In § 215.8, paragraph (b) is revised as follows, paragraph (c) is deleted, and paragraph (d) is redesignated paragraphs (d) and (e):

§ 215.8 Reimbursement payments.

(b) The rate of reimbursement per half pint (236 ml) of milk purchased and served to children under the following.

§ 215.11 Special responsibilities of State agencies.

(o) Records and Reports. (1) Each State agency shall supply information on Program operations on a form provided by FNS, and shall maintain current accounting records of Program operations which will adequately identify fund authorizations, obligations, unobligated balances, outlays and income.

(3) Revised reports shall be submitted within one month after the initial submission and continue to be submitted whenever appreciable changes from the prior submission have occurred.

§ 215.13a Determining eligibility for free milk in child care institutions.

(g) Public announcement of eligibility criteria. Each child care institution required to make free milk available under the Program shall annually make a public release announcing the availability of free milk to children who meet the approved eligibility criteria, available to the information media serving the area from which its attendance is drawn.

§ 215.16 Program information.

(b) Mid-Atlantic Regional Office, Food and Nutrition Service, U.S. Department of Agriculture, One Vahling Center, Robbinsville, N.J. 08691.

(g) Mountain Plains Regional Office, Food and Nutrition Service, U.S. Department of Agriculture, 2420 West 26th Avenue, Denver, Colo. 80211.

Note—The reporting and/or recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Federal Reports Act of 1942.


Carol Tucker Foreman,
Assistant Secretary for Food and Consumer Services.

[FED. REG. 78-315 filed 1-5-78:8:45 pm]
ACTION: Final rule.

SUMMARY: This action establishes the quantity of California-Arizona lemons that may be shipped to the fresh market during the period January 8-14, 1978, and invariability of such lemons that may be so shipped during the period January 1-7. Such action is needed to provide for orderly marketing of fresh lemons for the periods specified due to the prevailing situation confronting the lemon industry.


FOR FURTHER INFORMATION CONTACT: Charles R. Brader, 202-447-6393.

SUPPLEMENTARY INFORMATION:

Findings: Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, necessary under this marketing order, and upon other information, it is found that the limitation of handling of lemons, as hereafter provided, will tend to effectuate the declared policy of the act.

The committee met on January 3, 1978, to consider supply and market conditions and other factors affecting the need for regulation, and recommended quantities of lemons deemed advisable to be handled during the specified weeks. The committee reports the demand for lemons continues strong.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 40 days after publication in the Federal Register (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation and amendment are based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting, and the amendment relieves restrictions on the handling of lemons. It is necessary to effectuate the declared policy of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

1. §910.426 Lemon Regulation 127. Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period January 8, 1978, through January 14, 1978, is established at 3.5 percent of the national average milkfat content of 3.67 percent. The equivalent support price is $8.73 per 100 pounds.

2. Paragraph (a) of §910.426 Lemon Regulation 126 (42 FR 5613) is amended to read as follows: "The quantity of lemons grown in California and Arizona which may be handled during the period January 1, 1978, through January 7, 1978, is established at 240,000 cartons." (See 1-10, 48 Stat. 31, as amended; 7 U.S.C. 601-674.)


Charles R. Brader, Director, Fruit and Vegetable Division Agricultural Marketing Service.

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used in calculating CCC's purchase prices and submitting report to the Board of Directors, CCC, at a later date.

INCมาSE SALES PRICES FOR CCC-OWNED DAIRY PRODUCTS

On April 1, 1977, CCC prices of dairy products for sale for unrestricted use were increased from 105 to 110 percent of current purchase prices in order to encourage the industry to store its own dairy products for use in the short production season of fall and winter. It was estimated that the 10 percent add-on to the purchase prices would cover storage costs and risks and is sufficient incentive to encourage the industry to store dairy products in the spring and summer for sale in the fall and winter. A further increase in CCC sales prices to 115 percent of the current purchase prices would result in a markup that exceeds estimated storage costs and risks. The sales prices of CCC-owned dairy products serve as a ceiling on prices when CCC has large inventories. Therefore, the 15 percent add-on could have an undue inflationary effect on wholesale and retail prices of dairy products.

PURCHASE PROCESS CHEESE AT AN ANNOUNCED PRICE

CCC purchases natural cheese in 40-pound blocks and in approximately 500-pound barrels at announced prices that are calculated to result in an annual average price for manufacturing milk at least equal to the announced support price. CCC obtains process cheese for use in the domestic school lunch and other feeding programs either by contracting directly with the industry to process CCC-owned natural cheese or by purchasing process cheese under competitive offers. It has been determined that it is not advisable to announce a fixed price for process cheese because CCC would lose control over the quantities of process cheese contracted for specific program uses and CCC would lose the flexibility it now has to exchange sales of Cheddar cheese back to the industry. Moreover, purchasing process cheese would add a marketing barrier between CCC and dairy farmers and thereby reduce the assurance that dairy farmers will derive the maximum benefit from the program. Although CCC continued to pay the same price for all process cheese offered in April and May, market prices for barrel cheese dropped sharply and prices paid to farmers for cheese declined. Since then CCC has made several changes in its natural cheese purchase contract requirements that fasten delivery on farmers delivering milk to cheese plants. These changes have been made to encourage the industry to store its own dairy products for sale in the fall and winter.

FINAL RULE

Based on the $9.00 support price, the October 1-September 30 marketing year, and the reorganization of Agricultural Stabilization and Conservation Service which was effective August 25, 1977, paragraphs (a)(1) and (a)(4) of T CFR 1430.282 are revised to read as follows:

§ 1430.282 Price support program for milk.

(a)(1) The general level of prices to producers for milk will be supported from October 1, 1977, through September 30, 1978, at $9 per hundredweight for manufacturing milk, subject to adjustment as provided for by law.

(4) Purchase announcements setting forth terms and conditions of purchase may be obtained upon request from:
United States Department of Agriculture, Agricultural Stabilization and Conservation Service, Procurement and Sales Division, P.O. Box 2416, Washington, D.C. 20250; or
United States Department of Agriculture, Agricultural Stabilization and Conservation Service, Kansas City ASCS Commodity Office, P.O. Box 8377, Shawnee Mission, Kans. 66208.

Note: The Commodity Credit Corporation has determined that this document contains a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11581 and OMB Circular A-107 and certifies that an Economic Impact Statement has been prepared.

[3410-34]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 73—SCABIES IN CATTLE

Area Quarantined

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment is to quarantine a portion of Texas County in Oklahoma because of the existence of cattle scabies. Porcine scabies was confirmed December 21, 1977, in Texas County. Therefore, in order to prevent the dissemination of cattle scabies it is necessary to quarantine the infected area.


FOR FURTHER INFORMATION CONTACT:
RULES AND REGULATIONS

8010-01

Title 17—Commodity and Securities Exchanges

CHAPTER II—SECURITIES AND EXCHANGE COMMISSION


PART 210—FORM AND CONTENT OF FINANCIAL STATEMENTS, SECURITIES EXCHANGE ACT OF 1934, SECURITIES EXCHANGE ACT OF 1933, PUBLIC UTILITY HOLDING COMPANY ACT OF 1935, AND INVESTMENT COMPANY ACT OF 1940

Marketable Securities and Other Security Investments

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Commission hereby amends rules recently adopted regarding disclosures by commercial and industrial companies of investments and marketable securities and other security investments to clarify or modify the requirements of certain instructions to the schedule in which the securities are required to be listed. The effective date for these amendments coincides with the effective date provided for the rules previously adopted on September 8, 1977, in Accounting Series Release No. 226.

DATE: Effective for financial statements for fiscal years ending after December 31, 1977.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

In Accounting Series Release No. 226, dated September 8, 1977 (originally published in the Federal Register at 42 FR 46512 and correction of § 210.12-02 schedule published at 42 FR 51569), the Commission revised the disclosure requirements for commercial and industrial companies regarding investments in marketable securities and other security investments. The revisions were effected by amendments to Regulation S-X (17 CFR Part 210) in Captions 2 and 12 of § 210.5-02, Schedule I of § 210.5-04, and the captions and instructions in § 210.12-02.

Inquiries have been received, as summarized below, regarding certain of the revised captions and instructions to the schedule under § 210.12-02, “Marketable securities—other security investments,” to which this release is responsive.

A. Clarification was requested for the term “agency” as used in Instruction 1 of the schedule under § 210.12-02, e.g., the U.S. Government and its agencies as to be classed as one issuer of securities, in regard to whether a corporation in the private sector whose securities are guaranteed in whole or in part by a governmental unit could be considered an agency of that governmental unit for purposes of this instruction. For this purpose a corporation would not be considered an agency of the governmental unit unless it is wholly or partially owned by the governmental unit. The instruction with respect to the cross-referencing required between two issuers when one has guaranteed or otherwise supported the securities of the other is clarified in order to provide disclosure of any such supportive relationship between two issuers which cannot be grouped together as one issuer to enable a better evaluation of the investment risks of the securities of each issuer held by the registrant.

B. Modification of Instruction 2a of the schedule under § 210.12-02 requiring the grouping of securities was requested to permit grouping of individual issues whose cost or market value does not exceed two percent of total assets in order that cross-referencing between two issuers be more practical. The issue of securities, the amounts of which are not significant for any issue, may be avoided, and to permit grouping of all security holdings of the U.S. Government and its agencies whether or not they exceed two percent of total assets in view of their virtually risk free nature. Instruction 2a is amended to permit groupings for the U.S. Government and its agencies and reasonable groupings for other governmental and corporate issuers.

C. Requests were made for modification of the requirements of Schedule I of § 210.5-04 to permit omission of the schedule prescribed by § 210.12-02 if data required to be disclosed in the schedule are included in the related financial statements or in a note thereto. Registrants are reminded that omission of this or any other schedule may be permitted in these circumstances by paragraph (a)(2) of § 210.5-04 which states in part: “If the information required by any schedule (including the notes there- to) may be shown in the related financial statement or in a note thereto without making such statement unclear or confusing, that procedure may be followed and the schedule omitted.”

COMMISSION ACTION

The Commission hereby amends Part 210 of 17 CFR Chapter II by revision of Instructions 1 and 2a in § 210.12-02 to read as given below.

§ 210.12-02 Marketable securities—other security investments.

(Instruction) 1 For the purpose of this schedule, each of the following groups of entities shall be considered as one issuer: (a) The United States Government and its agencies; (b) any state of the United States and its agencies; (c) a political subdivision of a state of the United States and its agen-
AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations, temporary regulations.

SUMMARY: This document amends the Income Tax Regulations relating to the definition of pension plan reserves. It also amends the Temporary Income Tax Regulations Under the Employee Retirement Income Security Act of 1974 relating to section 403(b) annuity contracts and salary reduction agreements. The amendments have been prepared in response to comments. The amendment of the Income Tax Regulations affects life insurance companies and corrects an unintentional error in a recently adopted regulation. The amendment of the Temporary Regulations affects employees of some tax-exempt organizations and provides them with somewhat easier rules for complying with the law.

DATES: The amendments have varying effective dates. The amendment of the Income Tax Regulations is effective as of August 23, 1977. The amendment of the Temporary Income Tax Regulations is generally effective for taxable years ending before and with within the taxable year in which applicable final regulations under section 415 are first published in the Federal Register. However, with respect to salary reduction agreements the amendment is applicable only to those agreements which are entered into for the taxable year beginning in 1977.

FOR FURTHER INFORMATION CONTACT:


BACKGROUND

This document amends § 1.805-7(b) of the Income Tax Regulations (26 CFR Part 1), relating to the definition of pension plan reserves. This document also amends § 11.415(c) (4)–(1) of the Temporary Income Tax Regulations under the Employee Retirement Income Security Act of 1974, relating to annuity contracts and salary reduction agreements. The temporary regulations provided by this document will remain in effect until superseded by final regulations on this subject.

PENSION PLAN RESERVES

Section 805(d) (4) of the Code and § 1.805–7(b) of the Income Tax Regulations define the term "pension plan reserves". In general, life insurance companies receive favorable income tax treatment with respect to these reserves. Because December 31, 1976 (42 FR 45524, August 23, 1977), which amended this regulation, inadvertently deleted a provision that included reserves allocable to contracts to provide retirement annuities purchased for employees in public school systems and universities in the term "pension plan reserves". The amendment restores the inadvertently deleted material. It also deletes two paragraphs reflecting a statutory provision that was deleted by the "Pension Reform" title of the Tax Reform Act of 1976.

SP ecial Rules for Elections Pursuant to Annuity Contracts

The regulations provide guidance for an individual who wishes to make a special election with respect to amounts contributed for section 403(b) annuity contracts. Before 1977, the special rules pertaining to the making of the special election (whether by filing a statement of intention or by the individual's determining his income tax liability in a way consistent with one of the special elections) was available only for a limitation year which ended with or within a taxable year beginning in 1976. This amendment extends the applicability of these special rules to all limitation years that end before or with or within the taxable year in which applicable final regulations under section 415 are first published in the Federal Register. It also deletes two paragraphs reflecting a statutory provision that was deleted by the "Pension Reform" title of the Tax Reform Act of 1976.
shall not be treated as pension plan reserves unless they qualify as such under section 805(d) (1), (2), (3), or (5) or paragraph (b) (4) (ii) of this section.

(b) Special rules for elections and salary reduction agreements for years before final regulations are published—

(1) Election. (i) For a limitation year ending before or on April 15, 1976, the individual may make a special election under section 415(c) (4), (5) or (6) for a year ending on or before April 15, 1976, if he determines his income tax liability for the taxable year in which applicable final regulations under section 415 are first published in the Federal Register, and if his election is consistent with the alternative limitations which he used in determining his income tax liability for that taxable year. The individual may also choose any of the alternative limitations, even if he used one of them in determining his income tax liability for that taxable year, there may be an adjustment in his tax for that year. For purposes of section 415, there shall be made on or before (a) the applicable final regulations published in the Federal Register, an individual may choose one of the alternative limitations or to a final decision not to use one of the alternative limitations for the tax year.

(2) Salary Reduction Agreements for 1976 and 1977. (i) An individual who is employed by an organization described in paragraph (a) (3) may make a salary reduction agreement for his taxable year beginning after December 31, 1976, if it is entered into on or before April 15, 1977, if he determines his income tax liability for the taxable year, respectively, without the agreement being considered a new agreement within the meaning of section 415(c) (3). (ii) The agreement for 1975 may be made on or before June 15, 1977, if that date is later than the end of the individual's 1975 taxable year. For purposes of section 415, there shall be made on or before (a) the applicable final regulations published in the Federal Register, an individual may choose one of the alternative limitations or to a final decision not to use one of the alternative limitations for the tax year.

(3) Election is irrevocable. The election described in paragraph (a) (3) of this section, once made in accordance with the provisions of subparagraph (1) of this paragraph, shall be irrevocable with respect to the limitation years or
taxable years to which the election relates.

There is a need for immediate guidance with respect to the provisions contained in the Treasury decision. For this reason, it is found impracticable to issue it with notice and public procedure under subsection (b) of section 553 of Title 5 of the United States Code or subject to the effective date limitation of subsection (d) of that section.

(See 415(c) (4) (D) and 7805 of the Internal Revenue Code of 1954 (68 Stat. 963 and 66A Stat. 917; 26 U.S.C. 415(c) (4) (D) and 7805).)

JEROME KURTZ,
Commissioner of Internal Revenue.

Approved: December 27, 1977.

[FR Doc. 78-315 Filed 1-5-78; 8:45 a.m.]

[4410-01]

Title 28—Judicial Administration

CHAPTER I—DEPARTMENT OF JUSTICE

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

[Order No. 761-77]

Subpart C—Office of the Associate Attorney General

AUTHORITY TO REDELEGATE CERTAIN ATTORNEY PERSONNEL MATTERS

AGENCY: Department of Justice.

ACTION: Final rule

SUMMARY: Existing Department regulations assign to the Associate Attorney General authority to take final action in attorney personnel matters and to appoint Assistant U.S. Attorneys and other attorneys to assist U.S. Attorneys and fix their salaries in positions for which the pay is equivalent to grade GS-15 or below.


GRIFFIN B. BELL,
Attorney General.

[FR Doc. 78-310 Filed 1-5-78; 8:45 a.m.]

[4410-01]

PART 43—RECOVERY OF COST OF HOSPITAL AND MEDICAL CARE AND TREATMENT FURNISHED BY THE UNITED STATES

Settlement and Waiver of Claims

AGENCY: Department of Justice.

ACTION: Final rule

SUMMARY: This order increases from $20,000 to $40,000 the amount of certain claims of the United States for furnishing medical care and treatment which may be settled by agencies without prior approval of the Department of Justice. The increase reflects inflationary increases in costs of medical care and is designed to reduce unnecessary administrative delays in settling claims by agencies.

EFFECTIVE DATE: December 27, 1977.

FOR FURTHER INFORMATION CONTACT:

Barbara Allen Babcock, Assistant Attorney General, Civil Division, Department of Justice, Washington, D.C. 20530, telephone 202-739-3301.


GRIFFIN B. BELL,
Attorney General.

[FR Doc. 78-308 Filed 1-5-78; 8:45 a.m.]

[3810-70]

Title 32—National Defense

CHAPTER I—OFFICE OF THE SECRETARY OF DEFENSE

SUBCHAPTER M—MISCELLANEOUS

[DoD Directive 1000.10]

PART 230—CREDIT UNIONS SERVING DEPARTMENT OF DEFENSE PERSONNEL

AGENCY: Office of the Secretary of Defense.

ACTION: Final rule.

SUMMARY: This rule revises and updates Department of Defense policies governing the establishment, support of, and relationships with credit unions serving DoD personnel. The revision changes overall responsibilities for the DoD credit union program from the Assistant Secretary of Defense (Manpower and Reserve Affairs) to the Assistant Secretary of Defense (Comptroller). It also revises specific policies, procedures and definitions, and expands on the voluntary aspects of DoD personnel serving on credit union boards and committees.

EFFECTIVE DATE: June 22, 1977

FOR FURTHER INFORMATION CONTACT:

Mr. Ronald L. Adolph, Office of the Deputy Assistant Secretary of Defense, (Management Systems), OASD (Comptroller), telephone 202-697-8281.

SUPPLEMENTARY INFORMATION: In FR Doc. 69-6791 on July 25, 1969 (34 FR 12337) this part was published as a final rule. It was partially amended in FR Doc. 72-21705 on December 19, 1972 (37 FR 27629). In FR Doc. 76-35928 published in the Federal Register on December 7, 1976 (41 FR 53489) the Office of the Secretary of Defense published a proposed revision of this part. A total of 13 comments were received. All comments, insofar as they related to the subject matter were considered, and some aspects contained in 11 comments were incorporated into this final rule.

Maurice W. Roche,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.


Accordingly, Part 230 reads as follows:

Sec. 230.1 Reissuance and purpose.

230.2 Applicability.

230.3 Responsibilities.

230.4 General policies.

230.5 Specified policies and procedures.

230.6 Logistical support.

230.7 Definitions.


§ 230.1 Reissuance and purpose

This Part reissues Part 230 to update Department of Defense policies governing the establishment, support of, and relationships with credit unions serving DoD personnel, and reassign overall responsibility for policy direction of the DoD credit union program from the ASD (M&RA) to the ASD(C). ASD(M&RA) retains responsibility for morale and welfare aspects of the program.

§ 230.2 Applicability

The provisions of this Directive apply to the Office of the Secretary of Defense, the Military Departments, the Organization of the Joint Chiefs of Staff, the Unified and Specified Commands and the Defense Agencies (hereinafter referred to collectively as “DoD Components”).

§ 230.3 Responsibilities

(a) The Assistant Secretary of Defense (Comptroller) shall:

(1) Administer the overall DoD credit union program and assure its effective...
IMPLEMENTATION TO INCLUDE ANALYSES OF SERVICES RENDERED AND COST-BENEFIT RELATIONSHIPS.

(2) Maintain liaison, as appropriate, with the National Credit Union Administration, the Office of the Comptroller of the Currency, and equivalent State regulatory agencies.

(3) Maintain liaison with associations, leagues of credit unions and councils which include DoD credit unions in order to provide DoD policies to the industry and as an aid in solving mutual problems in the conduct of credit union operations.

(4) Coordinate all aspects of the credit union program which pertain to morale and welfare with ASD(MA&L).

(5) Take final action on requests for exceptions to the provisions of this Part.

(b) The Secretaries of the Military Departments shall:

(1) Have responsibility for recognizing and assisting credit unions in developing and expanding necessary credit union services for DoD personnel under their jurisdiction, consistent with the provisions of this Part.

(2) Establish liaison, as appropriate, with the National Credit Union Administration, the State agencies involved, as well as associations, leagues and councils which include DoD credit unions.

(3) Coordinate the development of credit unions with other Military Departments when required.

(4) Maintain a current listing of all credit unions, branches and facilities serving their Departments.

(e) All DoD Components shall:

(1) Recognize the right of military and civilian personnel to organize and join credit unions formed under duly constituted authority, and encourage the application and expansion of the principles of the credit union movement in the DoD worldwide.

(2) Recognize and support credit union associations, leagues of credit unions and councils which include DoD credit unions.

(3) Encourage DoD personnel who volunteer to serve on credit union boards and committees on a nonremunerative basis where neither conflict of duty nor interest exist, and to be employed by 32 CFR 40. These personnel may be allowed to attend credit union conferences and meetings in accordance with DoD Directive 1527.5 and DoD Instruction 1424.2.

§ 230.4 General policies.

(a) As stated in 12 U.S.C. 1751 and 12 CFR Chapter VII credit unions are recognized as legitimate institutions by 32 CFR 40. These personnel may be allowed to attend credit union conferences and meetings in accordance with DoD Directive 1527.5 and DoD Instruction 1424.2.

(b) Credit unions shall be made available to DoD personnel of all ranks and grades under conditions and in the manner set forth in § 230.5.

(c) Existing DoD credit unions, branches and facilities under their jurisdiction shall continue to operate in accordance with present agreements, as applicable.

§ 230.5 Specific policies and procedures for DoD Credit Unions.

(a) General.—(1) New Stateside DoD Credit Unions. (i) Where there is a demonstrated need for credit union services and when sufficient personnel capability and interest exist, primary shall be placed for establishing credit unions by the installation commander for review. The proposal will be forwarded, with a recommendation for approval or denial, through channels to the Military Department concerned for final determination in coordination with the ASD(C) and the appropriate credit union regulating agency.

(ii) Any group of persons seeking to establish a full-service credit union on an installation without a full-service credit union shall submit a proposal to the installation commander for review. The proposal will be forwarded, with a recommendation for approval or denial, through channels to the Military Department concerned for final determination in coordination with the ASD(C) and the appropriate credit union regulating agency.

(b) Share Insurance. Credit unions sponsored by DoD activities or operating branch offices or facilities on military installations must qualify for Federal Credit Union Insurance under the Federal Credit Union Act, or participate in the State-sponsored share insurance program of the State in which the credit union is operating, or in a private insurance plan. State and private insurance plans must provide essentially the same insurance coverage as provided by the National Credit Union Administration. Credit unions located by the installation commander that do not have share insurance as of the date of this Directive must provide such insurance within 2 years. Failure to provide insurance will result in a removal from the installation and a request by DoD to the appropriate regulatory body for charter revocation.

(3) Dual Credit Unions. At certain installations, two credit unions, each with its own board of directors, field offices and overlapping fields of membership, now exist. These credit unions are encouraged to take voluntary action to request charter amendments which would permit full credit union operations without discrimination to all eligible personnel.

(i) Where charter amendment is neither desired nor deemed appropriate by the officials of the credit union or where such proposed amendment is disapproved by the National Credit Union Administration or the appropriate State agency, affected credit unions should be encouraged to consider the advantages of merger. Mergers may not be directed by military officials.

(ii) Where neither charter amendments nor mergers are possible, existing credit unions, as an exception to § 230.5 (c), may retain but not expand existing facilities or may elect to operate from an off-base location. Priority in space acquisition and facilities will be rendered to that credit union offering full services.

(iii) Where neither of two existing credit unions on a military installation offers full services and another credit union receives approval to provide full credit union services to all personnel at the installation, the installation commander shall:

(A) Withdraw off-base space and support functions for credit unions which do not provide full services.

(B) Require their removal to an off-base operating location.

(iv) Except for those already in existence, only one credit union on a military installation is permitted, and its field of membership shall include all assigned DoD personnel.

(4) Credit Union Service Overseas. Credit unions established as a full-service branch or facility of a stateside DoD credit union on a military installation will continue to operate branch or facility of a stateside DoD credit union on an off-base location, and will confine their membership to DoD personnel and their dependents.

(A) Authorized unified commanders and/or designated component commanders and the Military Departments shall issue appropriate instructions consistent with this Directive, governing existing branches or facilities under their jurisdictions, and encourage the extension of credit union service overseas consistent with the principles established for stateside DoD credit unions and any international arrangements related to the presence of U.S. Force in the country concerned. One copy of any instructions so issued, and subsequent changes thereto, will be forwarded to the Assistant Secretary of Defense (Comptroller).

(B) The ASD(C) will be notified through military channels when a local credit union extends its field of membership to include personnel who need for credit union services in an overseas location. This notification shall include the name of a designated project officer and a statement that the require-
ment has been coordinated with the U.S. Chief of Mission or U.S. Embassy involved and that the country involved will permit the operation.

(1) The installation commander or, cause to be notified, state-side DoD Federal credit union branches will forward the proposal to the designated component commander, and to the appropriate Military Department, requesting recommendations. Concurrently, the proposals will be provided to the National Credit Union Administration for information.

(2) Upon receipt of recommendations a DoD position will be developed and a recommendation will be provided to the NCUA. The NCUA will make the final selection of the credit union to provide service in the overseas area.

(3) The NCUA will assign each approved branch office a primary installation from which to operate and a geographical territory for further expansion through branch offices and facilities. These may be permanent locations or traveling service through mobile outlets. The ASD(C) will be notified in advance of any expansions proposed in accordance with this paragraph.

(4) These branches and facilities will be authorized an exclusive-on-site franchise; however, any credit union having an approved charter which authorizes it to serve its members while stationed overseas may continue to do so by direct mail, including the use of available media for commercial solicitation through advertising.

(5) Should a credit union propose to provide any substantially new service (e.g., share drafts) to members which is an addition to or a departure from the original charter, a request detailing the proposal will be informally coordinated with the U.S. Chief of Mission or U.S. Embassy involved to determine if the country in question will permit the service. A statement citing such discussions will be included when forwarding the Command recommendation through military channels to the ASD(C) for review and approval in concert with the NCUA.

(6) Overseas credit union branch offices and facilities shall conduct business in accordance with this Part. Additionally, implementing regulations of the affected unified commanders and/or the designated component commander may be necessary. The Installation commander is responsible for the proper allocation of credit union publications.

(A) The recommendations and direction of the National Credit Union Administration through its rules, regulations, procedures, forms, reports and manuals (including the Board of Directors Manual and Federal Credit Union) apply directly to all overseas credit union branch offices and facilities.

(B) Funds shall be deposited and/or invested in accordance with the authority applicable to Federal credit unions.

(C) The final selection of the credit union to provide service in the overseas area shall be included when forwarding the proposal to the designated component commander and, to the appropriate Military Department, requesting recommendations. Concurrently, the proposal will be provided to the National Credit Union Administration for information.

(2) Counseling. Counseling service shall be made available to DoD credit union members without charge, and shall include helping members, particularly youthful and inexperienced servicemen and women, to solve money problems and to budget.

(3) Savings. Members will be encouraged to participate in a regular savings plan which:

(1) Meets their individual needs and provides a reasonable return on savings; and

(2) Is dictated by good management principles as to amounts that may be deposited at any one time or the total amount which may be held in savings.

(4) Relations. It is a mutual responsibility of the installation commander and the credit union manager to build a viable relationship in which there is an in-depth understanding intended. This relationship should be one in which continuous communications are maintained and problems are anticipated and resolved as smoothly as possible.

(5) Credit unions operating on military installations shall:

(A) Keep the installation commander advised of the credit union operations.

(B) Furnish him a copy of the monthly financial report and other local credit union publications.

(C) Invite him or his designees to attend annual meetings and other appropriate functions.

(6) Credit unions will, to the extent resources permit and when so requested, provide the installation commander with lecturers and material on consumer credit matters in support of educational programs for DoD personnel as prescribed by 32 CFR Part 43.

(7) Cooperation, linkage and exchange of information between credit unions of all DoD Components will be encouraged. Credit union associations, credit union leagues, and councils formed by DoD credit unions can provide an excellent means of communication.

(8) The support and sympathetic understanding intended by this Directive will not be construed as representing control, supervision, or financial responsibility for credit unions by installation commanders or DoD Components.

(9) Complaints Processing--(1) Discrimination. Installation commanders who suspect or receive complaints of discrimination or violations of standards of service may first attempt to solve the problem by negotiation. Failing this, a request in writing for investigation shall be made to the regional representative of the NCUA in the case of a Federal credit union, or to the State authority in the case of a State-chartered credit

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union. The request will clearly describe the problem. These regulatory bodies will attempt to resolve the situation. Information regarding each operation relating to the matter shall be sent through channels to the Military Department concerned for forwarding to ASD(C), as appropriate.

(ii) Malpractice. Any evidence of suspected malpractice shall be reported in writing by the installation commander suspending such malpractice to the regional military installation commander in the case of Federal credit unions, or to the State regulatory agency in the case of a State-chartered credit union.

(iii) Reporting. If action by the appropriate regulatory agency's local representative fails to solve the problem, a full report with recommendations shall be submitted through military channels to the ASD(C). Appropriate follow-up action, directly to the Administrator, NCUA, or to a State regulatory agency, if appropriate, which may include a request for coordination, shall be accomplished by the ASD(C), keeping the Military Department concerned informed.

(6) Facilities and staffing. (i) Full services shall be provided by on-site credit unions staffed by (a) a loan officer-authorized to act for the credit committee, (b) an individual authorized to sign checks, and (c) a qualified financial counselor available to the membership during operating hours. Exceptions to this requirement may be approved by the Military Department concerned in the case of newly organized credit unions.

(A) Where an on-site credit union requires only minimum staffing, the counselor duties may be assumed by § 230-5(b)(d)(a) or (b).

(b) Where an on-site credit union extends its services to one or more areas of the same installation and direct courier or message service is available to the main office, a one-person operation is authorized for the extended operation.

(ii) All staffing shall be accomplished in full compliance with the spirit and intent of the national equal employment opportunity policies and programs of the Department of Defense in accordance with 32 CFR 191.

(7) Hours of Operation. Credit unions will be permitted to conduct operations during normal duty hours, providing there is no undue interference with the performance of official duties. Credit unions are encouraged to establish operating hours consistent with the needs of the military installation to best serve the overall needs of the membership within sound management principles. Automated teller machines (ATMs) may be used by credit unions as a means to provide service and expand operating hours.

(8) Advertising. (i) Advertising in official Armed Forces newspapers and periodicals (32 CFR 202 and DoD Directive 5120.43) is prohibited. DoD credit unions may be afforded advertising space in civilian-enterprise newspapers on a paid basis.

(ii) The use of informational bulletin boards for promotional material is authorized.

(iii) Competitive literature from other credit unions will not be disseminated at that installation. This does not preclude any credit union whose approved charter permits it to do so, while still situated overseas from utilizing a direct mail approach or a commercial advertising campaign in the same area. Distribution of competing credit union literature through Military Exchange outlets in areas where an on-site credit union exists is not authorized.

(iv) The use of the American Forces Radio and Television Service (DoD Instruction 5120.28) to promote a specific credit union is prohibited.

(9) Support of Pay Allotment Privileges. DoD personnel may use the allotment of pay privileges to make allotments to the credit union of their choice to meet existing obligations and establish sound credit and savings practices as prescribed by 32 CFR Part 59.

(i) Mementum. Any funds to deposit funds by allotment shall have their accounts credited on the date the credit union is authorized to deposit funds received on behalf of the members.

(ii) Under no circumstances will the initiation of an allotment become a prerequisite for a loan approval or delivery of funds to the credit union member. Allotments voluntarily initiated to a credit union under 32 CFR Part 59 may continue in force at the pleasure of the allottee.

(iii) Change of Address. Members of credit unions having an outstanding loan balance should contact the credit union prior to departure from the installation and report a change of address. Individuals who are members of a credit union, but do not have an outstanding loan balance, shall be encouraged to file a change of address.

(iv) Locator Service. Requests for central locator service for military addresses of active duty personnel by credit unions located on a military installation will be processed at no cost in accordance with 32 CFR 288. Credit unions should cite this authority when requesting such service. This service is provided only when necessary to locate individuals for settlement of accounts including bad checks and delinquent loans in accordance with DoD Directive 1344.5.

(v) Utilization of Military Real Property and Space. One full-service credit union, including branches and facilities, at each DoD installation will be furnished space, when available, by no-cost for periods of 5 years as prescribed in DoD Directive 4165.6. The furnishing of space and related real property to credit unions will be governed by Section 1770 of the Federal Reserve Act and its member credit unions providing less than full service are not authorized to be furnished space. Credit unions assigned military real property and space will reimburse the DoD for all services such as telephone lines, long-distance toll calls, space alterations, air conditioning, heat, light, etc. However, no reimbursement will be made for furniture, fixtures, and maintenance when provided.

(1) Criteria governing the assignment of existing space facilities and construction of new space facilities (when authorized) for credit unions will be in accordance with those specified in DoD Manual 4270.1-M.

(2) Proposals by credit union officials for the construction of structures on DoD installations at credit union expense must receive the prior approval of the Assistant Secretary of Defense (Manpower, Reserve Affairs and Logistics) and the Assistant Secretary of the Treasury (Comptroller) and must be reported to Congress in accordance with DoD Instruction 7700.18. The following provisions are emphasized:

(a) The building must be confined to the needs of the credit union. The building will not be used to house other commercial enterprises or Government installations.

(ii) Credit unions submitting such plans for consideration must also agree to be financially responsible for and to reimburse the DoD for any maintenance, utilities and other improvements erected thereon shall be conveyed to the Government without reimbursement, or removed and the land restored to its original condition in the event of

(a) installation inactivation, closing or other disposal action, liquidation of the credit union, or revocation or other termination of the credit union lease.

(iii) Logistical support for overseas credit unions will be in accordance with the above and with DoD Directive 4635.1.

(4) Military Postal Service for overseas credit unions may be authorized in accordance with DoD Directive 4635.1.

§ 230.6 Logistical support.

Credit unions organized by and for DoD personnel may be provided logistical support as set forth in section (a) of § 230.5 and DoD Directive 4600.6.

§ 230.7 Definitions.

(a) Automated Teller Machine (ATM). A machine which dispenses cash, accepts deposits and transfers funds between a member's various accounts. Equipment generally is activated by a plastic card in combination with pushbuttons.

(b) Credit Union Branch or Credit Union. A subsidiary office of an existing full-service credit union.

(c) Credit Union Facility. A facility employing teletype or other communications systems with the main credit union to conduct business at remote locations (as defined in DoD Directive 5120.28) for a full-service credit union.
where a full-service credit union branch it impracticable. Credit union facilities need not provide cash transaction services, but do disburse loans and shares via check or draft. They provide qualified financial counseling service during normal working hours.

(d) Discrimination. Any differential treatment in the provision of services, including loan services, by a credit union to DoD credit union members and their dependents on the basis of race, color, religion, national origin, sex or marital status, age, or arrest.

(e) DoD Credit Union. A credit union organized primarily to serve DoD personnel.

(f) DoD Personnel. DoD personnel as used in this part, unless the context indicates otherwise, means all military personnel, Civil Service employees, and other civilian employees including special Government employees of all offices, agencies, and departments serving on a Defense installation (including non-appropriated fund instrumentalities).

(g) Fair Rental. Fair rental is a reasonable charge for on-base land and is not necessarily comparable with the rental charges will be applicable for the entire term of the lease.

(h) Federal Credit Union. Credit unions established and operated under the authority granted by the Federal Credit Union Act, as amended, as legal entities with specific powers and authorities as approved by law. They are supervised and examined periodically by the National Credit Union Administration.

(i) Full-Service Credit Union. A full-service credit union provides normal counter-transact services and is staffed with a loan officer, a person authorized to sign checks and a qualified financial counselor. (Counseling functions may be assumed by the loan officer or the person authorized to sign checks of the credit union.)

(j) Malpractice. Any action or inaction in the operation of a credit union that may result in injury, loss or damage to a member, or members, of that credit union or the violation of the State or Federal chartering agency’s regulations of a DoD credit union whether intentional, criminal, or merely negligent.

(k) Overseas Credit Union. A Federally chartered full-service credit union which serves its members through a branch or facility at U.S. military installations in foreign countries.

(l) Share Drafts. A negotiable (or nonnegotiable) draft or other order prepared by the credit union member and used to withdraw shares from a share draft account, normally through the commercial banking system.

(m) State Credit Union. Credit unions organized under State laws which operate on the same, general principles as Federal credit unions and are supervised and examined by State regulatory bodies.

(c) Stateside DoD Credit Union. A DoD credit union located in any State of the United States, the District of Columbia, the several territories and possessions of the United States, the Panama Canal Zone, and the Commonwealth of Puerto Rico.

[FR Doc.78-317 Filed 1-5-76; 6:45 am]

CHARTER VII—DEPARTMENT OF THE AIR FORCE
PART 816—RECREATION ACTIVITIES AND SERVICE PROGRAM
PART 861—AIR FORCE AERO CLUBS
Redesignation of Parts

ACTION: Department of the Air Force, Department of Defense.

ACTION: Final rule.

SUMMARY: The Department of the Air Force is adding a new Subchapter to Chapter VII, 32 CFR and redesignating two parts to move them into the new Subchapter. This is being done to place the parts under the subchapter heading which best suits them. Previously they were located under headings which were not homogeneous to their content. But the result intended by this action is better organized listing of parts, conforming with the Air Force series titles now in use within the Department of the Air Force.


FOR FURTHER INFORMATION CONTACT:

SOLUTIONARY INFORMATION: In the Federal Register of December 21, 1976 Interpretative Ruling (41 FR 65524), for the accommodation of the construction and operation of the Volkswagen Manufacturing Company of America (VWMOA) automobile assembly plant in New Stanton, Pa. See Supplementary Information for further explanation.


FOR FURTHER INFORMATION CONTACT:
Glenn Hanson, Regional Air New Source Coordinator, Air and Hazardous Materials Division, Environmental Protection Agency, Region III, Curtis Building, 6 and Walnut Street, Phila-


SOLUTIONARY INFORMATION: In the Federal Register of October 6, 1977 (42 FR 44160), the Environmental Protection Agency (EPA) approved a revision to the Commonwealth of Pennsylvania’s State Implementation Plan to include the requirement that the Pennsylvania Department of Transportation restrict the usage of liquid bituminous cutback asphalt material in its paving and road surface maintenance program. This action was taken in order to obtain non-methane hydrocarbon (NMHC) emission offsets, pursuant to the requirements of Section 110 of the Clean Air Act (as amended, 1977) and EPA’s December 21, 1976 Interpretative Ruling (41 FR 65524), for the accommodation of the construction and operation of the Volkswagen Manufacturing Company of America (VWMOA) automobile assembly plant in New Stanton, Pa.

Some questions have arisen as a result of language in the Supplementary Information section of the October 6 notice. Specifically, the language in the Notice could be read to impose restrictions on VWMOA different from those contained in the permit issued by the Pennsylvania Department of Environmental Resources (DER). In particular, the notice could be read to impose a one-shift limitation on the plant, and an eventual emission limitation of 280 tons of
PART 227—CRITERIA FOR THE EVALUATION OF PERMIT APPLICATIONS FOR OCEAN DUMPING OF MATERIALS

2. On page 2477, paragraph (a) (3) of § 227.6 should be changed so that the seventh line reads "** * * with appropriate sensitive benthic marine organisms. * * *"

3. On page 2481, paragraph (b) of § 227.27, the last word in the eleventh line should be "and" instead of "of."

PART 228—CRITERIA FOR THE MANAGEMENT OF DISPOSAL SITES FOR OCEAN DUMPING

4. On page 2484; paragraph (b) of § 228.11 should be changed on the eleventh line to refer to the provisions of § 232.2 instead of "228.2."

5. On page 2485 under Approved interim dumping sites, an additional site should be added as follows: Location (lat., long.): 30°04'20" N., 73°41'00" W. to 73°38'10" W.

EPA Region—VI

6. In the first column under Dredged Material Sites—Location, an additional site should be added to appear at the beginning of the listing as follows:

Newburyport, MA—42°48'50" N., 70°47'00" W. (3/4 M. N. square).

7. The four Puerto Rico sites should be changed to read as follows:

San Juan Harbor, PR—18°30'10" N., 65°09'31" W.; 18°30'10" N., 65°09'29" W.; 18°31'10" N., 65°09'31" W.


Arecibo Harbor, PR—18°30'00" N., 66°43'49" W.; 18°30'00" N., 66°43'47" W.; 18°31'00" N., 66°43'47" W.

Ponce Harbor, PR—17°55'54" N., 69°38'33" W.; 17°53'50" N., 69°39'31" W.; 17°54'30" N., 69°39'29" W.; 17°54'30" W., 69°38'39" W.

8. In the Wilmington Harbor entry, the second line of the first column should be changed to read 33°48'45" W.

9. In the Georgetown Harbor entry, the second and third lines should be changed to read W., 33°11'18" N., 78°05'13" W.; 33°10'38" N., 78°05'13" W.; 33°10'38" N., 78°07'21" W.

10. In the last entry in that column, the last line, first entry, should be changed to read 78°08'51" W.

11. In the second column, first entry, the second and third lines should be changed to read W., 32°10'06" W., 89°30'24" W.; 32°10'06" W., 89°29'24" W.; 32°09'54" W., 89°29'31" W.

12. In the second entry, Port Royal Harbor, the second and third lines should be changed to read W.; 32°08'32" N., 89°30'24" W.; 32°08'32" N., 89°30'24" W.; 32°08'41" N., 89°35'49" W.

13. In the third entry, Brunswick Harbor, the last coordinate on the next to last line should be changed to read 81°17'40" W.

14. In the fourth entry, Savannah Harbor, the eighth line that begins with the last line should be changed to read 80°46'48" W.; thence due east to 31°57'55" N. and 80°44'20" W., thence due south to 30°52'31" N. and 81°55'05" N., thence due west to 31°55'53" N. and 80°48'45" W., thence northward to the point of beginning.

15. In the third column, first Vhila-coechee River entry, the first coordinate should be changed to read 28°39'54" N.

16. In the first Gulfport entry, the second coordinate on the third line should be corrected to read 88°55'5" W.

17. On page 2486, second column, fourth entry, Mississippi River Outlets, Venice, La.—Tiger Pass, should be changed to read Maintenance dredging disposal area 0.5 miles wide by 2.5 miles long, parallel and adjacent to the channel and located on the south side, beginning at 29°05'28" W. and 89°23'35" N., following 270° azimuth to 29°08'25" W. and 89°28'05" N., thence to 29°07'54" W. and 89°28'55" N., thence to 29°07'54" W. and 89°23'55" N., thence to the point of beginning.

18. The sixth entry, Barataria Bay Waterway, La.—Bar channel, should be changed to read Maintenance dredging disposal area 0.5 miles wide by 2 miles long parallel to the channel and located on the east side 1,000 feet distance from the channel. Beginning at 29°16'13" N. and 89°53'54" W., following azimuth 312°07" to 29°14'43" N. and 89°54'05" W., thence to 29°14 30.5" N. and 89°53'45" W., thence to 29°15'54" N. and 89°55'34" to the point of beginning.

19. The final entry in that column, Houma Navigation Canal, La.—Cat Island Pass, should be changed to read Maintenance dredging disposal area approximately 0.5 miles wide by 5 miles long parallel to the Cat Island Channel and located on the west side 1,000 feet from the channel centerline. Beginning at 29°05'30" N. and 90°34'11" W., following azimuth 358°41" to 29°03'39.5" N. and 90°34'25.5" W., following azimuth 0°34" to 29°01'10" N. and 90°34'20" W., thence to 29°01'10" N. and 90°34'45" W., thence to 29°03'59" N. and 90°34'54" W. and 90°35'14" W., thence to the point of beginning.

20. On page 2487, first column, fourth entry from the bottom, Moss Landing 100 fathom, the first coordinate should be changed to read 38°47'53" N.

21. Following Moss Landing 100 fathom, an additional site should be added as follows:

Moss Landing—38°48'55" N., 121°47'22" W. (410 feet, southerly pier).
Title 43—Public Lands: Interior

SUBTITLE A—OFFICE OF THE SECRETARY OF THE INTERIOR

PART 20—EMPLOYEE RESPONSIBILITIES AND CONDUCT

Appendices C, D, E, and F to Part 20 of Title 43 of the Code of Federal Regulations


ACTION: Annual update of Appendices C, D, E, and F to Part 20 of Title 43 of the Code of Federal Regulations.

SUMMARY: In accordance with the provisions of 43 CFR 20.735–18, 19, 20 and 22, Appendices C, D, E, and F to Part 20 of Title 43 of the Code of Federal Regulations are published in their entirety in order to update the appendices.


For further information contact:


Supplementary Information:

Appendix C lists the department of the Interior positions, in addition to GS-15’s and higher, who are required by Executive Order 11232 and by 43 CFR 20.735–22 to file a Confidential Statement of Employment and Financial Interests. The positions in addition to GS-15’s and higher identified in Appendix C are effective for the February 1, 1978, filing date.

Appendices D, E and F are published to show bureaus and offices, or subunits thereof, performing functions or duties under the Federal Land Policy and Management Act (Pub. L. 94–579) and the Energy Policy and Conservation Act (Pub. L. 94–163) respectively and positions within those bureaus and offices which the Secretary has determined to be exempt from public disclosure requirements. As provided in 43 CFR 20.735–18, 19 and 20, all officers and employees of the Department who are employed in offices and bureaus, or subunits thereof, performing functions or duties under any of the three Acts are required to file applicable public disclosure statements unless specifically exempted by the Secretary. Such exemptions are identified in Appendices D, E and F and are effective for the February 1, 1978, filing date.

Appendix C was approved by the Civil Service Commission on December 14, 1977. These appendices were compiled by Gene Fredriksen and Gabe Paone of the Department Ethics Counselor’s staff, in coordination with Bureau Ethics and Deputy Ethics Counselors.


Leo M. Krulitz, Acting Secretary of the Interior.


Appendix C—List of Employees, in addition to GS-15’s and higher, required to file Confidential Statements of Employment and Financial Interests.

Office of the Secretary’s Immediate Office

Special Assistant to the Secretary.

Confidential Assistant.

Staff Assistant.

Deputy Executive Secretary.

Deputy Director, Resource and Development.

Assistant Administrator for Water and Hazardous Materials.

Assistant Department Ethics Counselor, Washington, D.C.

Deputy Department Ethics Counselor, Washington, D.C.

Assistant Department Ethics Counselor, Washington, D.C.

Deputy Department Ethics Counselor, Washington, D.C.

Deputy Director, Resource and Development.

Assistant Administrator for Water and Hazardous Materials.

Assistant Department Ethics Counselor, Washington, D.C.

Deputy Department Ethics Counselor, Washington, D.C.

Deputy Department Ethics Counselor, Washington, D.C.

Deputy Department Ethics Counselor, Washington, D.C.

Deputy Department Ethics Counselor, Washington, D.C.

Assistant Department Ethics Counselor, Washington, D.C.

Deputy Department Ethics Counselor, Washington, D.C.

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Deputy Department Ethics Counselor, Washington, D.C.
RULLES AND REGULATIONS

Agency Land Operations Officer, Cheyenne River Agency, Eagle Butte, S. Dak. (GS-12)
Agency Realty Officer, Cheyenne River Agency, Eagle Butte, S. Dak. (GS-12)
Agency Employment Assistance Officer, Cheyenne River Agency, Eagle Butte, S. Dak. (GS-12)

* Grow Creek Agency
Superintendent, Grow Creek Agency, Fort Thompson, S. Dak.
Administrator, Grow Creek Agency, Fort Thompson, S. Dak. (GS-11)
Loan Specialist, Grow Creek Agency, Fort Thompson, S. Dak. (GS-9)
Realty Specialist, Grow Creek Agency, Fort Thompson, S. Dak. (GS-7)

Flandreau School
Field Representative, Flandreau Sanilee Field Office, Flandreau, S. Dak. (GS-9)
School Superintendent, Flandreau School, Flandreau, S. Dak.

* Fort Berthold Agency
Administrator, Fort Berthold Agency, New Town, N. Dak. (GS-11)
Program Officer, Fort Berthold Agency, New Town, N. Dak. (GS-12)
Agendy Special Officer, Fort Berthold Agency, New Town, N. Dak. (GS-7)
Realty Specialist, Fort Berthold Agency, New Town, N. Dak. (GS-7)
Agency Employment Assistance Officers, New Town, N. Dak. (GS-11)

Ft. Totten Agency
Administrator, Ft. Totten Agency, Fort Totten, N. Dak.
Education Program Administrator, Ft. Totten Agency, Fort Totten, N. Dak. (GS-11)
Resource Development Officer, Ft. Totten Agency, Fort Totten, N. Dak. (GS-12)
Realty Specialist, Ft. Totten Agency, Fort Totten, N. Dak. (GS-7)

Lower Brule Agency
Superintendent, Lower Brule Agency, Lower Brule, S. Dak.
Administrator, Lower Brule Agency, Lower Brule, S. Dak. (GS-12)
Education Program Administrator, Lower Brule Agency, Lower Brule, S. Dak. (GS-11)
Community Services Officer, Lower Brule Agency, Lower Brule, S. Dak. (GS-12)
Realty Specialist, Lower Brule Agency, Lower Brule, S. Dak. (GS-9)

Pierre Boarding School
Education Program Administrator, Pierre Boarding School, Pierre, S. Dak. (GS-12).
**RULES AND REGULATIONS**

Agency Credit Officer, Southern Ute Agency, Ignacio, Colo. (GS-12).
Agency Realty Officer, Southern Ute Agency, Ignacio, Colo. (GS-11).

**Ute Mountain Ute Agency**
Administrative Officer, Ute Mountain Ute Agency, Towaoc, Colo. (GS-9).

Agency Special Officer, Ute Mountain Ute Agency, Towaoc, Colo. (GS-11).
Natural Resources Manager, Ute Mountain Ute Agency, Towaoc, Colo. (GS-11).
Agency Realty Officer, Ute Mountain Ute Agency, Towaoc, Colo. (GS-11).

Program Analyst, Ute Mountain Ute Agency, Towaoc, Colo. (GS-12).

**Antelope Area**
Agency Realty Officer, Antelope Agency, Antelope, Okla. (GS-11).

**Concho Agency**
Supervisor, Concho Agency, Concho, Okla. (GS-11).

**Shawnee Agency**
Supervisor, Shawnee Agency, Shawnee, Okla. (GS-11).

**Billings Area**
Billings Area Office Assistant Area Director (Administration), Billings Area Office, Billings, Mont. (GS-11).
Education Program Administrator, Billings Area Office, Billings, Mont. (GS-11).
Financial Officer, Billings Area Office, Billings, Mont. (GS-12).
Housing Coordinator, Billings Area Office, Billings, Mont. (GS-11).

**Supervisory Engineer, Billings Area Office, Billings, Mont.**

**Social Worker**
Agency Special Officer, Billings Area Office, Billings, Mont. (GS-11).

**Supervisory Loan Specialist, Billings Area Office, Billings, Mont.**

**Contracts Specialist**
Agency Special Officer, Billings Area Office, Billings, Mont. (GS-11).

**Indian**
Chief, Indian Affairs, Billings Area Office, Billings, Mont. (GS-11).

**Supervisory Loan Specialist, Indian Affairs, Billings Area Office, Billings, Mont.**

**Towaoc**
Agency Special Officer, Towaoc Agency, Towaoc, Colo. (GS-11).

**Crow**
Administrative Manager, Crow Agency, Crow Agency, Mont. (GS-12).

**Flathead**
Administrative Manager, Flathead Agency, Ronan, Mont. (GS-11).

**Fort Belknap**
Administrative Manager, Fort Belknap Agency, Harlem, Mont. (GS-12).

**Flathead Irrigation Project**
Supervisory General Engineer, Flathead Irrigation Project, St. Ignatius, Mont. (GS-12).

**Fort Belknap Agency**
Superintendent, Fort Belknap Agency, Harlem, Mont. (GS-12).

**Community Services Officer, Fort Belknap Agency, Harlem, Mont.** (GS-12).

**Housing Development Officer, Southern Ute Agency, Ignacio, Colo.** (GS-12).

**Agency Credit Officer, Southern Ute Agency, Ignacio, Colo.** (GS-11).

**Agency Realty Officer, Southern Ute Agency, Ignacio, Colo.** (GS-11).

**Ute Mountain Ute Agency**
Administrative Officer, Ute Mountain Ute Agency, Towaoc, Colo. (GS-9).

Agency Special Officer, Ute Mountain Ute Agency, Towaoc, Colo. (GS-11).
Natural Resources Manager, Ute Mountain Ute Agency, Towaoc, Colo. (GS-11).
Agency Realty Officer, Ute Mountain Ute Agency, Towaoc, Colo. (GS-11).

Program Analyst, Ute Mountain Ute Agency, Towaoc, Colo. (GS-12).

**Antelope Area**
Agency Realty Officer, Antelope Agency, Antelope, Okla. (GS-11).

**Concho Agency**
Supervisor, Concho Agency, Concho, Okla. (GS-11).

**Shawnee Agency**
Supervisor, Shawnee Agency, Shawnee, Okla. (GS-11).

**Billings Area**
Billings Area Office Assistant Area Director (Administration), Billings Area Office, Billings, Mont. (GS-11).
Education Program Administrator, Billings Area Office, Billings, Mont. (GS-11).
Financial Officer, Billings Area Office, Billings, Mont. (GS-12).
Housing Coordinator, Billings Area Office, Billings, Mont. (GS-11).

**Supervisory Engineer, Billings Area Office, Billings, Mont.**

**Social Worker**
Agency Special Officer, Billings Area Office, Billings, Mont. (GS-11).

**Supervisory Loan Specialist, Billings Area Office, Billings, Mont.**

**Contracts Specialist**
Agency Special Officer, Billings Area Office, Billings, Mont. (GS-11).

**Indian**
Chief, Indian Affairs, Billings Area Office, Billings, Mont. (GS-11).

**Supervisory Loan Specialist, Indian Affairs, Billings Area Office, Billings, Mont.**

**Towaoc**
Agency Special Officer, Towaoc Agency, Towaoc, Colo. (GS-11).

**Crow**
Administrative Manager, Crow Agency, Crow Agency, Mont. (GS-12).

**Flathead**
Administrative Manager, Flathead Agency, Ronan, Mont. (GS-11).

**Fort Belknap**
Administrative Manager, Fort Belknap Agency, Harlem, Mont. (GS-12).

**Community Services Officer, Fort Belknap Agency, Harlem, Mont.** (GS-12).

**FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978**
Agency Special Officer, Fort Belknap Agency, Harlem, Mont. (GS-11).

Housing Coordinator, Fort Belknap Agency, Harlem, Mont. (GS-11).

Agency Credit Officer, Fort Belknap Agency, Harlem, Mont. (GS-11).

Land Operations Officer, Fort Belknap Agency, Harlem, Mont. (GS-11).

Agency General Counsel, Fort Belknap Agency, Harlem, Mont. (GS-11).


Agency Credit Officer, Fort Peck Agency, Poplar, Mont. (GS-12).

Administrative Officer, Fort Peck Agency, Poplar, Mont. (GS-11).

Community Development Specialist, Fort Peck Agency, Poplar, Mont. (GS-11).

Housing Coordinator, Fort Peck Agency, Poplar, Mont. (GS-11).

Agency Credit Officer, Fort Peck Agency, Poplar, Mont. (GS-11).


Northern Cheyenne Agency

Superintendent, Northern Cheyenne Agency, Lame Deer, Mont. (GS-11).

Administrative Manager, Northern Cheyenne Agency, Lame Deer, Mont. (GS-12).

Community Development Specialist, Northern Cheyenne Agency, Lame Deer, Mont. (GS-11).

Agency Special Officer, Northern Cheyenne Agency, Lame Deer, Mont. (GS-11).

Housing Development Officer, Northern Cheyenne Agency, Lame Deer, Mont. (GS-11).

Agency Credit Officer, Northern Cheyenne Agency, Lame Deer, Mont. (GS-11).

Forester (Administrative), Northern Cheyenne Agency, Lame Deer, Mont. (GS-11).

Loan Specialist, Northern Cheyenne Agency, Lame Deer, Mont. (GS-9).

Appraiser, Northern Cheyenne Agency, Lame Deer, Mont. (GS-9).

Rocky Boy's Agency

Superintendent, Rocky Boy's Agency, Box Elder, Mont. (GS-12).

Administrative Assistant, Rocky Boy's Agency, Box Elder, Mont. (GS-9).

Community Development Specialist, Rocky Boy's Agency, Box Elder, Mont. (GS-9).

Police Officer, Rocky Boy's Agency, Box Elder, Mont. (GS-9).

Agency Credit Officer, Rocky Boy's Agency, Box Elder, Mont. (GS-11).

Agency Personnel Specialist, Rocky Boy's Agency, Box Elder, Mont. (GS-11).

Natural Resource Manager, Rocky Boy's Agency, Box Elder, Mont. (GS-11).

Wind River Agency


Agency Special Officer, Wind River Agency, Fort Washakie, Wyo. (GS-11).

Agency Credit Officer, Wind River Agency, Fort Washakie, Wyo. (GS-11).


Loan Operations Officer, Wind River Agency, Fort Washakie, Wyo. (GS-12).

Agency General Counsel, Wind River Agency, Fort Washakie, Wyo. (GS-12).


Eastern Area Office


Mallorovan, New York Liaison Office, Syracuse, N.Y. (GS-9).

Employment Assistance Officer, Cleveland Field Office, Cleveland, Ohio (GS-12).


Cherokee Agency

Superintendent, Cherokee Agency, Cherokee, N.C. (GS-12).

Administrative Officer, Cherokee Agency, Cherokee, N.C. (GS-12).

Reservation Planner, Cherokee Agency, Cherokee, N.C. (GS-12).


Housing Development Officer, Cherokee Agency, Cherokee, N.C. (GS-12).


Loan Specialist, Cherokee Agency, Cherokee, N.C. (GS-12).

Employment Assistance Officer, Cherokee Agency, Cherokee, N.C. (GS-12).

Forester (Administrative), Cherokee Agency, Cherokee, N.C. (GS-12).

Realty Officer, Cherokee Agency, Cherokee, N.C. (GS-12).

Supervisory Highway Engineer, Cherokee Agency (Snowbird), Cherokee, N.C. (GS-12).

Supervisory Engineer, Cherokee Agency (Snowbird), Cherokee, N.C. (GS-12).

Supervisory Soil Conservation Officer, Cherokee Agency, Cherokee, N.C. (GS-12).

Choctaw Agency

Superintendent, Choctaw Agency, Philadelphia, Miss. (GS-12).

Economic Program Manager, Choctaw Agency, Philadelphia, Miss. (GS-12).

Education Program Administrator, Choctaw Agency, Philadelphia, Miss. (GS-12).

Agency Special Officer, Choctaw Agency, Philadelphia, Miss. (GS-12).

Agency Programs Officer, Choctaw Agency, Philadelphia, Miss. (GS-12).

Employment Assistance Officer, Choctaw Agency, Philadelphia, Miss. (GS-12).

Supervisory Highway Engineer, Choctaw Agency (Snowbird), Philadelphia, Miss. (GS-12).

Supervisory Engineer, Choctaw Agency (Snowbird), Philadelphia, Miss. (GS-12).

Supervisory Soil Conservation Officer, Choctaw Agency, Philadelphia, Miss. (GS-12).

Seminole Agency


Community Services Officer, Seminole Agency, Hollywood, Fla. (GS-12).


Juneau Area Office

Assistant Area Director (Admin.), Juneau Area Office, Juneau, Alaska (GS-11).

Area Supply Management Officer, Juneau Area Office, Juneau, Alaska (GS-11).


Area Field Representative (Southeast Agency), Juneau Area Office, Juneau, Alaska (GS-11).

Tribal Operations Officer, Juneau Area Office, Juneau, Alaska (GS-11).


Industrial Development Specialist, Juneau Area Office, Juneau, Alaska (GS-11).

Realty Officer, Juneau Area Office, Juneau, Alaska (GS-11).

Forester, Juneau Area Office, Juneau, Alaska (GS-11).

Employment Assistance Officer, Juneau Area Office, Juneau, Alaska (GS-11).

Contract Specialist (Commercial), Juneau Area Office, Juneau, Alaska (GS-11).

Procurement Officer, Juneau Area Office, Juneau, Alaska (GS-12).

Area Supply Manager, Juneau Area Office, Juneau, Alaska (GS-11).

Anchorage Agency


Administrator, Anchorage Agency, Anchorage, Alaska (GS-11).

Employment Assistance Officer, Anchorage Agency, Anchorage, Alaska (GS-12).

Housing Development Officer, Anchorage Agency, Anchorage, Alaska (GS-11).

Loan Specialist (Commercial), Anchorage Agency, Anchorage, Alaska (GS-11).

Realty Officer, Anchorage Agency, Anchorage, Alaska (GS-11).

Bethel Agency


Education Program Administrator, Bethel Agency, Bethel, Alaska (GS-11).

Administrative Manager, Bethel Agency, Bethel, Alaska (GS-11).

Land Operations Officer, Bethel Agency, Bethel, Alaska (GS-11).

Housing Development Officer, Bethel Agency, Bethel, Alaska (GS-11).

Realty Officer, Bethel Agency, Bethel, Alaska (GS-12).

Loan Specialist, Bethel Agency, Bethel, Alaska (GS-9).


Supervisory Engineering Technician, Bethel Agency, Bethel, Alaska (GS-12).

Fairbanks Agency


Administrative Officer, Fairbanks Agency, Fairbanks, Alaska (GS-12).

Education Program Coordinator, Fairbanks Agency, Fairbanks, Alaska (GS-12).


Realty Specialist, Fairbanks Agency, Fairbanks, Alaska (GS-12) (2).

Nome Agency


Administrative Officer, Nome Agency, Nome, Alaska (GS-11).
RULES AND REGULATIONS

Education Program Administrator, Nome Agency, Nome, Alaska (GS-11).

Housing Development Officer, Nome Agency, Nome, Alaska (GS-11).


Realty Specialist, Nome Agency, Nome, Alaska (GS-12).

Loan Specialist, Nome Agency, Nome Alaska (GS-12).

Mt. Edgecumbe School

School Superintendent, Mt. Edgecumbe School, Nome Agency, Nome, Alaska (GS-12).

Administrative Officer, Mt. Edgecumbe School, Nome Agency, Nome, Alaska (GS-12).

Seattle Liaison Office

Administrative and Special Representative (Liaison Officer Seattle, Wash., Juneau Area), Seattle, Wash.

Assistant Administrative Officer and Special Representative, Seattle Liaison Office, Seattle, Wash.

Supply Officer, Seattle Liaison Office, Seattle, Wash. (GS-11).

MINNEAPOLIS AREA

Minneapolis Area Office

Assistant Area Director, Minneapolis Area, Minneapolis, Minn.

Administrative Officer, Minneapolis Area, Minneapolis, Minn.

Supervisory Contract Specialist, Minneapolis Area, Minneapolis, Minn. (GS-12).

Education Program Administrator, Minneapolis Area, Minneapolis, Minn.

Area Special Officer, Minneapolis Area, Minneapolis, Minn.

Housing Development Officer, Minneapolis Area, Minneapolis, Minn.

Area Credit Officer, Minneapolis Area, Minneapolis, Minn.

Supervisory Forester, Minneapolis Area, Minneapolis, Minn.

Realty Officer, Minneapolis Area, Minneapolis, Minn.

Supervisory Appraiser, Minneapolis Area, Minneapolis, Minn.

Resources Development Officer, Minneapolis Area, Minneapolis, Minn.

Contract Administrator, Minneapolis Area, Minneapolis, Minn. (GS-11).

Employment and Vocational Guidance Officer, Minneapolis Area, Minneapolis, Minn.

Appraiser, Minneapolis Area, Minneapolis, Minn. (GS-12).

Employment Assistance Officer, Minneapolis Area, Minneapolis, Minn. (GS-12).

Great Lakes Agency

Superintendent, Great Lakes Agency, Ashland, Wis. (GS-12).

Administrative Manager, Great Lakes Agency, Ashland, Wis. (GS-11).

Housing Development Officer, Great Lakes Agency, Ashland, Wis. (GS-11).

Agency Credit Officer, Great Lakes Agency, Ashland, Wis. (GS-11).

Employment Assistance Officer, Great Lakes Agency, Ashland, Wis. (GS-11).

Michigan Agency


Superintendent, Minnesota Agency, Bemidji, Minn.

Agency Special Officer, Minnesota Agency, Bemidji, Minn. (GS-12).

Administrative Officer, Minnesota Agency, Bemidji, Minn. (GS-12).

Housing Development Officer, Minnesota Agency, Bemidji, Minn. (GS-11).

Agency Credit Officer, Minnesota Agency, Bemidji, Minn. (GS-11).

Employment Assistance, Minnesota Agency, Bemidji, Minn. (GS-11).

Supervisory Forester, Minnesota Agency, Bemidji, Minn. (GS-12).

Agency Realty Officer, Minnesota Agency, Bemidji, Minn. (GS-12).

Red Lake Agency

Superintendent, Red Lake Agency, Red Lake, Minn.

Administrative Manager, Red Lake Agency, Red Lake, Minn. (GS-12).

Agency Special Officer, Red Lake Agency, Red Lake, Minn. (GS-12).

Housing Development Officer, Red Lake Agency, Red Lake, Minn. (GS-11).

Supervisory Loan Specialist (General), Red Lake Agency, Red Lake, Minn. (GS-11).


Supervisory Forester, Red Lake Agency, Red Lake, Minn. (GS-12).

Mill Manager, Red Lake Agency, Red Lake, Minn.

Administrative Officer, Red Lake Agency, Red Lake, Minn. (GS-12).

Soo and Fox Area Field Office

Field Office Manager, Soo and Fox Area Field Office, T McMinn, Tenn. (GS-9).

MUSKOGEE AREA

Muskogee Area Office

Deputy Area Director, Muskogee Area, Muskogee, Okla.

Supply Management Officer, Muskogee Area, Muskogee, Okla.

Supervisory Contract Specialist, Muskogee Area, Muskogee, Okla. (GS-12).

Area Realty Officer, Muskogee Area, Muskogee, Okla.

Area Credit Officer, Muskogee Area, Muskogee, Okla.

Self-Determination Office, Muskogee Area, Muskogee, Okla. (GS-12).

Industrial Development Specialist, Muskogee Area, Muskogee, Okla. (GS-12).

Program Analyst Officer, Muskogee Area, Muskogee, Okla.

Education Program Administrator, Muskogee Area, Muskogee, Okla.

Area Tribal Operations Officer, Muskogee Area, Muskogee, Okla.

Area Employment Assistance Officer, Muskogee Area, Muskogee, Okla.

Supervisory Maintenance Engineer, Muskogee Area, Muskogee, Okla.

Area Appraiser, Muskogee Area, Muskogee, Okla.

Area Roads Engineer, Muskogee Area, Muskogee, Okla.

Housing Development Officer, Muskogee Area, Muskogee, Okla.

Contract Specialist, Muskogee Area, Muskogee, Okla. (3) GS-11 (1); GS-9 (1); GS-7 (1).

Procurement, Muskogee Area, Muskogee, Okla. (GS-11).

Principal, Eufaula Dormitory, Muskogee Area, Eufaula, Okla. (GS-12).

Principal, Carter Seminary, Muskogee Area, Muskogee, Okla. (GS-12).

Principal, Jones Academy, Muskogee Area, Ardmore, Okla. (GS-12).

Ardmore Agency

Superintendent, Ardmore Agency, Ardmore, Okla.

Housing Development Officer, Ardmore Agency, Ardmore, Okla. (GS-12).

Vocational Development Officer, Ardmore Agency, Ardmore, Okla. (GS-12).

Appraiser, Ardmore Agency, Ardmore, Okla. (GS-12).

Agency Credit Officer, Ardmore Agency, Ardmore, Okla. (GS-12).

Miami Agency

Superintendent, Miami Agency, Miami, Okla.

Realty Specialist, Miami Agency, Miami, Okla. (GS-11).

Vocational Development Officer, Miami Agency, Miami, Okla. (GS-11).

Field Operations Officer, Miami Agency, Miami, Okla. (GS-11).

Land Operations Officer, Miami Agency, Miami, Okla. (GS-12).

Olmulgee Agency

Superintendent, Olmulgee Agency, Okmulgee, Okla.

Housing Development Officer, Olmulgee Agency, Okmulgee, Okla. (GS-12).

Vocational Development Officer, Olmulgee Agency, Okmulgee, Okla. (GS-12).

Appraiser, Olmulgee Agency, Okmulgee, Okla. (GS-12).

Administrative Officer, Osage Agency, Pawhuska, Okla. (GS-12).

Assistant to the Superintendent, Osage Agency, Pawhuska, Okla. (GS-9).

Osage Agency

Superintendent, Osage Agency, Pawhuska, Okla.

Administrative Officer, Osage Agency, Pawhuska, Okla. (GS-11).

Assistant to the Superintendent, Osage Agency, Pawhuska, Okla. (GS-12).

Supervisory Petroleum Engineer, Osage Agency, Pawhuska, Okla. (GS-12).

Appraiser, Osage Agency, Pawhuska, Okla. (GS-12).

Employment Assistance Officer, Osage Agency, Pawhuska, Okla. (GS-12).

Loan Specialist (General), Osage Agency, Pawhuska, Okla. (GS-12).

Seneca Indian School

School Superintendent, Seneca Indian School, Muskogee Area, Wyandotte, Okla.

Sequoyah High School

School Superintendent, Sequoyah High School, Muskogee Area, Tahlequah, Okla. (GS-12).

Tahlequah Agency

Superintendent, Tahlequah Agency, Tahlequah, Okla.

Appraiser, Tahlequah Agency, Tahlequah, Okla. (GS-12).

Housing Development Officer, Tahlequah Agency, Tahlequah, Okla. (GS-11).

Realty Officer, Tahlequah Agency, Tahlequah, Okla. (GS-11).

Agency Credit Officer, Tahlequah Agency, Tahlequah, Okla. (GS-12).

Land Operations Officer, Tahlequah Agency, Tahlequah, Okla. (GS-12).

Tahlequah Agency

Superintendent, Talihina Agency, Talihina, Okla.

Housing Development Officer, Talihina Agency, Talihina, Okla. (GS-12).

Loan Specialist (General), Talihina Agency, Talihina, Okla. (GS-12).

Employment Assistance Officer, Talihina Agency, Talihina, Okla. (GS-12).
Land Operations Officer, Talihina Agency, Talihina, Okla. (GS-12).
Agency Realty Officer, Talihina Agency, Talihina, Okla. (GS-11).
Wewoka Agency
Housing Development Officer, Wewoka Agency, Wewoka, Okla. (GS-12).
Vocational Development Officer, Wewoka Agency, Wewoka, Okla. (GS-12).
Natural Resources Officer, Wewoka Agency, Wewoka, Okla. (GS-12).
Dallas FEOA
Supervisory Vocational Development Specialist, Muskogee Area, Dallas, Tex. (GS-12).

Navajo Area
Navajo Area Office
Tribal Operations Officer, Navajo Area, Window Rock, Ariz.
Program Officer, Navajo Area, Window Rock, Ariz.
Assistant Area Director, Division of Administration, Navajo Area, Gallup, N. Mex.
Supervisory Contract Specialist, Navajo Area, Gallup, N. Mex. (3) GS-19 (1); GS-12 (1).
Supply Management Officer, Navajo Area, Gallup, N. Mex. (2) GS-12 (1); GS-11 (1).
Procurement Officer, Navajo Area, Gallup, N. Mex. (GS-12).
Financial Manager, Navajo Area, Gallup, N. Mex. (GS-12).
Supervisory Maintenance Engineer, Navajo Area, Window Rock, Ariz.
Supervisory Highway Engineer, Navajo Area, Window Rock, Ariz.
Supervisory Forester (Administration), Navajo Area, Window Rock, Ariz.
Realty Officer, Navajo Area, Window Rock, Ariz.
Supervisory Criminal Investigator, Navajo Area, Window Rock, Ariz. (GS-12).
Housing Development Officer, Navajo Area, Window Rock, Ariz. (GS-12).
Appraiser, Navajo Area, Window Rock, Ariz. (4) GS-12 (1); GS-12 (2); GS-11 (1).
Special Liaison Representative, Navajo Area, Window Rock, Ariz. (GS-12).
Contract Specialist, Navajo Area, Gallup, N. Mex. (7) GS-12 (3); GS-11 (2); GS-9 (2).
Procurement Agent, Navajo Area, Gallup, N. Mex. (GS-12).
Auditor, Navajo Area, Gallup, N. Mex. (GS-12).
Safety Manager, Navajo Area, Window Rock, Ariz.
Supervisory Social Worker, Navajo Area, Ariz.
Supervisory Vocational Development Specialist, Navajo Area, Window Rock, Ariz. (GS-12).

Chinle Agency
Superintendent, Chinle Agency, Chinle, Ariz. (GS-12).
Agency Administration Manager, Chinle Agency, Chinle, Ariz. (GS-12).
Education Program Administrator, Chinle Agency, Chinle, Ariz. (GS-12).
Supervisory Social Worker, Chinle Agency, Chinle, Ariz. (GS-11).
Agency Special Officer, Chinle Agency, Chinle, Ariz. (GS-11).

Navajo Irrigation Project
Project Manager, Navajo Irrigation Project, Farmington, N. Mex.
Supervisory Project Manager, Navajo Irrigation Project, Farmington, N. Mex. (GS-11).

Shiprock Agency
Superintendent, Shiprock Agency, Shiprock, N. Mex. (GS-12).
Supervisory Program Manager, Shiprock Agency, Shiprock, N. Mex. (GS-13)
Vocational Program Director, Shiprock Agency, Shiprock, N. Mex. (GS-12).

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Rules and Regulations
RULES AND REGULATIONS

Land Operations Officer, Phoenix Area Office, Phoenix, Ariz. (GS-12).
Appraiser, Phoenix Area Office, Phoenix, Ariz. (GS-12).
Housing Development Officer, Phoenix Area Office, Phoenix, Ariz. (GS-12).
Indian Self-Determination Specialist, Phoenix Area Office, Phoenix, Ariz. (GS-12).

Colorado River Agency
Superintendent, Colorado River Agency, Parker, Ariz. (GS-12).
Administrative Manager, Colorado River Agency, Parker, Ariz. (GS-12).
Agency Credit Officer, Colorado River Agency, Parker, Ariz. (GS-12).
Education Coordinator, Colorado River Agency, Parker, Ariz. (GS-12).
Agency Land Operations Officer, Colorado River Agency, Parker, Ariz. (GS-12).
Agency Special Officer, Colorado River Agency, Parker, Ariz. (GS-12).
Agency Realty Officer, Colorado River Agency, Parker, Ariz. (GS-12).
Agency Employment Assistant Officer, Colorado River Agency, Parker, Ariz. (GS-12).
Supervisory General Engineer, Colorado River Agency, Parker, Ariz. (GS-12).
Housing Development Officer, Colorado River Agency, Parker, Ariz. (GS-12).

Eastern Nevada Agency
Superintendent, Eastern Nevada Agency, Owyhee, Nev. (GS-12).
Administrative Manager, Eastern Nevada Agency, Owyhee, Nev. (GS-12).
Agency Credit Officer, Eastern Nevada Agency, Owyhee, Nev. (GS-12).
Agency Housing Officer, Eastern Nevada Agency, Owyhee, Nev. (GS-12).
Agency Special Officer, Eastern Nevada Agency, Owyhee, Nev. (GS-12).
Agency Realty Officer, Eastern Nevada Agency, Owyhee, Nev. (GS-12).
Commercial and Industrial Development Specialist, Eastern Nevada Agency, Owyhee, Nev. (GS-12).

Fort Apache Agency
Administrative Manager, Fort Apache Agency, Whiteriver, Ariz. (GS-12).
Agency Credit Officer, Fort Apache Agency, Whiteriver, Ariz. (GS-12).
Agency Housing Officer, Fort Apache Agency, Whiteriver, Ariz. (GS-12).
Agency Special Officer, Fort Apache Agency, Whiteriver, Ariz. (GS-12).
Agency Realty Officer, Fort Apache Agency, Whiteriver, Ariz. (GS-12).

Fort Yuma Agency
Superintendent, Fort Yuma Agency, Yuma, Ariz. (GS-12).
Administrative Manager, Fort Yuma Agency, Yuma, Ariz. (GS-12).
Agency Credit Officer, Fort Yuma Agency, Yuma, Ariz. (GS-12).
Agency Housing Officer, Fort Yuma Agency, Yuma, Ariz. (GS-12).
Agency Special Officer, Fort Yuma Agency, Yuma, Ariz. (GS-12).
Agency Realty Officer, Fort Yuma Agency, Yuma, Ariz. (GS-12).

San Carlos Agency
Administrative Manager, San Carlos Agency, San Carlos, Ariz. (GS-12).
Housing Development Officer, San Carlos Agency, San Carlos, Ariz. (GS-12).
Agency Special Officer, San Carlos Agency, San Carlos, Ariz. (GS-12).
Program Officer, San Carlos Agency, San Carlos, Ariz. (GS-12).

Sherman Indian School
School Superintendent, Sherman Indian School, Riverside, Calif. (GS-12).
Administrative Manager, Sherman Indian School, Riverside, Calif. (GS-12).

Stewart Boarding School
School Superintendent, Stewart Indian School, Stewart, Nev. (GS-11).
Administrative Manager, Stewart Boarding School, Stewart, Nev. (GS-11).

Truxton Canan Agency
Administrative Manager, Truxton Canan Agency, Valentine, Ariz. (GS-12).
Education Specialist, Truxton Canan Agency, Valentine, Ariz. (GS-12).
Housing Development Officer, Truxton Canan Agency, Valentine, Ariz. (GS-12).
Natural Resources Manager, Truxton Canan Agency, Peach Springs, Ariz. (GS-12).
Agency Special Officer, Truxton Canan Agency, Peach Springs, Ariz. (GS-12).

Uintah and Ouray Agency
Superintendent, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).
Administrative Manager, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).
Education Specialist, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).
Realty Officer, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).
Land Operations Officer, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).

Western Nevada Agency
Superintendent, Western Nevada Agency, Stewart, Nev. (GS-12).
Administrative Manager, Western Nevada Agency, Stewart, Nev. (GS-12).
Agency Credit Officer, Western Nevada Agency, Stewart, Nev. (GS-12).
Housing Development Officer, Western Nevada Agency, Stewart, Nev. (GS-12).
Agency Special Officer, Western Nevada Agency, Stewart, Nev. (GS-12).
Realty Officer, Western Nevada Agency, Stewart, Nev. (GS-12).

Salt River Agency

San Carlos Agency

Administrative Manager, San Carlos Agency, San Carlos, Ariz. (GS-12).
Housing Development Officer, San Carlos Agency, San Carlos, Ariz. (GS-12).
Agency Special Officer, San Carlos Agency, San Carlos, Ariz. (GS-12).
Program Officer, San Carlos Agency, San Carlos, Ariz. (GS-12).

Sherman Indian School
School Superintendent, Sherman Indian School, Riverside, Calif. (GS-12).
Administrative Manager, Sherman Indian School, Riverside, Calif. (GS-12).

Stewart Boarding School
School Superintendent, Stewart Indian School, Stewart, Nev. (GS-11).
Administrative Manager, Stewart Boarding School, Stewart, Nev. (GS-11).

Truxton Canan Agency
Administrative Manager, Truxton Canan Agency, Valentine, Ariz. (GS-12).
Education Specialist, Truxton Canan Agency, Valentine, Ariz. (GS-12).
Housing Development Officer, Truxton Canan Agency, Valentine, Ariz. (GS-12).
Natural Resources Manager, Truxton Canan Agency, Peach Springs, Ariz. (GS-12).
Agency Special Officer, Truxton Canan Agency, Peach Springs, Ariz. (GS-11).

Uintah and Ouray Agency
Superintendent, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).
Administrative Manager, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).
Education Specialist, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).
Realty Officer, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).
Land Operations Officer, Uintah and Ouray Agency, Fort Duchesne, Utah (GS-12).

Western Nevada Agency
Superintendent, Western Nevada Agency, Stewart, Nev. (GS-12).
Administrative Manager, Western Nevada Agency, Stewart, Nev. (GS-12).
Agency Credit Officer, Western Nevada Agency, Stewart, Nev. (GS-12).
Housing Development Officer, Western Nevada Agency, Stewart, Nev. (GS-12).
Agency Special Officer, Western Nevada Agency, Stewart, Nev. (GS-12).
Realty Officer, Western Nevada Agency, Stewart, Nev. (GS-12).

Salt River Agency

San Carlos Agency
RULES AND REGULATIONS

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Employment Assistance Officer, Sacramento, Calif.
Assistant Director (Resources), Sacramento, Calif.
Area Credit Officer, Sacramento Area, Sacramento, Calif.
Industrial Development Specialist, Sacramento Area, Los Angeles, Calif.
Superintendent, Sacramento Area, Sacramento, Calif. (GS-12) (6); (GS-14).
Deputy Officer, Sacramento Area, Sacramento, Calif. (GS-12).
Deputy Officer, Sacramento Area, Sacramento, Calif. (GS-11).

Superintendent, Southern California Agency, Riverside, Calif.
Administrative Officer, Southern California Agency, Riverside, Calif. (GS-13).

Deputy Officer, Southern California Agency, Riverside, Calif. (GS-12).

Tribal Operations Officer, Southern California Agency, Riverside, Calif. (GS-12).

Natural Resources Specialist, Southern California Agency, Riverside, Calif. (GS-12).

Housing Development Officer, Southern California Agency, Riverside, Calif. (GS-12).

Forester (Admin.), Southern California Agency, Riverside, Calif. (GS-12).

Bureau of Mines

Office of the Director

Deputy Procurement Officer.

Chief, Branch of Procurement and Property; Contract Specialists, GS-13 and above.

Division of Procurement

Deputy Procurement Officer, Chief, Branch of Procurement.

Contract Specialists and Analysts, GS-13 and above (regardless of official classification title).

Chief, and Deputy Chief, Branch of Procurement (Denver).

junior or senior grades not otherwise covered will be required to file if he/she supervises an employee who is required to file.

Geological Survey

Office of the Director

Program Analyst, Reston, Va.
Economist, Reston, Va.
Congressional Liaison Officer, Reston, Va.

LAND INFORMATION AND ANALYSIS OFFICE

Administrative Officer, Reston, Va.
Physical Scientists, Reston, Va.
Geographer, Reston, Va.
Geologists, Reston, Va.
Hydrologist, Reston, Va.
Hydrologist (Ground Water), Reston, Va.
Environmental Scientists, Reston, Va.
Environmental Scientists (Geology), Reston, Va.

Research Geographer, Reston, Va.

Supervisory Physical Scientists, Reston, Va.
Administrative Officer, EROS Data Center, Sioux Falls, S. Dak.
Research Forester, Sioux Falls, S. Dak.
Remote Sensing Scientists, Sioux Falls, S. Dak.

Research Geographer, Reston, Va.

Supervisory Physical Scientists, Reston, Va.
Administrative Officer, EROS Data Center, Sioux Falls, S. Dak.
Research Forester, Sioux Falls, S. Dak.
Remote Sensing Scientists, Sioux Falls, S. Dak.

General Engineer, Sioux Falls, S. Dak.
Physical Scientists, Sioux Falls, S. Dak.

Remote Sensing Specialist (Geologic Applications), Sioux Falls, S. Dak.

Data Management Officer, Sioux Falls, S. Dak.

Supervisory Computer Specialists, Sioux Falls, S. Dak.

Computer Specialist, Sioux Falls, S. Dak.

Photographic Technologist, Sioux Falls, S. Dak.

Remote Sensing Specialist, Sioux Falls, S. Dak.

Environmental Planner, Orange, Mass.

Phyiscal Scientists, Denver, Colo.

Geologist, Denver, Colo.

Office of National Petroleum Reserve in Alaska

Assistant Chief, NPSRA Operations Office, Environmental Specialists, all locations.

Physical Scientists, all locations.

Geophysicists, all locations.

Geologists, all locations—GS-11 and above.

Petroleum Engineers, all locations.

Civil Engineers, all locations.

Plans and Program Officer, Anchorage, Alaska.

Industrial Property Management Specialists, Anchorage, Alaska—GS-12 (1).

Administrative Officer, Anchorage, Alaska—GS-12 (1).

Contract Administrator, Anchorage, Alaska—GS-12 (1).

Contract Specialist, Anchorage, Alaska.

Contract Analyst, Anchorage, Alaska.

Petroleum Engineering Technicians, Anchorage, Alaska—GS-9 and above.

Administrative Division


Contract Specialists, Reston, Va.—GS-11 and above.

Procurement Analysts, Reston, Va.—GS-9 and above.

Procurement Agents, Reston, Va.—GS-11 and above.

Contract Price Analyst, Reston, Va.—GS-12 and above.

Supervisory Contract Specialist, Lakewood, Colo.

Contract Specialists, Lakewood, Colo.—GS-11 and above.

Procurement Officer, Menlo Park, Calif.

Contract Specialists, Menlo Park, Calif.—GS-11 and above.
CONSERVATION DIVISION

Area Oil and Gas Supervisor—Resource Evaluation, Metairie, La.
Assistant Oil and Gas Supervisor—Resource Evaluation, Metairie, La.
Deputy Oil and Gas Supervisor—Resource Evaluation, Washington, D.C.
Section Chief (Track Selection and Evaluation), Washington, D.C.
Section Chief (Hazard Analysis), Washington, D.C.
Section Chief (Frontier Data Analysis), Washington, D.C.
Area Oil and Gas Supervisor—Operations, Washington, D.C.
District Supervisor (Mid-Atlantic District), Washington, D.C.
District Supervisor (North Atlantic District), Washington, D.C.
District Supervisor (South Atlantic District), Washington, D.C.
District Engineer, Washington, D.C.
Assistant Conservation Manager, Anchorage, Alaska.
Assistant Conservation Manager, Los Angeles, Calif.

CLERICAL STAFF

Program Officer, Washington, D.C.
Staff Assistant for Environmental Analysis, Metairie, La.
Staff Assistant for Operations and Regulations, Metairie, La.
Staff Assistant for Programs, Metairie, La.
Scientific Staff Assistant, Reston, Va.
Legal Staff Assistant, Reston, Va.
Contracts Liaison Specialist, Reston, Va.
Production Rate Control Coordinator, Reston, Va.
Manpower Utilization Specialist, Reston, Va.
Program Analyst, Reston, Va.
Program Analyst Officer, Reston, Va.
Mathematical Statistician, Reston, Va.
Transportation Specialist, Reston, Va.—GS-10 (1).
Administrative Officers, all locations—GS-12 and above.
Accountants and Auditors, all locations—GS-9 and above.
Accounting Assistants, all locations—GS-7 and above.
Chemical Engineers, all locations—GS-9 and above.
Computer Equipment Analyst, Reston, Va.—GS-12 (1).
Computer Programmers, all locations—GS-9.
Computer Specialists, all locations—GS-9 and above.
Computer Systems Analysts, all locations—GS-9 and above.
Economists, all specialities, all locations—GS-12 and above.
Electrical Engineers, all locations—GS-9 and above.
Environmental Specialists and Environmental Scientists, all locations—GS-9 and above.
General Engineers, all locations—GS-9 and above.
Geologists, all locations—GS-9 and above.
Geophysicists, all locations—GS-9 and above.
Hydraulic Engineers, all locations—GS-9 and above.
Hydrologists, all locations—GS-9 and above.
Mechanical Engineers, all locations—GS-9 and above.

RULES AND REGULATIONS

Mine Inspectors, all locations—GS-9 and above.
Mining Engineering Technicians, all locations—GS-9 and above.
Mining Engineers, all locations—GS-9 and above.
Operational Research Analysts, all locations—GS-12 and above.
Petroleum Engineers, all specialities, all locations—GS-9 and above.
Physical Science Technicians, all locations—GS-9 and above.
Physical Scientists, all specialities, all locations—GS-9 and above.
Structural Engineers, all locations—GS-9 and above.

GEOLOGIC DIVISION

Administrative Officers, Reston, Va.
Assistant Deputy Chief Geologist for Program Development, Reston, Va.
Deputy Western Regional Geologist, Menlo Park, Calif.
Staff Geologist for Marine Engineering and Geology, Reston, Va.
Staff Geologist for Outer Continental Shelf Environmental Studies, Reston, Va.
Staff Geologist for Outer Continental Shelf Leasing Activities, Reston, Va.
Staff Geologist for Onshore Oil and Gas Resources, Reston, Va.
Mining Engineer, Office of Energy Resources, Branch of Uranium and Thorium Resources, Reston, Va.
Staff Geologist for Land Resource Programs, Reston, Va.
Staff Geologist for Special Programs, Office of Environmental Geology, Reston, Va.
Staff Geologist for Grants and Contracts, Reston, Va.
Program Manager, Office of Environmental Geology, Denver, Colo.
Program Manager, Office of Environmental Geology, Menlo Park, Calif.
Staff Geologist for Remote Sensing, Reston, Va.
Staff Geologist for Geochemistry and Geophysics, Reston, Va.
Chief, Branch of Analytical Laboratories, Reston, Va.
Chief, Branch of Regional Geochemistry, Lakewood, Colo.
Staff Geologist, Alaska Programs, Reston, Va.
Staff Geologist, Office of Mineral Resources, Reston, Va.
Chief, Branch of Exploration Research, Golden, Colo.
Assistant to Office Chief, Office of International Geology, Reston, Va.
International Activities Officer, Reston, Va.

PUBLICATIONS DIVISION

Chief, Branch of Administrative Services, Reston, Va.
Deputy Assistant Chief (Research and Technical Coordination), Reston, Va.
Printing Liaison Officer, Reston, Va.
Assistant Chief, Eastern Region, Reston, Va.
Chief, Administrative Services, Eastern Region, Reston, Va.
Assistant Chief, Administrative Services, Eastern Region, Reston, Va.—GS-11 (1).
Chief, Branch of Technical Editing, Eastern Region, Reston, Va.
Chief, Branch of Visual Services, Eastern Region, Reston, Va.
Chief, Branch of Printing, Eastern Region, Reston, Va.

Chief, Branch of Exhibits, Eastern Region, Reston, Va.
Chief, Branch of Visual Services, Eastern Region, Reston, Va.
Chief, Branch of Technical Editing, Eastern Region, Reston, Va.
Chief, Branch of Cartography, Eastern Region, Reston, Va.
Chief, Branch of Administrative Services, Eastern Region, Reston, Va.
Chief, Branch of Technical Editing, Eastern Region, Reston, Va.
Chief, Branch of Cartography, Western Region, Menlo Park, Calif.
Chief, Branch of Exhibits, Western Region, Menlo Park, Calif.—GS-12 (1).
Chief, Flagstaff Cartographic Section, Western Region, Flagstaff, Ariz.—GS-12 (1).

TOPOGRAPHIC DIVISION

Cartographers, Reston, Va.—GS-12 (1), GS-11 (1), GS-9 (1).
Research Cartographers, Reston, Va.
Mechanical Engineers, Reston, Va.
Electronics Engineers, Reston, Va.
Physical Scientists, Reston, Va.
Photographic Technologists, Reston, Va.

MINING ENFORCEMENT AND SAFETY ADMINISTRATION

Chief, State Grant Program Office.
Subdistrict Managers, Coal Mine Health and Safety and Metal and Nonmetal.
Supervisors, inspectors and engineers performing inspection work—GS-9 and above.
Deputy Assessment Officer.
Assessment Specialists.
Collection Officers.
Surveys, Land and Assessment Conference Specialists—GS-11 and above.
Procurement Officers.

NATIONAL PARK SERVICE

Washington, D.C.

Chief, Budget Division.
Chief, Park Planning and Environmental Compliance Division.
Chief, Design and Technology Division.
Chief, Maintenance Division.
Chief, Range Activities and Protection Division.

Realty Officers.
Realty Specialists, GS-15 and above.
Appraisers, GS-15 and above.
Concessions Analysts, GS-13 and above.
Safety Officers.
Environmental Sanitation Officer.
Chief, WASO Personnel Officer.
Chief, Youth Activities Division.
Chief, Training Division.
Chief, General Services Division.
Contract Specialist, GS-12.
Chief, Grants Administration Division.
Chief, Historic American Engineering Record Division.
Chief, Historic American Buildings Survey Division.
Chief, Geographic Sites Survey Division.
Chief, Federal and State Liaison Division.

HARPER'S FERRY CENTER

Harpers Ferry, West Virginia

Administrative Officer.
Chief, Division of Museum Services.
Chief, Division of Reference Services.
Chief, Division of Interpretive Planning.
Chief, Branch of Procurement and Property Management.
RULES AND REGULATIONS

ROCKY MOUNTAIN REGION
Denver, Colo.
Associate Regional Directors.
Assistant to Regional Director, Utah.
Superintendents, GS-13 and above.
Regional Chief, Division of Contracting and Property Management.
Administrative Officers, GS-13 and above.
Realty Officer.
Chief Appraiser.
Appraiser.
Chief, Operations Evaluation.
Equal Opportunity Officer.
Assistant to Regional Director, Public Affairs.
Chief, Division of Finance.
Supervisory Archivist, Denver Archival Office.
Deputy Associate Manager, Denver Service Center.
Chief, Contract Administration Division, Denver Service Center.
Chief, Quality Control and Compliance Division, Denver Service Center.
Chief, Surveys Division, Denver Service Center.
Chief, Graphics Services Division, Denver Service Center.
Chief, Professional Support Division, Denver Service Center.
Chief, Branch of Construction Contracts, Denver Service Center.
Chief, Branch of Professional Service Contracts, Denver Service Center.

SOUTHWEST REGION
Atlanta, Georgia
Associate Regional Director.
Superintendents, GS-13 and above.
Assistant Superintendents.
Conservation Center Directors.
Realty Officers, GS-13 and above.
Appraiser, GS-13 and above.
Supervisory Archaeologist, Southeast Archeological Center.
Supervisory Archivist, Atlanta Archeological Center.
Chief, Contracting and Property Management.
Accounting Officer.

SOUTHWEST REGION
Santa Fe, New Mexico
Associate Regional Director.
Assistant to the Regional Director, Tex.
Chief, Operations Evaluation.
Chief, Contracting and Property Management.
Chief, Land Acquisition.
Public Information Officer.
Superintendents, GS-13 and above.
General Superintendent.
Park Ranger (Management Consulting).
Realty Officer, GS-13 and above.

NORTH ATLANTIC REGION
Boston, Massachusetts
Associate Regional Directors.
Regional Chief, Division of Contracting and Property Management.
Regional Chief, Division of Programs and Budget.
Superintendents, GS-13 and above.
Assistant Superintendents, GS-13 and above.
Realty Officer.
Public Information Officer.
Regional Scientist.
Unit Manager.
Administrative Officers, GS-13 and above.
Concessions Specialists, GS-9 and above.

NATIONAL CAPITAL REGION
Washington, D.C.
Chief, Division of Property Management.
Chief, Division of Contracting and Procurement.
Superintendents, GS-11 and above.
General Managers.
Director, Wolf Trap Farm Park.
Chief, U.S. Park Police.
Assistant Chief, U.S. Park Police.

MID-ATLANTIC REGION
Philadelphia, Pennsylvania
Associate Regional Directors.
Superintendents, GS-11 and above.
Assistant Superintendents, GS-13 and above.
Regional Chief, Division of Contracting and Property Management.
Regional Chief, Division of Programs and Budget.
Administrative Officers, GS-13 and above.
Chief, Operations Evaluation.
Chief, Contracting and Property Management.
Chief Scientist.
Realty Officers.
Mining Engineers.
Chief, Contracting and Property Management.
Area Director, Alaska.
Staff Assistant, Alaska.
Management Assistant, Alaska.
Concessions Analysts.
Appraisers.

GS-12 AND BELOW POSITIONS
Washington, D.C.

Contract Specialist, GS-12.

A delegation of authority has been prepared within the Washington Office for enacting

FEDERAL REGISTER, VOL 43, NO. 4—FRIDAY, JANUARY 6, 1978


Regional Manpower Specialists, All regions.

Regional Supervisor of Power, Boise, Idaho.

Regional Supervisor of Power, Idaho.

Assistant Regional Planning Officer, Denver, Colo.

Supervisory Field Engineer, Denver, Colo.

Regional Contract Procurement Officer, Denver, Colo. (GS-12).

Supervisory Contract Procurement Officer, Denver, Colo. (GS-12).

Procurement Officer, Denver, Colo.

Regional Research Physical Scientists (3), Denver, Colo.

Research Physical Scientist, Denver, Colo.

Supplementary Inquiries, Denver, Colo.

Supervisory Computer Specialist, Denver, Colo.

Contract and Procurement Specialist, Property and Purchasing, Denver, Colo. (GS-11).

PACIFIC NORTHWEST REGIONAL OFFICE

Regional Engineer, Boise, Idaho.

Chief, Construction Branch, Boise, Idaho.

Chief, Construction Branch, Boise, Idaho.

Chief, Division of Water and Land Operations, Boise, Idaho.

Chief, Repayment and Statistics Branch, Boise, Idaho.

Chief, Lands Branch, Boise, Idaho.

Chief, Chief, Division of Water and Land Operations, Boise, Idaho.

Chief, Regional Procurement and Property Officer, Boise, Idaho.

Chief, Regional Supervisor of Power, Idaho.

Chief, Resources and Contracts Branch, Boise, Idaho.

Regional Planning Officer, Boise, Idaho.

Assistant Regional Planning Officer, Boise, Idaho.

Chief, Engineering and Surveys Branch, Boise, Idaho.

Chief, Economic Resource Branch, Boise, Idaho.

Chief, Recreation Branch, Boise, Idaho.

Regional Procurement and Property Officer, Boise, Idaho.

Chief, Supervisory Civil Engineer, Oroville-Tonasket Branch, Boise, Idaho.

Chief, Resources Utilization Branch, Boise, Idaho.

Regional Public Affairs Officer, Idaho Falls, Idaho.

Regional Public Affairs Officer, Idaho Falls, Idaho (GS-12).

Appraiser, Boise, Idaho (GS-12).

Appraiser, Boise, Idaho (GS-11).

Realty Specialists (4), Boise, Idaho (GS-11 and above).

Chief, Water Operations Branch, Boise, Idaho.

Chief, Salem Field Branch, Salem, Ore.

Project Superintendent, Central Snake Projects Office, Boise, Idaho (GS-12).

Project Superintendent, Central Snake Projects Office, Boise, Idaho (GS-11).

Center Director, Columbia Basin Civilian Conservation Center, Moses Lake, Wash.

Project Manager, Columbia Basin Project Office, Ephrata, Wash.

Chief, Engineering and Drainage Division, Ephrata, Wash.

Chief, General Construction Branch, Ephrata, Wash.

Chief, Construction Division, Ephrata, Wash.

Chief, Water and Lands Operations Division, Ephrata, Wash.

Chief, Realty Branch, Ephrata, Wash. (GS-12).

Appraiser, Ephrata, Wash. (GS-11).

Chief, Construction Field Branch, Coulee City, Wash.

Project Superintendent, Hungry Horse Project Office, Hungry Horse, Mont.

Project Superintendent, Minidoka Project Office, Burley, Idaho.

Realty Specialist, Minidoka Project Office, Burley, Idaho (GS-12).

Center Director, Marsing Civilian Conservation Center, Marsing, Idaho.

FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978
Rules and Regulations
RULES AND REGULATIONS

All Chiefs, Division of Operations, Outer Continental Shelf Office, Washington, D.C.

All Chiefs, Division of Environmental Assessment, Outer Continental Shelf Offices.

All Chiefs, Division of Environmental Assessment, Outer Continental Shelf Offices.

Supervisory Natural Resource Specialist, Alaska OCS Office.

Supervisory Leasing Specialist, Alaska OCS Office.

Supervisory Environmental Specialist, Atlantic OCS Office.

Supervisory Environmental Specialist, Atlantic OCS Office.

Chief, Division of Cadastral Survey, Anchorage, Alaska.

Chief, Branch of Contract Survey, Anchorage, Alaska.

Chief, Branch of Forestry, Portland, Ore.

Chief, Claims Section, Portland, Ore.

Chief, Division of Environmental Assessment, Portland, Ore.

Assistant to the Project Manager, Northern Tier Environmental Statement Team, Portland, Ore.

Assistant, Program Planning and Evaluation, Washington, D.C.

Assistant Manager, Water Resources Scientific Information Center, Washington, D.C.

Assistant Manager, Water Resources Scientific Information Center, Washington, D.C.

Assistant Manager, Water Resources Scientific Information Center, Washington, D.C.

Assistant Manager, Water Resources Scientific Information Center, Washington, D.C.


Chemical Engineer (2), Membrane Processes Division, Washington, D.C.

Chemical Engineer (2), Membrane Processes Division, Washington, D.C.

Desalting Project Specialist (2), Tel Aviv, Israel.

Desalting Project Specialist (2), Tel Aviv, Israel.

Deputy BLM Director, Boise Interagency Fire Control Center, Boise, Idaho.

Chief, Branch of Construction, Alaska Pipeline Project, Anchorage, Alaska.

All Authorized Officer's Field Representatives, Branch of Construction, Alaska Pipeline Project, Anchorage, Alaska.

Supervisory Natural Resource Specialist, GS-14 (Naval Petroleum Reserve) Anchorage, Alaska.

All Managers, Outer Continental Shelf Offices, GS-14 (1).

All Assistant Managers, Outer Continental Shelf Offices (4).
GS-15, Program Audit Manager, Fish, Wildlife, and Parks.
GS-15, Program Audit Manager, Bureau of Indian Affairs.
GS-14, Supervisory Auditor, Contract and Grant.
GS-14, Supervisory Auditor, ADP.
GS-13, Administrative Officer.
GS-9 and below, Auditors.
GS-9 and below, secretarial and clerical personnel.

OFFICE OF PERSONNEL MANAGEMENT
All employees are exempt except for the Director of Personnel.

OFFICE OF SECRETARIAL OPERATIONS—PERSONNEL
All employees.

OFFICE OF MINERALS POLICY AND RESEARCH ANALYSIS
GS-14, Mathematical Statistician.
GS-14, Computer Specialist.
GS-10, Administrative Assistant.
GS-8 and below, secretarial and clerical personnel.

ASSISTANT SECRETARY—ENERGY AND MINERALS
GS-15, Industrial Specialist.
GS-11, Staff Assistant.
GS-11, Confidential Assistant.
GS-11, Administrative Officer.
GS-9 and below, administrative, clerical and secretarial personnel.

ASSISTANT SECRETARY—POLICY, BUDGET & ADMINISTRATION
GS-15, Staff Assistants.
GS-15, International Program Officers.
GS-15, Management Resources Officer.
GS-14, Committee Management Officer.
GS-13, Equal Opportunity Officer.
GS-12 and below, support, secretarial and clerical personnel.

ASSISTANT SECRETARY—FISH, WILDLIFE AND PARKS
GS-15, Special Assistant.
GS-15, Special Assistants.
GS-15, Staff Assistant.
GS-11, Special Assistant.
GS-11, Confidential Assistant.
GS-10, Secretarial Assistant.
GS-9 and below, secretaries and student assistants.

ASSISTANT SECRETARY—LAND AND WATER RESOURCES
GS-15, Special Assistant (Emergency Water Planning).
GS-15, Deputy Assistant Secretary (Interagency Affairs).
GS-15, Public Information Officer.
GS-11, Confidential Assistant.
GS-7, Special Assistant.
GS-3 and below, secretarial, stenographic and clerical personnel.

SOLICITOR
All employees of the following subunits of the Solicitor's office perform duties under the Act. Clerical, administrative and paralegal employees of such subunits are exempt from filing.

Immediate Office of the Solicitor.
Division of Energy and Resources, Immediate Office of the Associate Solicitor.
Division of Energy and Resources, Branch of Land Utilization.
Division of Energy and Resources, Branch of Reclay.
Division of Energy and Resources, Branch of Onshore Minerals.
Division of General Law, Immediate Office of the Associate Solicitor.

Division of General Law, Branch of General Legal Services.
Division of General Law, Branch of Procurement.
All Regional Offices.
All Field Offices, except Aberdeen, S. Dak.
Office of Conservation Manager, Western Region.

The following categories of personnel, engaged only in matters relating to the Outer Continental Shelf in the offices listed below, are exempt:

GS-7, above, Cartographic Technicians.

All secretarial and clerical employees required to file.

Impeccable Office of the Division Chief.
Branch of Mining Operations.
Branch of Onshore Evaluation.
Office of Conservation Manager, Eastern Region.
Office of Conservation Manager, Central Region.
BUREAU OF MINES

[List of Covered Offices and Exempted Positions]

Immediate Office of the Associate Director—Mineral and Material Supply/Demand Analysis.
Administrative Officer (1).
Professional, administrative, secretarial and clerical employees GS-9 and below.

Immediate Office of the Assistant Director—Field and Environmental Activities.
All secretarial and administrative employees.

Mineral Assessment Specialists (not performing Wilderness Evaluation Studies under the Wilderness Act).
Mineral Assessment Specialists, GS-11 and below.

The positions in the above organizations are exempt because they are non-regulatory and non-policy making positions or because they perform no duties under the act.

BUREAU OF LAND MANAGEMENT

All personnel in the following offices of the Bureau are exempt since these offices have no functions or duties under the act: Alaska Outer Continental Shelf Office, Atlantic Outer Continental Shelf Office, Gulf Outer Continental Shelf Office, Pacific Outer Continental Shelf Office.

All personnel in other offices are exempt if they are incumbents of the positions listed below, since these positions are non-policy-making and non- regulatory:

All positions under the Federal Wage System.

All General Schedule positions in the occupational codes and grade levels indicated below:

GS-8 and below.

All accounting assistants.
All clerical personnel.

Division of General Law, Branch of Federal Wage System.
Division of General Law, Branch of Physical Science.
Division of General Law, Branch of Administrative Law.
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Division of General Law, Branch of Administrative Law.
335, Employment Development Series.
336, General Clerical and Administrative Series at GS-11 and below.
337, Messenger Series.
338, Information Receptionist Series.
339, Mail and File Series.
340, Clerk-Interpreter and Reporter Series.
341, Standards or Typing Unit Supervising Series.
342, Clerk-Dictating Machine Transcribing Series.
343, Secretary Series.
344, Office Services Management and Supervision Series.
345, Management Analysis Series.
346, Management Clerical and Assistance Series.
347, Program Analysis Series at GS-13 and below.
348, Office Machine Operator Series.
349, Data Recorder Series.
350, Telephone Operating Series.
351, Communications Management Series.
352, General Communications Series.
353, Communications Specialist Series.
354, General Biological Science Series at GS-12 and below.
355, Biological Technician Series.
356, Zoology Series.
357, Botany Series.
358, Range Conservation Series.
359, Range Technician Series.
360, Forestry Series at GS-12 and below.
361, Forestry Technician Series.
362, Soil Science Series at GS-11 and below.
363, Agronomy Series.
364, General Fish and Wildlife Administration Series.
365, Fishery Biology Series at GS-11 and below.
366, Wildlife Biology Series at GS-11 and below.
367, General Accounting Clerical and Administrative Series.
368, Account Maintenance Clerical Series at GS-13 and below.
369, Accounting Technician Series.
370, Cash Processing Series.
371, Voucher Examining Series.
372, Payroll Series.
373, Budget Administration Series at GS-12 and below.
374, General Engineering Series at GS-12 and below.
375, Engineering Technician Series.
376, Safety Engineering Series.
377, Landscape Architecture Series.
378, Architecture Series.
379, Civil Engineering Series.
380, Surveying Technician Series.
381, Engineering Drafting Series.
382, Sanitary Engineering Series.
383, Mechanical Engineering Series.
384, Electrical Engineering Series.
385, Electronics Engineering Series.
386, Electronics Technician Series.
387, Mining and Metallurgy Series.
388, Petroleum Engineering Series.
389, Agricultural Engineering Series.
390, Industrial Engineering Series.
391, Engineering and Architecture Student Trainee Series.
392, Contact Representative Series.
393, Legal and linister Examining Series.
965, Legal and Administrative Series at GS-11 and below.
966, Land Law Examining Series at GS-11 and below.
968, Legal Clerk and Technician Series at GS-9 and below.
1001, General Arts and Information Series.
1050, Illustrating Series.
1057, Information Series.
1058, Photography Series.
1061, Public Information Services at GS-14 and below.
1062, Writing and Editing Series.
1054, Visual Information Series.
1057, Editorial Assistance Series.
1051, General Business and Industry Series.
1102, Contract and Procurement Series at GS-10 and below.
1104, Property Disposal Series.
1105, Purchasing Series.
1106, Procurement Clerical and Assistance Series.
1107, Property Disposal Clerical and Technician Series.
1110, General Business Series at GS-12 and below.
1170, Realty Series at GS-11 and below.
1171, Appraising and Assessing Series at GS-10 and below.
1301, General Physical Science Series.
1311, Physical Science Technician Series.
1316, Hydrology Series.
1320, Chemistry Series.
1340, Meteorology Series.
1350, Geology Series.
1360, Oceanography Series at GS-12 and below.
1770, Cartography Series.
1771, Cartographic Technician Series.
1772, Geodesy Series.
1773, Land Surveying Series at GS-12 and below.
1410, Librarian Series.
1411, Library Technician Series.
1412, Technical Information Services Series.
1413, Archives Technician Series.
1415, Operations Research Series.
1416, Statistician Series.
1531, Statistical Assistant Series.
1610, Facility Management Series.
1654, Printing Management Series.
1670, Equipment Specialist Series.
1702, Education and Training Technician Series.
1710, Education and Vocational Training Series.
1712, Training Instruction Series.
1715, Criminal Investigation Series at GS-11 and below.
2001, General Supply Series.
2066, Supply Clerical and Technician Series.
2010, Inventory Management Series.
2150, Transportation Operations Series.
2151, Dispatching Series.
2181, Aircraft Operations Series.

OFFICE OF PERSONNEL MANAGEMENT

GS-12 and below, Attorney Advisors.
All clerical, paralegal, and administrative personnel.

APPENDIX E — LIST OF BUREAUS AND OFFICES, OR SUBORDINATE THERETO, PERFORMING FUNCTIONS ON WHICH THE SECRETARY HAS DETERMINED TO BE EXEMPT FROM RECOMMENDING REQUIREMENTS OF SECTION 13

All employees in the following bureaus, offices, and units thereto, are subject to the filing requirements of the Act except for the following positions which do not involve policymaking or regulatory responsibility under the Act.

SECRETARY'S IMMEDIATE OFFICE

GS-14, Confidential Assistant, Washington, D.C.
GS-12, Staff Assistant, Washington, D.C.
GS-12, Confidential Assistant to the Under Secretary, Washington, D.C.

GS-15, Investigative Assistant, Washington, D.C.

OFFICE OF THE SECRETARY

GS-13, Staff Assistant, Washington, D.C.
GS-11, Staff Assistant, Washington, D.C.
GS-11 and below, Confidential Assistants, Washington, D.C.
GS-11 and below, Correspondence Management Specialists, Washington, D.C.

GS-9 and below, Correspondence Analysts, Washington, D.C.

GS-7, Correspondence Assistant (Typing), Washington, D.C.
GS-13 and below, Staff Assistants, Secretary's regional offices.
GS-13, Staff Officer, Secretary's regional offices.
GS-9 and below, secretarial, stenographic and clerical personnel, Secretary's regional offices.

GS-8 and below, secretarial, stenographic and clerical personnel, Secretary's regional offices.

GS-8 and below, clerical and administrative personnel.

OFFICE OF ENVIRONMENTAL PROJECT REVIEW

All personnel on the Water Resources Staff, GS-12, Staff Assistant.
GS-9 and below, administrative, clerical, and support personnel.

OFFICE OF AUDIT AND INVESTIGATION

GS-15, Manager, Staff Development and Resources.
GS-16, Program Audit Manager, Land and Water.
GS-16, Program Audit Manager, Bureau of Indian Affairs.
GS-14, Supervisory Auditor, Contract and Grant.

GS-14, Supervisory Auditor, ADP.
GS-16, Chief, Division of Investigations.
GS-14, Investigator.
GS-13, Investigator.
GS-12, Investigator.
GS-12, Administrative Officer.

GS-9 and below, Auditors.

OFFICE OF INTERNAL AUDIT

GS-9 and below, secretarial and clerical personnel.

OFFICE OF PERSONNEL MANAGEMENT

All employees are exempt except for the Director of Personnel.

OFFICE OF SECRETARIAL OPERATIONS—PERSONNEL

GS-9 and below, administrative, clerical, and support personnel.
OFFICE OF OCEAN CONTINENTAL SHELF
PROGRAM COORDINATION

All employees are exempt except:
Director, GS-16.

OFFICE OF BUDGET

All employees are exempt except:
GS-17, Director.
GS-16, Deputy Director.
GS-15, Program and Budget Specialist.
GS-14, 15, Budget Analyst.

OFFICE OF PUBLIC AFFAIRS

All employees are exempt except:
Assistant to the Secretary and Director of Public Affairs, GS-16.

ASSISTANT SECRETARY—POLICY AND ADMINISTRATION

GS-15, Staff Assistants.
GS-16, International Program Officers.
GS-15, Management Resources Officer.
GS-14, Committee Management Officer.
GS-13, Equal Opportunity Officer.
GS-12 and below, support, secretarial and clerical personnel.

ASSISTANT SECRETARY—ENERGY AND MINERALS

Director, Ocean Resources:
GS-15, Industrial Specialist.
GS-14, Staff Assistant.
GS-11, Confidential Assistant.
GS-11, Administrative Officer.
GS-9 and below, administrative, clerical, and secretarial personnel.

ASSISTANT SECRETARY—FISH, WILDLIFE AND PARKS

GS-16, Special Assistant.
GS-15, Special Assistants.
GS-14, Staff Assistant.
GS-11, Confidential Assistant.
GS-11, Administrative Assistant.
GS-9 and below, secretaries and student assistants.

ASSISTANT SECRETARY—LAND AND WATER RESOURCES

GS-16, Special Assistant (Emergency Water Planning).
GS-16, Staff Assistant (Economists).
GS-15, Deputy Assistant Secretary (Inter-governmental Affairs).
GS-15, Special Assistant (2).
GS-16, Staff Assistant.
GS-15, Public Information Officer.
GS-14, Staff Assistant (2).
GS-11, Confidential Assistant.
GS-7, Special Assistant.
GS-9 and below, secretarial, stenographic, and clerical personnel.

ECOLOGICAL DIVISION

OFFICE OF THE DEPUTY DIRECTOR, EASTON, WA. IMMEDIATE OFFICE

Assistant Director—Program Analysis.
Assistant Director—Environmental Conservation.
Assistant Director—Eastern Region.
Program Analyst.
Economist.
Physical Scientists (3).
Legislative Specialist.
Congressional Liaison Officer.
Biological Scientist.
Staff Scientist.
Public Information Officers (2).
Operations Research Analyst.
Technical Information Specialist.
Special Assistant for Environmental Analysis.
Staff Assistant.
Computer Specialist.
Computer Systems Analyst.
Secretarial, clerical, and administrative personnel.

RULES AND REGULATIONS

GEOLGIO DIVISION

Immediate Office of the Chief Geologist
Deputy Chief Geologist for Program and Budget.
Administrative Officer.
Fiscal Officer.
Geologic, clerical, and other administrative personnel.

Reserve, Va.

Deputy Chief for Mineral Resources Specialist Program.
Secretarial and clerical personnel.
Dentor, Colo.

Secretarial and clerical personnel.

CONSERVATION DIVISION

In addition to the specific exemptions identified below by office, the following groups are exempt in all offices required to file:
All secretarial personnel.
All accounting assistants, GS-9 and below.
All clerical personnel.
All cartographers, engineering, and physical science aides.
All engineering, geologic, hydrologic, and topographic field assistants.
All cartographers, engineering, petroleum engineering, and physical science technicians, GS-9 and below.

Office of the Division Chief.
Branch of Water Operations.
Branch of Oushoro Evaluation.
Office of Conservation Manager, Eastern Region.
Office of Conservation Manager, Central Region.
Office of Conservation Manager, Western Region.

The following categories of personnel, engaged only in matters relating to the Outer Continental Shelf in the offices listed below, are exempt:

Electrical Engineers.
General Engineers.
Mechanical Engineers.
Petroleum Engineers.
Petroleum Engineering Technicians.
Structural Engineers.
Environmental Scientists.
Oceanographers.
Geologists.
Geophysicists.
Physical Science Technicians.
Accountants, GS-7 and above.

Cartographic Technicians.

Office required to file, in which some personnel are engaged solely in outer continental shelf activities:
Office of Area Geologist, Eastern Region.
Office of District Geologist, Los Angeles, Calif.
Office of District Geologist, Ventura, Calif.
Office of Area Oil and Gas Supervisor, Los Angeles, Calif.
Office of Area Oil and Gas Supervisor, Anchorage, Alaska.
Office of Area Geologist, Anchorage, Alaska.

NATIONAL PARK SERVICE

List of Covered Offices, Parks and Arcas:
All employees in the following organizational units perform duties under the mining in the Parks Act. Employees paid under the Federal Wage System; employees in clerical, secretarial and maintenance positions; and employees in positions GS-8 and below not exempted from the filing requirements of the act since their positions do not involve policymaking or regulatory responsibility under the act.

Immediate Office of the Director.
Immediate Office of the Associate Director, Management and Operations.
Immediate Office of the Assistant Director, Special Services.
Immediate Office of the Division of Mining and Minerals.
Division of Land Acquisition.
Immediate Office of the Regional Director, Western Region.
Immediate Office of the Associate Regional Director, Management and Operations.
Immediate Office of the Division of Mining and Minerals.
Immediate Office of the Division of Land Acquisition.
Immediate Office of the Superintendent, Division of Mining, and Division of Administration in the following parks and areas:
Death Valley National Monument.
Organ Pipe Cactus National Monument.
Grand Canyon National Park.
Lake Mead National Recreation Area.
Whiskeytown-Shasta-Trinity National Recreation Area.
Coronado National Memorial.
Joshua Tree National Monument.
Immediate Office of the Regional Director, Rocky Mountain Region.
Immediate Office of the Assistant to the Regional Director, Utah.
Immediate Office of the Associate Regional Director, Management and Operations.
Immediate Office of the Division of Mining and Minerals.
Immediate Office of the Division of Land Acquisition.
Immediate Office of the Superintendent, Division of Mining, and Division of Administration in the following parks and areas:
Arches National Park.
Glacier National Park.
Canyonlands National Park.
Capitol Reef National Park.
Grand Teton National Park.
Rocky Mountain National Park.
Bighorn Canyon National Recreation Area.
Glenn Canyon National Recreation Area.
Natural Bridges National Monument.
Rockefeller National Parkway.
Theodore Roosevelt National Memorial Park.
Immediate Office of the Regional Director, Pacific Northwest Region.
Immediate Office of the Associate Regional Director, Management and Operations.
Immediate Office of the Division of Mining and Minerals.
Immediate Office of the Superintendent, Division of Mining, and Division of Administration in the following parks and areas:
North Cascades National Park.
Crater Lake National Park.
Olympic National Park.
Bays Ledge-Chinat National Recreation Area.
Mount McKinley National Park.
Glacier Bay National Monument.
Katmai National Monument.
Immediate Office of the Regional Director, Southwest Region.
Immediate Office of the Associate Regional Director, Management and Operations.
Immediate Office of the Division of Land Acquisition.
Immediate Office of the Superintendent and Division of Administration in the following park:
Big Bend National Park.
RULES AND REGULATIONS

OFFICE OF BUDGET
All employees are exempt except:
GS-17, Director.
GS-16, Deputy Director.
GS-15, Program and Budget Specialist.
GS-14, 15, Budget Analyst.

OFFICE OF PUBLIC AFFAIRS
All employees are exempt except:
Assistant to the Secretary and Director of Public Affairs, GS-10.

ASSISTANT SECRETARY—POLICY, BUDGET AND ADMINISTRATION

GS-15, Staff Assistants.
GS-16, International Program Officers.
GS-16, Management Resources Officer.
GS-14, Committee Management Officer.
GS-15, Equal Opportunity Officer.
GS-12 and below, support, secretarial and clerical personnel.

ASSISTANT SECRETARY—ENERGY AND MINERALS

GS-11, Staff Assistant.
GS-11, Confidential Assistant.
GS-11, Administrative Officer.
GS-9 and below, administrative and clerical personnel.

ASSISTANT SECRETARY—LAND AND WATER RESOURCES

GS-16, Special Assistant (Emergency Water Planning).
GS-16, Deputy Assistant Secretary (Intergovernmental Affairs).
GS-15, Special Assistant (3).
GS-10, Staff Assistant.
GS-18, Public Information Officer.
GS-14, Staff Assistant (2).
GS-11, Confidential Assistant.
GS-7, Special Assistant.
GS-8 and below, secretarial, stenographic, clerical personnel.

GEODETICAL SURVEY, OFFICE OF THE DIRECTOR, RESTON, VA.

Immediate Office
Assistant Director—Program Analyst.
Assistant Director—Environmental Conservation.
Assistant Director—Western Region.
Program Analyst.
Economist.
Physical Scientist.
Legislative Specialist.
Congressional Liaison Officer.
Biological Scientist.
Computer Specialist.
Public Information Officer (3).
Operations Research Analyst.
Technical Information Specialist.
Special Assistant for Environmental Analysis.

Assistant to the Solicitor

GS-12, Staff Assistant to the Solicitor.

SECRETARY'S IMMEDIATE OFFICE

GS-14, Confidential Assistant, Washington, D.C.
GS-12, Staff Assistant, Washington, D.C.
GS-12, Confidential Assistant to the Under Secretary, Washington, D.C.
GS-12, Secretary Assistant, Washington, D.C.
GS-11, Staff Assistant, Washington, D.C.
GS-11 and below, Confidential Assistants, Washington, D.C.
GS-11 and below, Secretary Assistants, Washington, D.C.
GS-11 and below, Correspondence Management Specialists, Washington, D.C.
GS-8 and below, Correspondence Analysts, Washington, D.C.
GS-7, Correspondence Assistant (Typing), Washington, D.C.
GS-13 and below, Staff Assistants, Secretary's regional offices.

GS-13, Staff Officer, Secretary's regional offices.

GS-9 and below, Secretary, Stenographic and Clerical Personnel, Secretary's regional offices.
Desk Officers, Land and Water Resources and Indian Affairs.
Desk Officers, Fish and Wildlife and Parks.

OFFICE OF THE SECRETARY

GS-13, Staff Assistants and Officers, Field Offices.

OFFICE OF ENVIRONMENTAL-PROJECT REVIEW

All personnel on the Water Resources and Transportation Staff.
GS-13, Staff Assistant.
GS-8 and below, administrative, clerical and secretarial personnel.

OFFICE OF CONGRESSIONAL AND LEGISLATIVE AFFAIRS

GS-9, Staff Assistant to the Director (Steno), Division of Congressional Liaison.
GS-12, Management Specialist.
GS-11, Management Specialist.
GS-11, Liaison Specialist.
GS-8 and below, administrative, clerical and secretarial personnel.

DIVISION OF LEGISLATION

GS-14, Attorney-Advisor.
GS-13, Attorney-Advisor.
GS-12, Attorney-Advisor.
GS-10, Legislative Assistant.
GS-9, Legislative Assistant.
GS-8 and below, secretaries, clerks and administrative personnel.

OFFICE OF AUDIT AND INVESTIGATION

* Headquarters Audit Office:
GS-15, Manager, Staff Development and Resources.
GS-12, Administrative Officer.
GS-16, Program Audit Manager for Fish, Wildlife and Parks.
GS-15, Program Audit Manager for Land and Water.
GS-14, Supervisory Auditor, Contract and Grant.
GS-13, Supervisory Auditor, Contract and Grant.
GS-14, Supervisory Auditor, ADP.
GS-8 and below, Secretarial and Administrative personnel.

OFFICE OF PERSONNEL MANAGEMENT

All employees are exempt except for the Director of Personnel.

OFFICE OF SECRETARIAL OPERATIONS-PERSONNEL

All Employees.

OFFICE OF MINERALS POLICY AND RESEARCH ANALYSIS

GS-14, Mathematical Statistician.
GS-14, Computer Specialist.
GS-11, Statistician.
GS-10, Administrative Assistant.
GS-8 and below, secretarial and clerical personnel.

OFFICE OF ADMINISTRATIVE & MANAGEMENT POLICY

All employees are exempt except:
GS-16, Director.
GS-12, Staff Assistant—Departmental Energy Management Coordinator.

OFFICE OF POLICY ANALYSIS

GS-8 and below, secretarial, clerical, and administrative personnel.

OFFICE OF OUTER CONTINENTAL SHELF PROGRAM COORDINATION

GS-14, Staff Assistants.
GS-8 and below, secretarial and administrative personnel.
is corrected to read as follows: "Section 255.7(d) (3) is changed to".

**EFFECTIVE DATE:** January 6, 1978.

**FOR FURTHER INFORMATION CONTACT:**


Accordingly, FR Doc. 77-55144 is amended by deleting line 1 of Item 2 and substituting "Section 255.7(d) (3) is changed to" therefor. (45 U.S.C. 101 et seq. 49 U.S.C. 1651 et seq. 49 CFR 1.49 (q) and (u).)


**JOHN M. SULLIVAN,**

Administrator.

[FR Doc.78-273 Filed 1-5-78;8:45 am]

**[7035-01]**

**CHAPTER X—INTERSTATE COMMERCE COMMISSION**

**SUBCHAPTER A—GENERAL RULES AND REGULATIONS**

**PART 1011—COMMISSION ORGANIZATION; DELEGATIONS OF AUTHORITY**

**Chairman**

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Final rules.

**SUMMARY:** Part 1011 of Title 49 of the Code of Federal Regulations, which becomes effective January 1, 1978, provides for the assignment of responsibilities and authority vested by law in the Interstate Commerce Commission or the Chairman of the Commission. The Chairman of the Commission is assigned certain authority to act for the Commission, largely in matters of a procedural nature. Section 1011.7 of Title 49, which is the subject of this issuance, redesignates to specified Commission employees the authority to act in certain matters assigned to the Chairman of the Commission. Because these rules involve the internal organization and procedures of the Commission, they are issued by the Chairman of the Commission in final form, and public comments are not being requested.

**EFFECTIVE DATE:** January 3, 1978.

**FOR FURTHER INFORMATION CONTACT:**


Section 1011.7 is added to 49 CFR Part 1011 as follows:

§ 1011.7 Delegations of authority by the Chairman of the Interstate Commerce Commission.

(a) (1) This section provides for delegations of authority by the Chairman of the Interstate Commerce Commission to individual employees of the Commission.

(2) The Chairman of the Commission may remove for disposition any matter delegated under this section, and an employee of the Commission may refer any matter delegated to him or her under this section to the Chairman of the Commission for disposition.

(b) (1) Appeals from the decision of employees acting under authority delegated pursuant to this section will be acted upon by the Chairman of the Commission. Appeals must be filed within 10 days of the date of the action taken by the employee, and responses to appeals must be filed within 10 days thereafter. Such appeals are not favored; they will be granted only in exceptional circumstances to correct a formal error or to prevent manifest injustice.

(2) The Chairman may, on his or her own motion, reverse, modify any decision of an employee acting under authority delegated under this section.

(c) (1) As used in this paragraph, the term "procedural matter" includes, but is not limited to, the assignment of the time and place of hearing; the assignment of proceedings to Administrative Law Judges; the issuance of orders directing special hearing procedures; the establishment of dates for filing statements, in cases assigned for handling under modified (non-oral hearing) procedure; the consolidation of proceedings for hearing or disposition; the postponement of hearings and of the final date; the waiver of formal specifications for pleadings; and extensions of time for filing pleadings. It does not include interlocutory appeals from the rulings of hearing officers; nor does it include decisions or orders concerning the granting of exceptions, their disposition, or the non-filing of documents.

(2) Unless otherwise ordered by the Commission in individual proceedings, authority to dispose of procedural matters arising prior to the issuance of an initial decision in proceedings assigned for handling under oral hearing procedure or assigned to an administrative law judge under modified procedure is delegated to the Chief Administrative Law Judge of the Commission. Notwithstanding this delegation, Commissioners, Administrative Law Judges, and Joint Boards appointed under 49 U.S.C. 365 retain the authority to dispose of procedural matters in proceedings assigned to them.

(3) Unless otherwise ordered by the Commission in individual proceedings, authority to dispose of procedural matters arising prior to the issuance of an initial decision in proceedings assigned for handling under modified procedure, other than those assigned to an administrative law judge or arising in a proceeding after the issuance of an initial decision of a hearing officer in proceedings which have been the subject of an oral hearing.
is delegated to the Director of the Office of Proceedings of the Commission.

(d) Except as provided in Rule 86(a) of the general rules of practice, 49 CFR 1100.66(a), authority to dismiss complaints at the request of the complainant, or applications at the request of applicants, is delegated to the Director of the Office of Proceedings of the Commission.

(e) The entry of separation orders, responsive to findings authorizing the filing of statements of claimed damages in transit for unloading by this elevator at the time of its destruction. Rebuilding of the elevator cannot be accomplished within a reasonable time. Other arrangements for the unloading of these cars will require diversion and reconsignment of many of them in a manner prohibited by the applicable tariffs. It is the opinion of the Commission that such diversions and reconsignments are necessary in the public interest to enable the prompt unloading of these cars and their continued use in transportation service and to enable the fulfillment of export grain commitments; that notice and public procedure herein are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered, That:

§ 1033.1293 Service Order 1293.

(a) Railroads authorized to divert traffic consigned to Farmers Export Elevator located at Galveston, Tex. Any railroad holding a car loaded with grain consigned, reconsigned or intended for unloading by the Farmers Export grain elevator located at Galveston, Tex., which originated on or before December 29, 1977, and which cannot be unloaded by Farmers Export because of the destruction of its grain elevator, may be reconsigned, diverted or reshipped to any other grain elevator in the United States which is located on the Gulf of Mexico. In the application of this section grain elevators located on the lower Mississippi River from Port Allen, La. to the mouth of the river and grain elevators located on the Houston, Tex., ship channel shall be deemed to be located on the Gulf of Mexico.

(b) Reconsignments and diversions charges. Carloads of grain reconsigned, diverted, or reshipped under the provisions of this order shall be subject to reconsignments or diversion charges provided in the applicable tariffs.

(c) Rates applicable. The rates applicable to carloads of grain reconsigned, diverted or reshipped under the provisions of this order shall be the rates that would have been applicable on the shipments at the time of shipment had they been originally destined to the point to which reconsigned, diverted or reshipped. When the applicable tariffs provide routes from origin to the new designation via the line and the point at which the car is held, such routes must be utilized for the rerouting, diversion or reshipment. When no such route exists any available route may be used. In the application of this section cars which have arrived at Galveston, Tex., and which are located on a line performing only terminal or intermediate switching service shall be considered as being held by the intermediate haul carrier.

(d) Divisions of Revenues. In executing the directions of the Commission provided for in this order, the common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic. Divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(e) Waybills to be endorsed. Waybills authorizing movement of cars reconsigned, diverted or reshipped under this order shall be endorsed as follows:

"(Reconsigned) (Diverted) (Reshipped) authority I.C.C. Service Order No. 1293"

(1) Application. The provisions of this order shall apply to interstate, intrastate, and foreign traffic.

(2) Effective date. This order shall become effective at 12:01 a.m., December 30, 1977.

(3) Expiration date. The provisions of this order shall expire at 11:59 p.m., January 31, 1978, unless otherwise modified, changed, or suspended by order of the Commission.

It is further ordered, That copies of this order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns and John R. Michael. Member Robert E. Turcotte not participating.

H. G. Homie, Jr., Acting Secretary.

[FR Doc. 78-312 Filed 1-5-78; 8:45 am]

PART 1033—CAR SERVICE

Railroads Authorized to Divert Traffic Consigned to Farmers Export Elevator Located at Galveston, Tex.

AGENCY: Interstate Commerce Commission.

ACTION: Emergency Order (Service Order No. 1293).

SUMMARY: The Export Farmers grain elevator at Galveston, Tex., was destroyed by explosion and fire on December 27, 1977. Service Order No. 1293 authorizes diversion or reconsignments of carloads of grain except by the carrier authorized to operate on or before December 29, 1977, to any other elevator on the Gulf of Mexico without assessment of diversion or reconsignments charges and subject to the through rates from origin to the new destination.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: The Order is printed in full below.

At a Session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 20th day of December, 1977.

On December 27, 1977, the Farmers Export grain elevator located at Galveston, Tex., was destroyed by an explosion and fire. Approximately sixteen hundred (1600) carloads of grain were on hand or in transit for unloading by this elevator at the time of its destruction. Rebuilding of the elevator cannot be accomplished within a reasonable time. Other arrangements for the unloading of these cars will require diversion and reconsignments of many of them in a manner prohibited by the applicable tariffs. It is the opinion of the Commission that such diversions and reconsignments are necessary in the public interest to enable the prompt unloading of these cars and their continued use in transportation service and to enable the fulfillment of export grain commitments; that notice and public procedure herein are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered, That:

§ 1033.1293 Service Order 1293.

(a) Railroads authorized to divert traffic consigned to Farmers Export elevator located at Galveston, Tex. Any railroad holding a car loaded with grain consigned, reconsigned or intended for unloading by the Farmers Export grain elevator located at Galveston, Tex., which originated on or before December 29, 1977, and which cannot be unloaded by Farmers Export because of the destruction of its grain elevator, may be reconsigned, diverted or reshipped to any other grain elevator in the United States which is located on the Gulf of Mexico. In the application of this section grain elevators located on the lower Mississippi River from Port Allen, La. to the mouth of the river and grain elevators located on the Houston, Tex., ship channel shall be deemed to be located on the Gulf of Mexico.

(b) Reconsignments and diversions charges. Carloads of grain reconsigned, diverted or reshipped under this order remain in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(e) Waybills to be endorsed. Waybills authorizing movement of cars reconsigned, diverted or reshipped under this order shall be endorsed as follows:

"(Reconsigned) (Diverted) (Reshipped) authority I.C.C. Service Order No. 1293"

(1) Application. The provisions of this order shall apply to interstate, intrastate, and foreign traffic.

(2) Effective date. This order shall become effective at 12:01 a.m., December 30, 1977.

(3) Expiration date. The provisions of this order shall expire at 11:59 p.m., January 31, 1978, unless otherwise modified, changed, or suspended by order of this Commission.

It is further ordered, That copies of this order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association; and that notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns and John R. Michael. Member Robert E. Turcotte not participating.

H. G. Homie, Jr., Acting Secretary.

[FR Doc. 78-312 Filed 1-5-78; 8:45 am]

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:
The Order is printed in full below.

At a Session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 30th day of December, 1977.

Operation of the line of the former Penn Central Transportation Co. (PC) between Bicknell, Ind., (City), and Vincennes, Ind., was discontinued on April 1, 1974, in accordance with the Final System Plan of Reorganization of the bankrupt eastern railroads authorized by the Regional Rail Reorganization Act of 1970. Operation of the line between Indianapolis, Ind., and Bicknell was assumed by the Consolidated Rail Corp. (CR) on that same date. The city has acquired 1.1 miles of the former CR trackage and is in need of immediate restoration of railroad service in order to commence operations. The city has leased its tracks to the Inter-State Interstate Railway Co., Inc., in order to commence operations immediately in order to serve a major industry which has purchased an unused factory by city's agreement, and upon the American Short Line Railroad Association; and that notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns and John R. Michael. Member Robert S. Turlington not participating.

H. G. Homer, Jr.,
Acting Secretary.

[4310-55]

Title 50—Wildlife and Fisheries

CHAPTER I—UNITED STATES FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 20—MIGRATORY BIRD HUNTING

Emergency Closure of Canada Goose Season in Certain Illinois Counties

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This rulemaking closes the Canada goose hunting season in the Illinois counties of Alexander, Jackson, Williamson and Union. The Canada goose season in these counties opened November 21, 1977, with a January 20, 1978, closing date. The Service gives notice as required by 50 CFR 20.23 that the season for taking Canada geese in the remainder of Illinois closed at sunset on Friday, December 29, 1977, as required by the Marine Mammal Protection Act of 1972. The season for taking Canada geese in the remainder of Illinois closed at sunset on Friday, December 29, 1977, as required by the Marine Mammal Protection Act of 1972.


Harvey K. Nelson,
Acting Director,
U.S. Fish and Wildlife Service.

[3510-22]

CHAPTER II—NATIONAL MARINE FISHERIES SERVICE, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

Importation of Yellowfin Tuna and Tuna Products

AGENCY: National Marine Fisheries Service.

ACTION: Final rule.

SUMMARY: The Assistant Administrator for Fisheries, National Marine Fisheries Service (NMFS), in consultation with the Department of State, finds that Panama is in substantial conformance with U.S. regulations governing the taking of marine mammals (i.e., purpose incidental to commercial fishing operations. In finding that this nation is not fishing in a manner proscribed for per-
Rules and Regulations

Subject to the jurisdiction of the United States, the Assistant Administrator for Fisheries exempts this nation from the importation prohibition provisions affecting yellowfin tuna and tuna products.

**Effective Date:** December 30, 1977.


**Supplementary Information:** The NMFS published regulations in the Federal Register on December 23, 1977, 42 FR 64551-64560 governing the taking of marine mammals incidental to commercial fishing operations. (50 CFR 216-24.) These regulations include provisions concerning the importation of yellowfin tuna and tuna products from nations known to be involved in the tuna purse seine fishery in the eastern tropical Pacific Ocean (ETP). Effective January 4, 1978, importation of certain yellowfin tuna and tuna products from these countries will be contingent upon certain findings by the Assistant Administrator for Fisheries in accordance with § 216.24 (e) (5).

Canada, Ecuador, Mexico, the Netherlands Antilles, and Nicaragua previously supplied the NMFS with adequate information to indicate that their tuna purse seine operations in the ETP are in substantial conformance with U.S. regulations. Subsequently, the Assistant Administrator for Fisheries published in the Federal Register (42 FR 56417, October 21, 1977, and 42 FR 64121, December 22, 1977) notice that yellowfin tuna and tuna products from these five nations are exempted from the importation prohibition provisions that would have affected them after December 31, 1977. Panama is hereby given a similar exemption.

This finding by the Assistant Administrator for Fisheries, made in accordance with § 216.24 (e) (5) (1), exempts Panama from the import provisions concerning yellowfin tuna and tuna products listed in § 216.24 (e) (2) (i). However, the requirements listed in § 216.24 (e) (4) will continue to apply. The Assistant Administrator considered all available information in making this finding. Information submitted by Panama is available to the public at the information contact address set out above, and is summarized in the following:

**Panama**

(a) Fleet. Five Panamanian tuna purse seine vessels will operate in the ETP in 1978. The majority of these vessels are equipped with porpore rescue gear similar to that required on U.S. vessels. The remainder of the gear is on order. The skippers on these vessels are familiar with the U.S. regulations and will follow them while fishing in the ETP. Arrangements have been made to provide skipper training sessions in Panama by U.S. Federal employees to bring Panamanian skippers up to date on the latest porpore release techniques.

(b) Porpore Mortality. The Panamanian government is presently gathering data on the estimated porpore mortality by their seiners during the 1977 season. This information will be transmitted to the National Marine Fisheries Service as soon as it is available.

(c) Miscellaneous. Panama, as a member of the Inter-American Tropical Tuna Commission (IATTC), will participate in the IATTC international tuna-porpore research and observer program. Panama has already informed the National Marine Fisheries Service that they intend to send two biologists to San Diego, California to attend an observer training course in late January, 1978, prior to placement on their vessels.

This finding will be subject to an annual review. NMFS will require an update of the items listed in § 216.24 (e) (5) (ii) to ensure that the conditions which supported the original finding continue to exist. Submission of the 1977 porpore mortality information, as stated in paragraph (b) above, will be expected before July 1, 1978.

NMFS will continue monitoring the status of the international tuna purse seine fleet operating in the ETP. Changes to the list of nations affected by the importation prohibitions of yellowfin tuna and tuna products under § 216.24 (e) (5) will be published in the Federal Register.


Winfred H. Meiboom, Associate Director, National Marine Fisheries Service.

[FR Doc. 78-172 Filed 1-6-78; 10:34 am]

**3510-22**

**Subchapter G—Processed Fishery Products, Other Fishery Therewith, and Certain Other Processed Food Products**

**Part 260—Inspection and Certification**

**Fees and Charges**

**Agency:** National Marine Fisheries Service, Commerce.

**Action:** Final rule.

**Summary:** The purpose of this rule is to increase the hourly rates for inspection fees.

On September 28, 1977, the President, by Executive Order 12010 (42 FR 5825), increased the rates for Federal General Schedule employees. Section 260.61 (a) requires that the hourly rates for inspection fees be automatically increased on the effective date of the pay adjustment by an amount equal to the increase received by the average General Schedule grade level of fishery product inspectors receiving such pay increases. This pay increase resulted in a 7.0 percent increase in the basic pay of fishery product inspectors.

**Dates:** These amended rates became effective October 1, 1977.

**For Further Information Contact:**


**Supplementary Information:** Notice is hereby given that pursuant to the authority vested in the Secretary of Commerce by Reorganization Plan No. 4 of 1970 (35 FR 15637), § 260.70 of Part 260, Inspection and Certification is hereby amended by adding the rates for fees and charges to provide for the recovery of increased costs attributable to the upward adjustment of the rates of basic pay of fishery product inspectors. In § 260.70, paragraphs (b) (1), (2), and (3) are revised as follows:

§ 260.70 Schedule of fees.

Per hour

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<tr>
<th>Type</th>
<th>Rate</th>
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<tbody>
<tr>
<td>I</td>
<td>$25.65</td>
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<tr>
<td>II</td>
<td>$33.60</td>
</tr>
<tr>
<td>III</td>
<td>$33.60</td>
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</tbody>
</table>

The contracting party shall be charged at an hourly rate of $25.65 per hour for regular time; $33.60 per hour for overtime in excess of 8 hours per shift per day; and $33.60 per hour for Sunday and national legal holidays for service performed by inspection personnel established under Federal inspection. The contracting party shall be billed monthly for services rendered in accordance with contractual provisions at the rates prescribed in this section. At an official establishment designated in a contract, products also designated therein will be inspected during processing at a basic hour rate for regular time, plus overtime, when appropriate. Products not designated in the contract will be inspected upon request on a lot inspection basis at lot inspection rates as prescribed in this section.

(2) Type II—Lot inspection—Officially and unofficially drawn samples:

Per hour

<table>
<thead>
<tr>
<th>Type</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>$25.65</td>
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<tr>
<td>II</td>
<td>$33.60</td>
</tr>
<tr>
<td>III</td>
<td>$33.60</td>
</tr>
</tbody>
</table>

For lot inspection services performed between the hours of 7 a.m. and 5 p.m. Monday through Friday—$25.65 per hour for lot inspection services performed at times Monday through Friday other than 7 a.m. to 5 p.m. and on Saturdays (3 hour minimum)—$33.60 per hour; and Sunday and national legal holidays (2 hour minimum) $43.10 per hour; The minimum service fee to be charged and collected for inspection of any lot or lots of products requiring less than 1 hour shall be $10.40.

(3) Type III—Miscellaneous inspection and consultative services. When any
inspection or related service, such as, but not limited to, initial and final establishment surveys, appeal inspection, sanitation evaluation, SIFE inspections, sampling product evaluation, and label and product specification review, rendered is such that charges based on the foregoing sections are clearly inapplicable, charges will be based on the rates set forth below:

<table>
<thead>
<tr>
<th>Per hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular time</td>
</tr>
<tr>
<td>$21.55</td>
</tr>
<tr>
<td>Overtime</td>
</tr>
<tr>
<td>27.60</td>
</tr>
<tr>
<td>Sunday and legal holidays (2 h minimum)</td>
</tr>
<tr>
<td>35.00</td>
</tr>
<tr>
<td>Minimum fee</td>
</tr>
<tr>
<td>16.25</td>
</tr>
</tbody>
</table>

For miscellaneous inspection and consultative services performed between the hours of 7 a.m. and 6 p.m., Monday through Friday—$31.55 per hour;

For miscellaneous inspection and consultative services performed at times Monday through Friday other than 7 a.m. to 6 p.m. and on Saturdays (2 hr. minimum)—$37.50 per hour;

For miscellaneous inspection and consultative services performed on Sunday and national legal holidays (2 hr. minimum)—$35.00 per hour. The minimum service fee to be charged and collected for miscellaneous inspection and consultative services requiring less than 1 hour shall be $16.25.


THEODORE P. GEITNER,
Assistant Administrator
for Administration.

[FR Doc.78-210 Filed 1-5-78; 8:45 am]
POTATOES GROWN IN IDAHO—MALHEUR COUNTY, OREG.

Decision on Proposed Further Amendment of Marketing Agreement and Order

AGENCY: Agricultural Marketing Service

ACTION: Proposed rule.

SUMMARY: This decision would amend the Federal marketing agreement and order for potatoes grown in Idaho and Malheur County, Oreg. The amendment was requested by the Idaho Potato Committee, the industry group established under the provisions of the Federal Marketing Act, to terminate its term. The amendment would improve procedural operations and program effectiveness.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of Hearing—Issued April 8, 1977; published April 12, 1977 (42 FR 19148) with a minor correction on April 20 (42 FR 23076).

Notice of Recommended decision—Issued November 9, 1977; published November 14, 1977 (42 FR 58951).

PRELIMINARY STATEMENT

A public hearing was held upon proposed further amendment of the marketing agreement, as amended, and Order No. 945, as amended (7 CFR Part 945), (hereinafter referred to collectively as the "order") regulating the handling of Irish potatoes grown in Idaho and Malheur County, Oreg. The hearing was held, 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 (7 CFR Part 900), at Pocatello, Idaho, on April 28, 1977, pursuant to notice thereof.

Upon the basis of the evidence introduced at the hearing and the record thereof, the Deputy Administrator, on November 9, 1977, filed with the Hearing Clerk, U.S. Department of Agriculture, his recommendation containing notice of the opportunity to file written exceptions thereto. One exception was filed by the Malheur County Potato Growers Association stating it opposes the amendment dealing with an additional public member to serve with the eight potato producers and handlers who now make up the committee. No evidence, brief or arguments supporting that position was included. However, the exception was considered.

The material issues, findings and conclusions, rulings, and general findings of the recommended decision published November 14, 1977, in Volume 42 of the Federal Register (42 FR 58951) are hereby incorporated by reference herein and made a part hereof.

Rulings on exceptions. In arriving at the findings and conclusions, and the regulatory provisions of this decision, the exception to the recommended decision was carefully and fully considered in conjunction with the record evidence. To the extent that the findings and conclusions, and the regulatory provisions of this decision are at variance with the exception, such exception is hereby overruled for the reason previously stated in this decision.

Marketing agreement and order. Annexed hereto and made a part hereof are two documents entitled, respectively, "Marketing Agreement, as Amended, Regulating the Handling of Irish Potatoes Grown in Idaho-Malheur County, Oregon," and "Order Amending the Order, as Amended, Regulating the Handling of Irish Potatoes Grown in Idaho-Malheur County, Oregon," which have been deemed upon as the detailed and appropriate means of effectuating the foregoing conclusions.

It is hereby ordered, that this entire decision, except the annexed marketing agreement, be published in the Federal Register. The regulatory provisions of the marketing agreement are identical with those contained in the order as hereby proposed to be amended by the annexed order which is published with this decision.

Referendum order. It is hereby directed that a referendum be conducted in accordance with the procedure for the conduct of referenda (7 CFR 900.400 et seq.), to determine whether the issuance of the annexed order as amended and as hereby proposed to be further amended, regulating the handling of Irish potatoes grown in Idaho-Malheur County, Oregon, is approved or favored by producers, as defined under the terms of the order, who during the representative period were engaged in the production area in the production of the regulated commodity for fresh market.

The representative period for the conduct of such referendum is hereby determined to be June 1, 1976 through May 31, 1977.

The agent of the Secretary to conduct such referendum is hereby designated to be Dennis L. West and Robert F. Matthews.

Signed at Washington, D.C., on December 30, 1977.

Jerry C. Hill,
Deputy Assistant Secretary for Marketing Services.

Order 1 Amending the Order, as Amended, Regulating the Handling of Irish Potatoes Grown in Idaho-Malheur County, Oregon.

Findings and determinations. The findings and determinations hereinafter set forth are supplementary to the findings and determinations previously made in connection with the issuance of the aforesaid order and of the previously issued amendments thereto; and all of said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) Findings upon the basis of the hearing record. 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 governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon proposed amendment of the marketing agreement, as amended, and Order No. 945, as amended (7 CFR Part 945), regulating the handling of Irish potatoes.

1This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.
grew in Idaho-Malheur County, Oregon.

Upon the basis of the record it is found that: (1) The order, as amended, and as hereby further amended, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act; (2) The order, as amended, and as hereby further amended, regulates the handling of potatoes grown in the production area in the same manner as, and is applicable only to persons in the respective classes of commercial and industry activity specified in, the marketing agreement and order upon which hearings have been held; (3) The order, as amended, and as hereby further amended, is limited in its application to the smallest regional production area which is practicable, consistently with carrying out the declared policy of the act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the act; (4) The order, as amended, and as hereby further amended, prescribes, so far as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of potatoes grown in the production area; and (5) All handling of potatoes grown in the production area is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

ORDER RELATIVE TO HANDLING

It is therefore ordered. That on and after the effective date hereof the handling of potatoes shall be in conformity to and in compliance with the terms and conditions of the order, as hereby amended, as follows:

The provisions of the proposed marketing agreement and order, amending the order, contained in the recommended decision issued by the Deputy Administrator on November 9, 1977, and published in the Federal Register on November 14, 1977, shall be and are the terms and provisions of this order, amending the order, and are set forth in full hereafter.

Recommended amendment of the marketing agreement and order. The following amendment of the marketing agreement and order, as amended, is recommended as the detailed means by which the foregoing conclusions may be carried out:

1. Amend § 945.20 by revising paragraph (a) and adding a new paragraph (d) as follows:

§ 945.20 Establishment and membership.

(a) The Idaho-Eastern Oregon Potato Committee is hereby established and shall include at least five producers and three handlers. Upon recommendation of the committee and approval by the Secretary it may be increased by one public member who shall be nominated by the committee and selected by the Secretary. Each member shall have a respective alternate with the same qualifications as the member.

(d) Each person selected as a public member or alternate shall be a resident of the production area. Also, each shall at the time of selection and during the term of office not be engaged in the commercial production, buying, grading or processing of any agricultural commodity, except as a consumer, nor shall such person be a director, officer or employee of any firm so engaged.

2. Revise § 945.31 to read as follows:

§ 945.21 Term of office.

(a) Except as otherwise provided for in this section, the term of office of committee members and alternates shall be for two years beginning June 1 or such other date as recommended by the committee and approved by the Secretary. The term of office of members and alternates shall be so determined that approximately one-half of the total number of members and handling committee members shall terminate each May 31.

(b) Committee members and alternates shall serve during the term of office for which they are selected and have qualified and continue until their successors are selected and have qualified.

§ 945.24 [Amended]

3. Amend § 945.24 Selection by adding the following to the end: "and (d) any public member or public alternate from the production area-at-large."

4. Amend §§ 945.23 as follows: 1. Revise paragraphs (a) and (c). 2. Reletter paragraph (f) as paragraph (e). 3. Reletter paragraph (g) as paragraph (f). 4. Revise paragraph (e) and add new paragraph (g). 5. Add a new paragraph (d).

§ 945.25 Nomination.

(a) In order to provide nominations for producer and handling committee members and alternates, the committee shall hold, or cause to be held, prior to April 1 of each year, or such other date as the Secretary may designate, one or more meetings of producers and of handlers in each district to nominate such members and alternates, or the committee may conduct nominations by mail in a manner recommended by the committee and approved by the Secretary.

(b) At least one nominee shall be designated for each position as member and for each position as alternate member on the committee.

(g) Names of nominees shall be supplied to the Secretary in such manner and form as he may prescribe not later than May 1 of each year, or such other date as the Secretary may specify.

5. Nominations for public member and alternate shall be made at a committee meeting. The names of nominees shall be submitted to the Secretary prior to May 1 of the year nominations are made, or such other date as the Secretary may designate. The Secretary shall establish rules, based on the committee's recommendations or other available information, for the following:

(1) Establishing eligibility requirements for the public member and alternate positions;

(2) Publicizing the positions and recipients of persons to be considered for nomination; and

(3) Electing the nominees.

§ 945.28 [Amended]

5. Amend § 945.28 Vacancies by deleting the words "from the district involved" at the end of the first sentence and inserting in lieu thereof "for the position involved."

6. Revise § 945.31 to read as follows:

§ 945.31 Expenses and compensation.

Committee members and alternates shall be reimbursed for reasonable expenses necessarily incurred by them in the performance of their duties and in the exercise of their powers under this subpart. In addition they may receive reasonable compensation at a rate to be determined by the committee and approved by the Secretary, for each day or portion thereof, spent in conducting committee business.

7. Revise paragraph (b) of § 945.42 to read as follows:

§ 945.42 Assessments.

(b) Assessments shall be levied upon handlers at a rate per unit established by the Secretary. Such a rate may be established by the Secretary upon the basis of the committee's recommendation or other available information.

8. In § 945.44 revise the heading; delete the introductory paragraph; revise paragraph (b) and add new paragraphs (c) and (d) to read as follows:

§ 945.44 Excess funds.

(a) The funds remaining at the end of a fiscal period which are in excess of the expenses necessary for committee operations during such period may be carried over into following periods as a reserve. Such reserve may be established at an amount not to exceed approximately one fiscal period's budgetary expenses. Funds in such reserve shall be available for use by the committee for expenses authorized under § 945.40.

(b) Funds in excess of those placed in the operating reserve shall be credited proportionately against each handler's
operations of the following fiscal period, provided that if he demands payment, such proportionate refund shall be paid to him.

[FR Doc. 78-280 Filed 1-5-78; 8:45 am]

[3410-02 ]

[7 CFR Part 980 ]

ONION IMPORTS

Inspection; Extension of Time for Filing Comments

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Extension of time for filing comments.

SUMMARY: At the request of the Association of Food Distributors, Inc., the time for filing comments regarding proposed onion import requirements is extended from January 3 to January 13, 1978.


ADDRESSES: Comments should be sent to: Hearing Clerk, Room 1355, South Building, U.S. Department of Agriculture, Washington, D.C. 20250. Two copies of all written comments shall be submitted, and they will be made available for public inspection at the office of the Hearing Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Notice was given in the December 21, 1977 Federal Register (42 FR 63894) of proposed grade, size, quality and maturity requirements to be made applicable to the importation of onions into the United States under the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.). Interested persons were given until January 3, 1978 to file data, views, or comments. The data by which comments are due is changed to January 13, 1978 to afford producers and other interested parties additional time in which to comment on the proposed regulation.


(Charles R. Brader, Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.)

[FR Doc. 78-281 Filed 1-5-78; 8:45 am]

PROPOSED RULES

[3510-15 ]

Rural Electrification Administration

[FEDERAL REGISTER VOLUME 43 PART 1707 FRIDAY, JANUARY 6, 1978]

RURAL TELEPHONE PROGRAM

Proposed New REA Specification for Carbon Arresters and Protectors

AGENCY: Rural Electrification Administration.

ACTION: Proposed rule.

SUMMARY: REA proposes to issue REA Bulletin 345-78 to announce the issuance of REA Specification PE-78 for Carbon Arresters and Protectors. The specification was developed to provide performance requirements for surge protective devices containing carbon block electrodes. Arresters are considered acceptable. On issuance of REA Bulletin 345-78, Appendix A to Part 1701 will be modified accordingly.


C. R. Ballard, Assistant Administrator—Telephone.

[FR Doc. 78-282 Filed 1-5-78; 8:45 am]

[3410-07 ]

Farmers Home Administration

[7 CFR Part 1823 ]

[FMHA Instruction 442.11]

ASSOCIATION LOANS AND GRANTS, COMMUNITY FACILITIES, DEVELOPMENT, CONSERVATION, UTILIZATION

Loans to Indian Tribes and Tribal Corporations

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration proposes an amendment which provides that the amount of loan funds used to acquire property will not exceed its market value. The intended effect of this amendment is to allow more loans for land purchase by permitting applicants to use their own funds to pay the difference between market value and purchase price.

DATE: Comments must be received on or before February 6, 1978.

ADDRESSES: Submit written comments to the office of the Chief, Farmers Home Administration, U.S. Department of Agriculture, Room 6316, Washington,
Pursuant to this notice will be available for public inspection at the address given above.

FOR FURTHER INFORMATION CONTACT:

Carl O. Opstad, 202-447-4573.

SUPPLEMENTARY INFORMATION:

The Farmers Home Administration (FmHA) proposes to revise §1823.410 of Subpart N of Part 1823, Title 7 in the Code of Federal Regulations. This revision will provide that the amount of loan funds used to acquire land will not exceed its market value.

As proposed, §1823.410 will read as follows:

§1823.410 Appraisals.

The amount of loan funds used to acquire property will not exceed its market value as determined by FmHA. Market value will be based on an appraisal made by authorized FmHA personnel, BIA appraisers, or appraisers approved by the State Director. The value of any existing buildings that pass with the land will be deducted from the market value.

(7 U.S.C. 1989; delegation of authority by the Sec. of Agr., 7 CFR 2.23; delegation of authority by the Asst. Sec. for Rural Development 7 CFR 2.70.)

Note—The FmHA has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11281 and OMB Circular A-107.


JAMES E. THORNTON, Associate Administrator, Farmers Home Administration.

[FR Doc. 78-207 Filed 1-5-78; 8:45 am]

[1505-01]

Food Safety and Quality Service

[9 CFR Parts 317 and 381]

MEAT OR POULTRY PRODUCTS

Proposed Net Weight Labeling

CORRECTION

In FR Doc. 77-34601 appearing at page 61279 in the issue of Friday, December 2, 1977 the format of Table II, which appeared in §317.18(b)(2)(vi), page 61283, and in §381.121(b)(2)(vi) page 61284, was incorrect. Table II should read as follows:

<table>
<thead>
<tr>
<th>GROUP</th>
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<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>10%</td>
<td>0.15 oz.</td>
<td>0.29 oz.</td>
<td>0.73 oz.</td>
<td>1.47 oz.</td>
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<tr>
<td>0%</td>
<td>4/32 oz.</td>
<td>9/32 oz.</td>
<td>23/32 oz.</td>
<td>1 15/32 oz.</td>
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<tr>
<td>1/10 oz.</td>
<td>2/16 oz.</td>
<td>11/16 oz.</td>
<td>7/16 oz.</td>
<td>1 4/16 oz.</td>
<td>**</td>
</tr>
<tr>
<td>1/8 oz.</td>
<td>2/16 oz.</td>
<td>7/32 oz.</td>
<td>1 3/8 oz.</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>3/16 oz.</td>
<td>5/32 oz.</td>
<td>1 1/4 oz.</td>
<td>**</td>
<td>**</td>
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</tr>
<tr>
<td>0.01 lbs.</td>
<td>0.02 lbs.</td>
<td>0.04 lbs.</td>
<td>0.09 lbs.</td>
<td>**</td>
<td>**</td>
</tr>
</tbody>
</table>

1/ Use the limits recorded in terms of calibrations of the scale being used. E.g. — If the scale is in 16ths, use limits in 16th; if in grams, use gram limits. Do not convert.

2/ If a sample of packages marked with random weights spans two or more groups, the limits for the smallest numbered group represented shall apply to all packages in the sample.

3/ The limit is the labeled net weight when the sensitivity of the scales being used does not permit calibrations as precise as those recorded above.

4/ The limit for Group 6 shall be 4 ounces.

[4810-22]

DEPARTMENT OF THE TREASURY

Customs Service

[19 CFR Part 153]

ANTIDUMPING

Proposed Amendments to Customs Regulations Relating to Disclosure Conferences in Connection With Full-Scale Antidumping Investigations

AGENCY: U.S. Customs Service, Treasury Department.

ACTION: Proposed rulemaking.

SUMMARY: This proposed amendment applies to an administrative procedure under the Antidumping Act, 1921, as amended. During the course of an antidumping investigation, the Customs Service traditionally has followed a procedure whereby it will, if requested, provide interested persons with an informal oral disclosure of the bases for a tentative, and in some cases for a final, antidumping determination. Such disclosures are as detailed as possible, consistent with the need to protect confidential or other information, as authorized by law. It is now desired to reflect this procedure in regulations, as well as effect a change in the timing of such disclosure conferences.

EFFECTIVE DATE: Comments must be received on or before: February 6, 1978.

ADDRESS: Comments must be addressed to the Commissioner of Customs, Attention: Regulations and Legal Publications Division, U.S. Customs Service, 1501 Constitution Avenue NW., Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

Under the Antidumping Act of 1921, as amended, the Secretary of the Treasury is required to make a determination whether a class or kind of foreign merchandise is being, or is likely to be, sold in the United States or elsewhere at less than its fair value (19 U.S.C. 1601(a)). In order to inform interested persons of the bases for tentative findings and conclusions, it has been found helpful, in addition to providing such statements in a notice of tentative determination published in the Federal Register, to disclose to such persons orally the bases for the tentative disposition of an antidumping investigation. In the past, on an informal basis, the Customs Service has disclosed the bases for calculations leading to tentative determinations prior to the publications of the tentative de-
termination. It has now been decided that such disclosure should be reflected in regulations and should be continued, but at a time after publication of the tentative determination, not before; or before a final affirmative determination pursuant to § 153.36 of the Customs Regulations (19 CFR 153.36). This disclosure is independent of the opportunity provided to present oral views before the Treasury Department, which interested persons may request in connection with a tentative Treasury action, or as appropriate, prior to a final Treasury action, or as appropriate, after a tentative determination, not before; or at a time after publication of the regulations and should be continued, but at a time after publication of the regulations. It has now been decided that such disclosure should be reflected in regulations and should be continued, but at a time after publication of the regulations.

Accordingly, it is proposed that § 153.31 of the Customs Regulations (19 CFR 153.31) be amended by inserting a new paragraph 153.31(d) to read as follows: 

§ 153.31 Full-scale investigation.

(d) Disclosure Conference. After the publication in the Federal Register of a “Withholding of Appraiser Notice,” or any other notice of tentative disposition of an antidumping investigation, the Commissioner of Customs shall conduct at the request of any interested person, a disclosure conference during which the Customs Service will disclose to such interested person the bases for the tentative disposition of an antidumping investigation. Where it appears to the Secretary that an affirmative determination pursuant to § 153.36 is required, and no request has been made for a withholding of appraiser notice under § 153.35(b), persons known to be interested in the proceeding will be so informed in sufficient time so they may request a disclosure prior to the hearing which may be requested pursuant to § 153.40. Confidential information will be treated consistently with the procedures set forth in § 153.22. Nothing in this subsection will affect access to information which is otherwise available pursuant to § 153.21.

The Customs Service invites comments from all interested persons on the proposed amendments to the Customs Regulations. Comments submitted will be available for public inspection in accordance with § 153.8(b) of the Customs Regulations (19 CFR 153.8(b)) during regular business hours at the Regulations and Legal Publications Division, Headquarters, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229.

R. E. CHASEN, Commissioner of Customs.


HARRY C. STOCKWELL, Jr., Acting General Counsel of the Treasury.

[FR Doc. 78-267 Filed 1-5-78; 8:45 am]

PROPOSED RULES

[4110-03] DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration

[21 CFR Part 343] [Docket No. 77N-0094]

OVER-THE-COUNTER DRUGS
Establishment of a Monograph for OTC Internal Analgesic, Antipyretic and Anti-rheumatic Products; Extension of Time

AGENCY: Food and Drug Administration.

ACTION: Extension of time for reply comments.

SUMMARY: The Food and Drug Administration is extending by 30 days the time for filing reply comments on a proposal to establish conditions under which over-the-counter (OTC) internal analgesic, antipyretic and antirheumatic drugs are generally recognized as safe and effective or not misbranded.

The extension is in response to requests for such extensions.

DATE: Reply comments by February 6, 1978.

ADDRESS: Written comments to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5800 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HPD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5800 Fishers Lane, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

In the Federal Register of July 8, 1977 (42 FR 35345), the Commissioner of Food and Drugs issued a proposed regulation containing the monograph recommended by the Advisory Review Panel on OTC Internal Analgesic and Anti-rheumatic Products establishing: (1) conditions under which OTC internal analgesics, antipyretics and antirheumatic drugs are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the data available data are insufficient to classify such conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel to the Commissioner.

Interested persons were given until October 6, 1977 to submit comments on the proposal and until November 7, 1977 to reply to any comments so filed.

In response to several requests, an extension of time of 60 days was granted both for comments and reply comments until December 5, 1977 and January 6, 1978, respectively. This extension was published in the Federal Register of October 4, 1977 (42 FR 53980).

The agency has received subsequent requests from Proprietor Associations, Federation, McNeil Laboratories, and Sterling Drug, Inc. to extend the time for reply comments, arguing that 30 days after the comment period, as granted in the proposal, is insufficient time to respond, in view of the delay encountered in receiving requested copies of comments on file in the office of the Hearing Clerk. The requests for extension are on file in the office of the Hearing Clerk, Food and Drug Administration.

The Commission is persuaded that granting additional time for reply comments is appropriate. Accordingly, interested persons are invited to submit reply comments (preferably four copies and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding the comments on the July 8, 1977 proposal on file with the Hearing Clerk. Such reply comments should be addressed to the office of the Hearing Clerk (HPD-50), Food and Drug Administration, Rm. 4-65, 5800 Fishers Lane, Rockville, MD 20857 and submitted on or before February 6, 1978. Received comments may be seen in the above-named office between 9 a.m. and 4 p.m., Monday through Friday.

This action is taken under the Federal Food, Drug, and Cosmetic Act (sees. 502, 505, 701(a), 52 U.S.C. 1050-1053 as amended, 1055 (21 U.S.C. 352, 355, 711(a))) and under authority delegated to the Commissioner (21 CFR 5.1).


WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 78-188 Filed 1-3-78; 12:14 pm.]

[4110-03] [21 CFR Part 511] [Docket No. 77N-0336]

EXPORT OF NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

Proposed Rule Making

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This is a proposal to amend the new animal drug regulations to set...
forth requirements for the export of new animal drugs for investigational use. The Federal Food, Drug, and Cosmetic Act provides for the distribution of unapproved new animal drugs for investigational use. However, the existing regulations do not address the matter of export of such drugs to perform clinical investigational studies. These requirements do not provide for the distribution of unapproved new animal drugs for investigational purposes. New animal drugs intended for clinical investigation in animals may be exported, provided:

(1) A “Notice of Claimed Investigational Exemption for a New Animal Drug” is filed in accordance with paragraph (b) of this section and;

(2) The notice is accompanied by written statements as follows:

(i) By the sponsor that the government of the country to which the drug is to be exported has notified the Commissioner of the country to which the drug is to be exported of the intended investigational use of the drug in that country.

(ii) By the foreign investigator that:

(A) He is aware of the existence of investigational studies. These require-ments are necessary so that authoriza-tion for extra-territorial clinical in vestigations of new animal drugs may be accomplished with the same assurances of control as provided by the new animal drug regulations for domestic investigational studies. The Commissioner of Foods and Drugs proposes to amend § 511.1 to read as follows:

§ 511.1 New animal drugs for investigational use exempt from section 512 (a) of the act.

(1) Export of new animal drugs for investigational use. New animal drugs intended for clinical investigation in animals may be exported, provided:

(a) By the sponsor that the government of the country to which the drug is to be exported has notified the Commissioner of the country to which the drug is to be exported that it is intended for export and that neither the treated animals nor food from the animals will be exported to the United States unless they are in compliance with Part 511 requirements.

(b) The drug bears labeling to show that it is exempt from section 512 (a) of the act and contains a new animal drug for use only in investigational clinical trials. Not for use in humans. Edible products of investigational animals are not to be used for food in any manner contrary to the requirements of the country in which the clinical trials are to be conducted.

(c) The drug has been labeled, and poster requirements s based on the intended investigational use of the drug. The proposed warning will inform consumers about the risk of cancer that may result from the use of hair dyes containing these ingredients.


WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance,

ACTION: Proposed rule.

SUMMARY: This is a proposal to require a warning statement and warning post- ers concerning coal tar hair dyes containing 4-methoxy-m-phenylenediamine (also known as 2,4-dianisolesulfate). The proposed warning will inform consumers about the risk of cancer that may result from the use of hair dyes containing these ingredients.


ADDRESS: Written comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
John A. Wenninger, Bureau of Foods (HFF-441), Food and Drug Administration, Department of Health Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The decision of the Commissioner of Foods and Drugs to propose warning labels and poster requirements is based on scientific studies employing currently accepted methods of determining whether compounds can cause cancer, including a recent study sponsored by the National Cancer Institute (NCI), which in-
It or its closely related compound, 4-methoxy-m-phenylenediamine sulfate is carcinogenic in animals. It or its closely related compound, 4-methoxy-m-phenylenediamine, is widely used in permanent hair dyes. Under conditions of use, these substances may be absorbed through the scalp during hair dyeing, and pose a risk to cancer to users. Coal tar hair dyes are exempt from the adulteration and color additive provisions found in sections 171 and 172 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 361, 376) provided that the label bears a statutory caution statement and "4,6-diamino-2,4-diaminoanisole sulfate. The terminology of that report refers to this compound as 2,4-diaminoanisole sulfate. The toxicity of 2,4-diaminoanisole sulfate is carcinogenic to the thyroid gland and integumentary system of Fischer 344 rats of both sexes, and also carcinogenic to the thyroid gland and lymphatic system of B6C3F1 mice.

In a letter to the Commissioner dated October 1, 1977, Dr. John F. Schachar, Associate Director for the Carcinogenesis Testing Program for NCI, stated that "minor changes will appear in the statistical evaluation in the final draft but the conclusion that this chemical is carcinogenic in animals will not change." (Ref. 2.)

The NCI study augments an accumulating literature on the suspected carcinogenic and mutagenic hazards posed by coal tar hair dyes and by 4-methoxy-m-phenylenediamine sulfate in particular (Refs. 3 through 22). Reportedly, among regular users of hair dyes, and approximately three out of every four dollars spent on hair coloring is spent on the permanente type of dye. (Ref. 20). 4-Methoxy-m-phenylenediamine sulfate is present in many if not most permanent hair dyes at concentrations generally not greater than 1 percent, although it has been reported as high as 2 to 4 percent in some formulations. The exposure to 4-methoxy-m-phenylenediamine sulfate among the general population and especially among professional users is therefore widespread and significant.

The NCI study firmly establishes that technical grade 4-methoxy-m-phenylenediamine sulfate is carcinogenic in rodents. The National Toxicology Program at the National Institute of Health, other Federal agencies and scientific organizations have long recognized that animal studies are the best available means of assessing the possible carcinogenic effect of chemical substances on human beings, as discussed in the April 15, 1977 FEDERAL REGISTER (42 FR 19965). Experience has indicated that compounds that are carcinogenic in human beings are also carcinogenic in one or more experimental animal systems. Additionally, compounds first detected as carcinogens in experimental animals have later been found to cause human cancer. Therefore, the clear demonstration that a compound causes cancer in animals must be taken as evidence that it is carcinogenic for causing cancer in humans, unless there is strong evidence to the contrary.

4-Methoxy-m-phenylenediamine sulfate has also been demonstrated to be mutagenic on the Ames Salmonella microsome test (Ref. 10 and 11). This test, particularly when confirmed by other mutagenicity tests (Results through 20), serves as collateral supporting evidence in establishing the substance's probable carcinogenicity.

These data are supported by data on percutaneous absorption, which indicate that 4-methoxy-m-phenylenediamine sulfate is absorbed through the skin and thus poses a risk under conditions of hair dye use (Refs. 20 through 23). The findings of the NCI study and the preceding studies, in the absence of strong evidence to the contrary, lead the Commissioner to conclude that 4-methoxy-m-phenylenediamine sulfate is potentially carcinogenic to humans.

DERMAL ABSORPTION

During application, hair dye ingredients such as 4-methoxy-m-phenylenediamine sulfate, undergo complex chemical reactions which result in the formation of dyes which color the hair. The use of 4-methoxy-m-phenylenediamine sulfate present at the start of the hair dyeing procedure decreases during the process. However, some unreacted ingredients are certainly in contact with the skin at the start of application and possibly throughout most of the 20 to 30 minutes required to dye the hair. Evidence indicates, as discussed below, that during this dyeing process, 4-methoxy-m-phenylenediamine sulfate penetrates the skin of the scalp and enters the blood.

The skin penetrability of a closely related phenylenediamine, p-phenylenediamine, is a fact established by very broad clinical experience with its sensitizing capacity (Ref. 20). It was the known sensitizing property of p-phenylenediamine that produced the requirement for the cautionary legend on coal tar hair dyes as part of the adulteration provisions of section 601 of 50 U.S.C. 361, 376.

It has been reported (Refs. 30 and 32) that the phenylenediamines are absorbed by the skin of dogs when applied in a manner similar to that used in dyeing human hair. An intravenous injection of N,N'-diacetyl-p-toluenediamine (Ref. 31), an average of 3.7 milligrams (mg) of N,N'-diacetyl-p-toluenediamine was found in the urine of humans in the 48 hour period following treatment with an oxidation hair dye containing 2.5 grams of p-toluenediamine. From studies with intravenously injected doses of p-toluenediamine it was determined that an average of 47.6 percent of the p-toluenediamine absorbed by the body is converted to the dicetyl metabolite. Therefore, the concentration of N,N'-diacetyl-p-toluenediamine in an internal Bài to detect only approximately half of the p-toluenediamine absorbed. On this basis, it was estimated that during hair dyeing approximately 4.6 milligrams of the p-toluenediamine was either directly absorbed through the skin or produced in vivo as a consequence of the absorption of other intermediates produced during the hair dyeing process.
The excretion rate of p-toluenediamine was slowed and the absorbed material was still detectable in the urine 2 days after hair dying. In a preliminary unpublished study, the absorption of 4-methoxy-m-phenylenediamine in humans and monkeys was in the same range (Ref. 33).

It should be noted that these studies were conducted on unbroken skin. Several cutaneous diseases occurring in the scalp area may result in a damaged stratum corneum, which can markedly increase skin permeation.

**RELEVANT ROUTE OF EXPOSURE**

Available evidence (Refs. 31 and 33) indicates that the 4-methoxy-m-phenylenediamine is absorbed through the skin and is distributed systemically. In the NCI ingestion study, 4-methoxy-m-phenylenediamine was absorbed from the digestive tract into the bloodstream, and tumors occurred in the skin, lymph system, and tumors were found at sites other than the site of application. It would appear reasonable that any route of administration capable of delivering systemic doses would be appropriate unless there is substantial evidence indicating that a given route of administration is metabolically or pharmacologically inappropriate for the compound tested.

The National Cancer Advisory Board in a report (85 JNCI 461, Feb. 1977, NCI Subcommittee on Environmental Carcinogenesis) has recommended:

- Any substance which is shown conclusively to cause tumors in animals should be considered carcinogenic and therefore a potential cancer hazard for man. Exceptions should be considered only where the carcinogenic effect is clearly shown to result from physical, rather than chemical, induction, or where the route of administration is shown to be grossly inappropriate in terms of conceivable human exposure.

- A recent Occupational Safety and Health Administration (OSHA) proposed a Method of Tumor Weighting and Regulation of Toxic Substances Positing a Potential Occupational Carcinogenic Risk, Federal Register No. 192, Vol. 42, October 4, 1977 (stated):

  "In cases where the test compound is absorbed by the experimental animals and is circulated systemically, giving rise to tumors at sites other than the point of application, it seems reasonable to regard the route of administration as irrelevant to weighing the potential risks to man."

- **DOSAGE**

  Under the conditions of the NCI study, 4-methoxy-m-phenylenediamine sulfate is an animal carcinogen when ingested at doses approaching 250 mg/kg/day. These findings indicate that 4-methoxy-m-phenylenediamine sulfate poses a risk of cancer to humans. The Commissioner recognizes that the estimated dose to which hair dye users would be exposed is considerably less than the dose level at which cancer was found in animals. High doses must be used in animal cancer studies in order to provide a reasonable chance of detecting weak carcinogens.

Tests using a feasible number of animals without any extrapolation of the dose level simply do not provide a reasonable assurance of safety.

The significance of the NCI study is that it shows that 4-methoxy-m-phenylenediamine in animals and has the potential for producing cancer in man. The Commissioner believes that the established threshold posed by 4-methoxy-m-phenylenediamine sulfate cannot be disregarded simply because the anticipated exposure levels are low. At the present time, it is not feasible to determine a safe exposure level for carcinogens.

Furthermore, the population exposed to hair dye is estimated at 30 million, and people vary in their susceptibility to carcinogens.

As the Commissioner has previously stated in the Federal Register of April 15, 1977 (42 FR 99996), "The predominant opinion among experts in the field of carcinogenesis is that the dose-response principle extends to very low doses of the carcinogens—that is, that there is no dose, however small, at which one can be certain that there is no risk. In other words, there is no so-called 'safe level' beyond which a carcinogen may be considered safe in the absolute sense." The preamble to the OSHA proposed rule establishing a threshold limit value for 4,4'-methylenebis(2-chloroaniline) (42 FR 54148) reviews the scientific basis for questioning the existence of threshold doses for carcinogens and for believing that no safe level can be established for any carcinogen on the basis of current scientific knowledge. Furthermore, to reduce the total incidence of cancer, it is important to reduce the prolonged general exposure of the public to numerous carcinogenic substances in our environment by eliminating exposure wherever possible.

The Commissioner recognizes that there continue to be differences of view among experts who study the dose-response principle and that some may question whether some secondary toxic effect at the high dose levels may have been associated with the carcinogenic response. The recovery processes might be unable to operate at high dose levels but be more effective at lower levels. Not all substances tested at high dose levels in animals produce carcinogenic responses, however, and there is no scientific evidence that a high dose of a substance alone causes the carcinogenic response. In an NCI sponsored study from 1963-68, for example, approximately 130 pesticide and industrial chemicals were tested for carcinogenic activity in two strains of mice at a maximum tolerated dose. These substances were considered significant because of their high biologic activity and because of their similarity to known carcinogens. Despite this biased selection, less than 10 percent proved tumorigenic. Furthermore, some of the others gave no evidence of carcinogenicity notwithstanding the high dose administered. (T.R.M. Innis et al., J. Natl. Cancer Inst., 42:1101, 1969.) Further more, there is no process in this case that would show that the carcinogenic responses at the observed levels were caused by factors that would not be present at lower dose levels.

**INDUSTRY STUDIES**

Representatives of the hair dye industry have questioned the relevance of feeding studies to hair dyes since these are used on the skin and are not likely to be ingested. They argue that the route of administration used in the NCI study is inappropriate in terms of human exposure and that skin painting studies should be used to evaluate the carcinogenic hazard. Under the auspices of the Cosmetic, Toiletry, and Fragrance Association (CTFA), the hair dye industry established a cooperative program for the safety evaluation of hair dye ingredients, under which a number of tests were conducted, including carcinogenicity tests in mice and rats.

All of these tests involved only repeated application of test material to the skin under conditions resembling those used in hair dyeing except that the site of application was shaved before application and the formulation was left on the skin for approximately 1 week before being rinsed off after a short period of time as in the normal use of the product.

No adverse effects were found in any of these studies. However, they cannot be weighed as heavily as the positive NCI data in the same species. It is generally held that negative results of biological testing are less significant than positive results in evaluating human risk. This is all the more true, when, as with topical application, the testing procedures are insensitive.

The National Cancer Advisory Board Subcommittee on Environmental Carcinogenesis addressed this issue:

Because of the limitations inherent in animal bioassays, a negative result obtained in a particular animal bioassay does not exclude the potential carcinogenicity of a compound in humans. The inappropriate experimental species may have been chosen; the route of application may have been too small; or the duration of observation may have been too short. Alternatively, test conditions may have been inappropriate in terms of their predictive value for the response of man.

The Cosmetic, Toiletry, and Fragrance Association states that their choice of topical application rather than ingestion was in conformity with NCI Guidelines for Carcinogenesis Testing in Small Rodents in that it more closely resembles the route of human exposure. However, the route of application may be different than any statistically significant positive effects at one half of the maximum tolerated dose, one would clearly not expect to observe tumors at even lower doses.

Skin painting tests, as commonly conducted, are not statistically reliable bioassays for detecting the potential of compounds to produce malignancies in human skin.
internal organs. To make such tests statistically meaningful, the effect of the skin in reducing the quantity absorbed and the tissue concentrations produced must be compensated for by very much larger numbers of animals, so large as to become unfeasible. The skin, by impeding absorption, effectively decreases the ability of an animal bioassay to reveal the potential toxic properties of chemicals.

It lowers the dose absorbed, and, unless this effect is compensated for by a much larger number of animals, many carcinogens would not be detected.

By not compensating for the reduction in the dose absorbed through the skin, the CTFA studies lost the dose exaggeration necessary to overcome the statistical limitations inherent in a test with a limited number of animals. They therefore fail to show that hair dyes containing 4-methoxy-m-phenylenediamine are safe.

The Commissioner is aware that other hair dye intermediates are also under study with respect to their carcinogenic potential. In particular, 2,4-toluenediamine (2,4-TDA), a compound closely related to 4-methoxy-m-phenylenediamine, has been reported to cause cancer in laboratory tests (Ref. 5). The NCI is currently evaluating the results of a bioassy on this chemical, but their evaluation is not yet available. Other aromatic amines are also being tested by NCI. The Commissioner intends to monitor the results of the NCI studies and will take appropriate action should the results show that other hair dye ingredients are animal carcinogens.

LEGAL AUTHORITY

The warning statement is being proposed pursuant to sections 201(n) and 602 of the act to alert consumers that the hair dyes containing 4-methoxy-m-phenylenediamine and 4-methoxy-m-phenylenediamine sulfate may pose a cancer risk. Section 603 prohibits false and misleading labeling, and section 201(n) makes regulating deceptive advertising necessary to overcome the failure to reveal material facts with respect to the consequences which may result from use.

The Commissioner believes that the information about 4-methoxy-m-phenylenediamine and 4-methoxy-m-phenylenediamine sulfate indicates that it may pose a risk of serious harm to users. This is a material fact about the consequences of use that consumers should be informed about when considering purchase and use. Cosmetic manufacturers make an implied representation of safety when offering a product for sale, and consumers should be alerted to information that indicates the product poses a risk of grave harm.

Warnings about safety risks can clearly be required on cosmetics under the act. The Food and Drug Administration’s authority to require warnings on cosmetics about the risks of harm from improper storage and intentional misuse has been upheld on judicial review. Cosmetic Toiletry and Fragrance Assn. v. Schmidt, 409 F. Supp. 87 (D.D.C 1976), affirmed without opinion, C.A. No. 75-1242 (D.C. Cir., August 19, 1977). These warnings were required pursuant to the misbranding provisions of sections 201(n) and 602 of the act, as well as the adulteration provisions of section 601 of the act. Explicit warnings can be required under section 201(n) about the toxic properties of a product subject to the misbranding provisions of the act. The NCI, in its report on 4-methoxy-m-phenylenediamine sulfate (Ref. 1), requested in V. Klinfield and C. Dunn, “Federal Food, Drug, and Cosmetic Act 1938–1949” at 553. The agency has required warnings on an interim basis pending further regulatory action to reduce the risks of health and environmental harm from ozone depletion that may result from the use of chlorofluorocarbon propellants in aerosolized foods, drugs, and cosmetics, e.g., 21 CFR 740.11. The agency has also issued regulations requiring other warning statements on cosmetics (21 CFR 740.1, 740.10, 740.12).

Thus, through both administrative and judicial interpretation, it is established that explicit warnings can be required on cosmetics about specific potential health hazards for which the patch test caution is appropriate, though, when the information indicates that a risk is a material one in light of the gravity of the harm posed. In the case of 4-methoxy-m-phenylenediamine and 4-methoxy-m-phenylenediamine sulfate, the Commissioner concludes that the risk is material and therefore warrants informing the consumer. Since customers of beauty salons may not see the labels on hair dye containers, it is appropriate to require the displaying of warning posters in beauty salons in order to bring the warning to the attention of those customers.

Coal tar hair dyes are exempt from the adulteration and color additive provisions of the act provided the label bears the statutory caution statement alerting consumers to the risk of skin irritation. Consequently, no action can be taken to prohibit the use of coal tar hair dye ingredients in hair colors bearing the caution statement because of risk of cancer or any other harm posed by the use of the coal tar color in the product. The agency attempted to limit the statutory exemption for coal tar hair dyes to only those hazards for which the patch test caution was applicable and adequate to safeguard the consumer. The administrative interpretation was ruled invalid in Toilet Goods Assn v. Finch, 419 F. 2d 27 (2d Cir. 1969). The court held:

"The Government’s argument should indeed be appealing to a legislative that good is the warning to make a patch test if the test will not disclose the danger? But a court must take the point at which Congress wrote with great specificity, Whether it relied solely on that patch test warning because it was imposed in 1938 that coal-tar dyes might have damaging effects not detectable by such a test, as the Government asserts but the industry denies, or because it thought such instances so rare as not to warrant inadvertent exposure of the consumers, the language is too general to be sufficient to apprise home users of these products of the risk involved. However, a considerable number of consumers have
their hair dyed by hairdressers at beauty salons and are unlikely to see any warning on the package. These consumers should be made aware of the risks associated with these products. To ensure that the warning reaches consumers in these circumstances, the Commission has proposed that with each shipment of hair dye containing 4-methoxy- or phenylenediamine or 4-methoxy- or phenylenediamine sulfate, the manufacturer distribute to beauty salons posters containing an appropriate notice for placement in a prominent display. The proposed posters are needed to ensure that the consumer is alerted to the warning statement under the conditions of purchase and use in beauty salons.

Under section 602(c) of the act, a cosmetic is misbranded if required information is not "prominently placed" on the label or labeling with "such conspicuousness (as compared with other words * * * in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary circumstances of purchase and use." It is clear that the labeling requirements of the act extend to written material relating to a product that is separate from the immediate package. Leaflets containing representations mailed separately from a drug and medical device have been regarded as labeling that made the articles misbranded. Kordel v. United States, 335 U.S. 245 (1948). United States v. Urbetett, 355 U.S. 355 (1949). Display cards have also been specified as optional places for required cosmetic labeling (21 CFR 701.3). It is proposed that 21 CFR Part 740 be amended to require the Commissioner to develop a system of certification to ensure that the consumer is alerted to the principal mutagenic activity of any hair dye that is sold, to require distributors to distribute the posters to hairdressers that they be prominently displayed to customers, and to require the principal mutagenic activity to be expressed in scientific terms. Under section 602(c) of this section distributed for purchase and use in beauty salons.

The Commission has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Examiner and is available for inspection at the Hearing Examiner's office.

§ 740.18 Coal tar hair dyes posing a risk of cancer.

(a) The label of a coal tar hair dye containing any ingredient listed in paragraph (e) of this section shall bear on the principal display panel the following: "Warning—Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals.

(b) Each shipment of hair dyes containing an ingredient listed in paragraph (e) of this section distributed for professional application in beauty salons shall be accompanied by at least one 11-by 14-inch poster meeting the conspicuousness requirements of this part, with the quantity of the distribution is sufficient to distribute them to hairdressers and to customers. Hairdressers shall place the posters at locations where their hair dyes are sold. The posters shall be displayed in places in business, as well as in beauty salons where they are fully visible to, and are likely to attract the attention of, customers whose hair may be dyed. The posters shall continue to be so displayed.
PROPOSED RULES

throughout the period the beauty salon is open for business. The posters shall bear the words "Hair Dye Notice" in letter of not less than 1 inch in height, and the following in letters of not less than \( \frac{1}{2} \) inch in height.

Some hair dyes contain ingredients which may cause cancer. These hair dyes are required to bear a label warning. Ask to see the label or the product intended for your hair.

(c) Hair dyes containing any of the following ingredients shall comply with the requirements of this section: (1) \( 4\)-methoxy- \( m \)-phenylenediamine (2,4-diaminoanisole) and (2) \( 4\)-methoxy- \( m \)-phenylenediamine sulfate (2,4-diamino- anisole sulfate).

Interested persons may, on or before March 7, 1978, submit to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk dock number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Note.—The Food and Drug Administration has determined that this document does not contain a major proposal requiring publication in the FEDERAL REGISTER. Therefore, it is not being published in the FEDERAL REGISTER.


DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 78-254 Filed 1-5-78; 8:45 am]

1505-01
 [21 CFR Part 900]
 [Docket No. 77-0218]

MEDICAL DEVICES
Proposed Administrative Detention Procedures

Correction

In FR Doc. 77-73238 appearing at page 54574 in the issue of Friday, October 7, 1977, on page 54577, in § 800.58 (g) (3), in the third line, between the words "conducted" and "with" insert "in accordance".

4110-03
 [21 CFR Part 801]
 [Docket No. 77-0235]

MEDICAL DEVICES
Impact-Resistant Lenses in Eyeglasses and Sunglasses

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This is a proposal to amend the medical device regulations by providing technological alternatives in the testing of impact-resistant lenses for eyeglasses-and sunglasses. The current method of testing, known as the "impact" or the "drop ball test" would be designated by the Food and Drug Administration (FDA) as a "referee test" under this proposal. All lenses required to be impact resistant must currently pass the drop ball test, but under the proposed amendment, a manufacturer or dispensing firm would be able to use any other equivalent or superior test.


ADDRESS: Written comments to the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Peter B. Carstensen, Bureau of Medical Devices (HFK-300), Food and Drug Administration, Department of Health, Education, and Welfare, 8751 Georgia Avenue, Silver Spring, Md. 20910, 301-227-7222.

SUPPLEMENTARY INFORMATION:
For many years prior to 1970, a number of public and private organizations advocated the universal use of impact-resistant lenses in eyeglasses and sunglasses. Several studies indicate that it would be desirable to develop test methodologies which would be more reliable than the drop ball test, since the drop ball test only indicates flaws that may be present near the point of impact, but does not indicate flaws located at the periphery of a lens.

Nevertheless these same studies suggest that lenses sold today are far more safe than those sold just a few years ago and that the drop ball test requirement has been a significant factor in this regard (Ref. 4 through 9).

The Commissioner may at a later date reconsider his designation of the drop ball test as a referee test if it can be demonstrated that such other test can produce results more consistent and more reliable than the drop ball test.
Under the proposed amendments, a manufacturer would not be inhibited from using other test methods that are equal to or better than the drop ball test.

Proposed § 801.410(d) (1) also would identify the “referee test” for the purpose of the amendments, namely, the impact, or drop ball, test.

Proposed § 801.410(d) (2) would delete the following sentence: “This statement of requirement that such lenses be subjected to the testing of finished lenses has been abandoned.”

Regulations are proposed to assure competence in uncut and inspections over manufacturer for test data that must be kept.

The provision in § 801.410(d) relating to the testing of finished lenses has been redesignated § 801.410(c) (3), and the requirement that such lenses be subjected to the drop ball test has been eliminated.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (FPC-20), Rm. 4-65, 5600 Fishers Lane, Rockville, and may be obtained by interested persons from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays:

2. Memorandum to Mr. J. Lamb from Mr. J. Lamb, on section (d) of the proposed regulation on impact resistance, October 17, 1977.
3a. Memorandum to D. S. Wolochen from Mr. J. Lamb, on revisions of Federal regulation on impact resistance, October 1, 1977.
3b. Memorandum to Mr. Robert J. Carley from Mr. J. Lamb, on revisions of Federal regulation on impact resistance, September 30 to October 1, 1977 meeting on Foley catheter, October 5, 1977.
10. Correspondence to and from FDA concerning the Wright Lens Hammer.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 519, 701(a), 52 Stat. 1040-1042 as amended, 1949-1951 as amended, 1955, 50 Stat. 501, 502, 504-505 (21 U.S.C. 321, 351, 352, 3601, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend § 801.410 by redesignating the existing text of paragraph (c) as (c) (1) and adding (c) (2) and (3), and by revising paragraphs (d) and (e) to read as follows:

§ 801.410 Use of impact-resistant lenses in eyeglasses and sunglasses.

(c) (1) To protect the public more adequately from potential eye injury, eyeglasses and sunglasses must be fitted with impact-resistant lenses, except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs in writing the use of other lenses, and gives written notification thereof to the patient.

(2) The physician or optometrist shall have the option of ordering heat-treated glass lenses, plastic lenses, laminated glass lenses, or glass lenses made impact-resistant by other methods; however, all such lenses shall be capable of withstanding the impact test described in paragraph (d) (2) of this section.

(3) Each finished impact-resistant glass lens for prescription use shall be capable of withstand the impact test described in paragraph (d) (2) of this section. Raised edge multifocal lenses must be impact-resistant but need not be tested beyond initial design testing. To demonstrate that all other types of impact-resistant lenses, including impact-resistant laminated glass lenses, are capable of withstanding the impact test described in this regulation, the manufacturer shall conduct tests of the lenses to demonstrate that the impact test a statistically significant sampling of lenses from each production batch, and the lenses so tested shall be capable of withstanding the impact test as worn by the wearer, including finished forms that are of minimal lens thickness and have been subjected to any treatment used to impact resistance. Plastic prescription and all non-prescription lenses, tested on the basis of statistical significance, may be tested in uncut finished or semifinished form at the point of original manufacture.

(d) (1) For the purpose of this regulation, the impact test described in paragraph (d) (2) of this section shall be the “referee test,” defined as “one which will be held to define the standard by which a regulation.” The referee test method provides the Food and Drug Administration with the means of examining a medical device for performance and does not inhibit the manufacturer from using equal or superior test methods. A lens manufacturer shall conduct tests of lenses for prescription use, using the impact test described in paragraph (d) (2) of this section, and using the “referee test,” in the test. Whatever test is used, the lenses shall be capable of withstand the impact test described in paragraph (d) (2) of this section in the event the Food and Drug Administration examines them for performance.

(2) In the impact test, a ½ inch steel ball weighing approximately 0.56 ounces is dropped from a height of 50 inches upon the horizontal upper surface of the lens. The ball shall strike within a ½ inch diameter circle located at the geometric center of the lens. The ball may be guided, but not restricted, in its fall by being dropped down a tube extending to within approximately 4 inches of the lens. In order to pass the test, the lens must not fracture; for the purpose of this section, a lens will be considered to have fractured if it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two or more separate pieces or if any lens material visible to the naked eyes becomes detached from the optical surface of the lens. The test shall be conducted with the lens supported by a tube 1-inch inside diameter, 1½-inch outside diameter, and approximately 1-inch high affixed to a rigid iron or steel base plate. The total weight of the base plate and its rigidly attached fixtures shall be not less than 27 pounds. For lenses of small minimum diameter, a support tube having an outside diameter of less than 1½ inches may be used. The support tube shall be made of rigid acrylic plastic, steel or other suitable substance and shall have securely bonded on the top edge a ¼ inch neoprene gasket having a hardness of 40±5, as deter-
SUMMARY: The Environmental Protection Agency (EPA) is considering establishment of a program to test new motorcycles at the assembly line for compliance with applicable emission standards under the Clean Air Act. The program would apply to motorcycles manufactured after the calendar year 1978, as determined by the Agency.

In order to provide the general public an opportunity to receive information and offer comments on the proposed rulemaking, public meetings will be announced in the Federal Register. An additional public hearing will be held in Winnemucca, Nev., on January 20, 1978 at the National Guard Armory, 735 W. Fourth St. at 9:30 a.m.

Representatives of the Bureau of Land Management, U.S. Department of the Interior and Forest Service, U.S. Department of Agriculture, will participate in the meetings. A brief explanation of the proposed rulemaking will be presented at the opening of each session. Following the presentation, the public will be invited to offer comments on the proposed rulemaking. Comments may be offered in writing and summarized by the author. Comments may also be offered orally. A verbatim transcript will not be made of the meeting; however, summaries will be made of each oral comment. The summaries and any written statements presented during the meeting will be analyzed in conjunction with development of final regulations setting grazing fees for 1978 and beyond. Further information is available from Bureau of Land Management, Public Affairs Staff, Room 3006 Federal Building, 300 Booth Street, Reno, Nev. 89509; telephone 702-784-6311.


E. T. Rowland, State Director.

[FR Doc. 78-283 Filed 1-6-78; 9:45 am]

[4910-06]

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[49 CFR Part 266]

[FRA Economic Docket No. 4; Notice No. 3]

SUBSTITUTE SERVICE ASSISTANCE

Advance Notice of Proposed Rulemaking

AGENCY: Federal Railroad Administration ("FRA"), Department of Transportation.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: FRA is considering amending 49 CFR Part 266 to provide more comprehensive regulations dealing with substitute service assistance under section 5(f) (4) of the Department of Transportation Act as amended by section 803 of the Railroad Revitalization and Regulatory Reform Act of 1976. This action is taken because of public inquiries as to the scope of "substitute service assistance" under the local rail service program.

DATES: Written comments must be received on or before February 6, 1978. Comments received after that date will be considered to the extent practicable.

ADDRESSES: (1) Submission of written comments: Written comments should identify the docket number and notice...
number and be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, 400 Seventh Street SW., Washington, D.C. 20590.

(2) Examination of written comments: All written comments received will be available for examination both before and after the closing date for written comments, during regular business hours in Room 5101, Nashif Building, 400 Seventh Street SW., Washington, D.C. 20590.

FOR FURTHER INFORMATION CONTACT THE AUTHORS OF THIS DOCUMENT:


SUPPLEMENTARY INFORMATION: FRA is considering amending 49 CFR Part 266 to provide more comprehensive regulations implementing section 5(f) (4) of the Department of Transportation Act ("Act") (49 U.S.C. 1654) as amended by section 503 of the Railroad Revitalization and Regulatory Reform Act of 1978 ("RRRRA") (Pub. L. 95-242). That section states:

The Secretary shall, in accordance with this section, provide financial assistance to states for rail freight assistance programs that are designed to cover-

(4) The cost of reducing the costs of lost rail service in a manner less expensive than this section, provide financial assistance to section

All

PROPOSED RULES

On August 9, 1976, Proposed Procedures and Requirements Regarding Applications and Disbursements for Assistance to States for Rail Service Assistance under Section 5 of the Department of Transportation Act were published in the Federal Register (41 FR 3354) as proposed Part 266 of the Code of Federal Regulations. Comments received in response to the proposed rules requested clarification of the scope of "substitute service assistance" to be provided pursuant to section 5(f) (4) of the act.

It was also suggested that both the relocation of shippers located on eligible lines and operating subsidies for use of non-rail freight transportation be included as eligible assistance programs. Adoption of these suggestions and promulgation of eligibility criteria, procedures and requirements to implement them would have significant implications with respect to the scope of assistance provided under the act. In light of this and because the question of substitute service assistance was not widely addressed in either the proposed rules or the comments received, it is felt that interested parties should be given an opportunity to participate in the formulation of specific rules regarding such assistance.

Comments are requested regarding the potential impact, both positive and negative, upon the States, railroads, shippers, and the general public resulting from such assistance programs. Comments are specifically requested regarding the following areas of interest:

A. Relocation of shippers. 1. Should relocation of shippers be considered substitute service assistance?

2. If relocation is included as substitute service assistance what should such assistance consist of?

3. What should be allowed as proper relocation costs? If necessary explain the methods of arriving at such costs.

4. What eligibility criteria should govern receipt of such assistance? To what extent should such assistance be limited by shipper location, duration of use, and traffic density?

B. Operating subsidies for use of non-rail freight transportation. 1. Should such operating subsidies be considered substitute service assistance?

2. If such subsidies are to be provided, what geographic or modal requirements should be considered?

3. What should be considered proper allowable costs? If necessary explain the methods of arriving at such costs. Suggest methods for determining substitute service costs.

4. What eligibility criteria should govern receipt of such assistance? To what extent should such assistance be limited by shipper location, duration of use, and traffic density?

5. To what extent are any administrative problems foreseen as a result of such assistance?

C. General. What other assistance programs, if any, should be considered substitute service assistance?

This advance notice of proposed rulemaking is issued under authority of section 5 of the Department of Transportation Act, as amended, 49 U.S.C. 1654 and 49 CFR 1.49(u).

Issued in Washington, D.C., on December 23, 1977.

John M. Sullivan, Administrator.

[FR Doc. 78-368 Filed 1-5-78: 8:45 am]

INTERSTATE COMMERCE COMMISSION

[49 CFR Part 1057]

[Ex Parto No. MC-43 (Sub-No. 7)]

LEASE AND INTERCHANGE OF VEHICLES

Proponent of time for filing comments

AGENCY: Interstate Commerce Commission.

ACTION: Extension of time for filing comments in the above-entitled rulemaking proceeding.

SUMMARY: The purpose of this document is to announce an extension of the time for filing comments in the above-entitled rulemaking proceeding.

DATES: Comments must be received on or before February 22, 1978.

APPLICATIONS FOR RELOCATION OF SHIPPERS.

To what extent are any administrative problems foreseen as a result of such assistance?

What other assistance programs, if any, should be considered substitute service assistance?

The time for filing comments in the above-entitled proceeding, originally set as January 23, 1978, is now extended to February 22, 1978. No further extensions will be granted.


SUPPLEMENTARY INFORMATION: The time for filing comments in the above-entitled proceeding, originally set as January 23, 1978, is now extended to February 22, 1978. No further extensions will be granted.


[FR Doc. 78-365 Filed 1-5-78: 8:45 am]
[3410-07]

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

(Designation No. A5441)

ARKANSAS

Designation of Emergency Areas

The Secretary of Agriculture has determined that farming, ranching, or aquaculture operations have been substantially affected in certainArkansas Counties as a result of various adverse weather conditions shown in the following chart:

ARKANSAS (9 COUNTIES)


Greene: drought June 1 to September 13, 1977 flood conditions September 14 to 30, 1977.

Lawrence: flooding along Cache River, Village Creek, and other tributaries September 24 through 30, 1977 (with high winds).


Therefore, the Secretary has designated these areas as eligible for emergency loans pursuant to the provisions of the Consolidated Farm and Rural Development Act, as amended, and the provisions of 7 CFR Part 1904 Subpart C, Exhibit B, Paragraph V B, including the recommendation of Governor David H. Pryor that such designation be made.

Applications for emergency loans must be received by this Department no later than June 19, 1978, for physical losses and December 20, 1978, for production losses, except that qualified borrowers who receive initial loans pursuant to this designation may be eligible for subsequent loans. The urgency of the need for loans in the designated area makes it impracticable and contrary to the public interest to give advance notice of proposed rulemaking and invite public participation.

Done at Washington, D.C., this 23rd day of December 1977.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 78-211 Filed 1-5-78; 8:45 am]

[3410-30]

Food and Nutrition Service

NATIONAL SCHOOL LUNCH PROGRAM AND
CHILD CARE FOOD PROGRAM


Pursuant to sections 6(e), and 17(e) of the National School Lunch Act, as amended by Pub. L. 95-166, and the regulations governing the Donation of Foods (7 CFR Part 240); notice is hereby given that the national average minimum value of donated foods, or cash in lieu thereof, per lunch under the National School Lunch Program (7 CFR Part 210) and per lunch and supper under the Child Care Food Program (7 CFR Part 220), shall be 12.75 cents for the period July 1, 1977-June 30, 1978. This value was derived by applying the percentage increase in the series for food away from home of the Consumer Price Index during the period June 1976 to May 1977 (from 184.8 in May 1976 to 190.3 in May 1977) to the national average minimum value prescribed for the period July 1, 1976-September 30, 1977, adjusted to the nearest one-fourth cent.

(Catalog of Federal Domestic Assistance Numbers 10.555 and 10.565.)

Effective date: This notice shall be effective as of July 1, 1977.


CAROL TUCKER FOREMAN,
Assistant Secretary for Food and Consumer Services.

[FR Doc. 78-444 Filed 1-5-78; 8:45 am]

[3410-30]

SPECIAL MILK PROGRAM FOR CHILDREN

Rate of Reimbursement for the Period July 1, 1977-June 30, 1978

Pursuant to section 3 of the Child Nutrition Act of 1966 and section 215(b) of the regulations governing the Special Milk Program for Children (7 CFR Part 215), notice is hereby given that the rate of reimbursement per half pint (226 ml) of milk shall be 6.25 cents for the period July 1, 1977-June 30, 1978. This rate applies to all milk served to children in nonpricing programs and to children other than...
needy children in pricing programs. This rate was derived by applying the percentage increase in the series for food away from home of the Consumer Price Index during the twelve month period June 1976-May 1977 (from 196.9 to 209.3 in May 1977) to the unrounded rate of reimbursement prescribed for the period July 1, 1976-September 30, 1977. The new rate is adjusted to the nearest one-fourth cent as required by law.

(Catalog of Federal Domestic Assistance Number 10.558.)

Effective date: This notice shall be effective as of July 1, 1977.


CAROL TUCKER FOREMAN, Assistant Secretary for Food and Consumer Services.

[FR Doc. 78-445 Filed 1-5-78; 8:45 am]

[3410-11]

Forest Service Land Management Plan
TRABUCO PLANNING UNIT—CLEVELAND NATIONAL FOREST

Availability of Draft Environmental Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the U.S. Forest Service, Department of Agriculture, has prepared a Draft Environmental Statement for the Land Management Plan, Trabuco Planning Unit, Cleveland National Forest, Calif., USDA-FS-R5-DES (Adm)-78-01.

This draft statement concerns a proposed land management plan for 134,500 acres of National Forest lands known as the Trabuco Ranger District on the Cleveland National Forest, in Orange, Riverside, and San Diego Counties, Calif. These 50 acres of land have been inventoried as unroressed and unappropriated. Four alternatives have been developed for consideration but none has been identified as preferred at this time.

This draft statement was transmitted to the Council on Environmental Quality on November 1, 1977.

Copies are available for inspection during regular working hours at the following locations:

USDA, Forest Service, South Agricultural Building, Room 3210, 12th Street & Independence Avenue SW, Washington, D.C. 20250.

Regional Forest, U.S. Forest Service, Room 292-390 Sansome Street, San Francisco, Calif. 94111.

Cleveland National Forest, 880 Front Street, Room 6-S-5, San Diego, Calif. 92118.

Trabuco Ranger, 34 Civic Center Plaza, Room 926, Santa Ana, Calif. 92701.

A limited number of copies are available, upon request, from Forest Supervisor Frederik G. deHoll, Cleveland National Forest, 880 Front Street, Room 6-S-5, San Diego, Calif. 92118.

Comments are invited from the public, from State and local agencies which are authorized to develop and enforce environmental standards, and from Federal agencies having jurisdiction by law or special expertise with respect to any environmental effect for which comments have not been specifically requested.

Comments concerning the proposed action, and requests for additional information should be addressed to Frederik G. deHoll, Forest Supervisor, Cleveland National Forest, 880 Front Street, Room 6-S-5, San Diego, Calif. 92118. Comments must be received by February 6, 1978, in order to be considered in preparation of the Final Environmental Statement and Land Management Plan.

CURTIS L. SCHRIF, Deputy Regional Forester.

[FR Doc. 78-213 Filed 1-5-78; 8:45 am]

NOTICES

[3410-11]

SILVICULTURAL TREATMENTS WITH HERBICIDES NORTH IDAHO FORESTS

Availability of Draft Environmental Statement

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Forest Service, Department of Agriculture, has prepared a draft environmental statement for Silvicultural Treatments with Herbicides, North Idaho Forests, USDA-FS-DES-2-R-1 (adz).

The environmental statement concerns a proposed reduction of competing vegetation, with herbicides, as a part of the timber resource management activities on National Forest lands.

This draft environmental statement was transmitted to EPA on December 28, 1977.

Copies are available for inspection during regular working hours at the following locations:

USDA, Forest Service, South Agriculture Building, Room 3230, 12th St. & Independence Ave. SW, Washington, D.C. 20250.

USDA, Forest Service, Federal Building, Missouri, Mont. 59807.

USDA, Forest Service, 1201 Ironwood Drive, Coeur D'Alene, Idaho 83814.

USDA, Forest Service, Route 4, Orofino, Idaho 83544.

USDA, Forest Service, 319 East Main Street, Grangeville, Idaho 83530.

A limited number of single copies are available upon request to Forest Supervisor, Idaho Panhandle National Forests, P.O. Box 310, Coeur D'Alene, Idaho 83814.

Copies of the environmental statement have been sent to various Federal, State, and local agencies as outlined in CEQ guidelines.

Comments are invited from the public, and from State and local agencies which are authorized to develop and enforce environmental standards, and from Federal agencies having jurisdiction by law or special expertise with respect to any environmental impact involved for which comments have not been requested specifically.

Comments concerning the proposed action and requests for additional information should be addressed to the Forest Supervisor, Idaho Panhandle National Forests, Box 310, Coeur D'Alene, Idaho 83814. Comments must be received by February 27, 1978, in order to be considered in the preparation of the final environmental statement.


RALPH D. KIZER, Forest Supervisor.

[FR Doc. 78-239 Filed 1-5-78; 8:45 am]

[6320-01]

CIVIL AERONAUTICS BOARD

(Docket Nos. 31870, 31791 and Order 77-12-115)

BALTIMORE/WASHINGTON-HOUSTON LOW-FARE ROUTE CASE AND TEXAS INTERNATIONAL AIRLINES

Order Instituting Investigation; Houston-Baltimore/Washington Low Fare "Peanuts Route Extension; Correction"

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 22nd day of December 1977.

In FR Doc. 77-37251, appearing at page 65227 in the issue of December 30, 1977, ordering paragraph No. 9 on page 65227 should read as follows:

"9. Texas International Airlines, Delta Air Lines, Eastern Air Lines, the Department of Justice, the Department of Transportation, the City of Houston, the Houston Chamber of Commerce, the City of Harlingen, and the State of Maryland be made parties to the proceeding instituted by paragraph 2, above; and"

By the Civil Aeronautics Board.


PHYLLIS T. KAYLO, Secretary.

[FR Doc. 78-275 Filed 1-5-78; 8:45 am]

[6320-01]

(Dockets 31818, 31823, 31824, and Order 77-12-149)

SOCIETE ANONYME BELGE D'EXPLOITATION DE LA NAVIGATION AERIENNE ET NATIONAL AIRLINES, INC.

Proposed United States-Italy Fares, Order Dismissing Complaints

Adopted by the Civil Aeronautics Board at its office in Washington,
D.C., on the 28th day of December 1977.

By tariff revisions filed December 7, 1977, for effect January 6, 1978, Societe Anonyme Belge d'Exploitation de la Navigation Aereenne (Sabena) and National Airlines, Inc. (National), propose to match reduced fares recently implemented by Alitalia-Linee Aeree Italiane, S.p.A. (Alitalia) and other carriers operating under United States-Italy Market. Sabena’s fares would apply on routings via Belgium, and National’s fares would apply on its routings from Miami via London or Paris.

Complaints requesting suspension pending investigation of both tariff filings have been submitted by Alitalia, and a complaint against Sabena’s filing has been filed by Trans World Airlines, Inc. (TWA).

In its complaints, Alitalia asserts that neither Sabena nor National is authorized to serve the U.S.-Italy market; the proposed tariffs are an unlawful extension of those carriers’ operations rather than a mere “matching” competitive filing; although Sabena’s tariff implies that it would conduct U.S.-Italy services without stopovers, in fact its passengers would have to disembark in Belgium and take a different Sabena flight to Italy; since Sabena’s New York-Brussels and New York-Italy promotional fares would be approximately equal, the Brussels/Italy segment would provide no revenue to cover its total costs; and National’s fares would be basically interline fares since National has no authority to carry passengers through to Italy and therefore does not qualify to match Alitalia’s fares.

In its complaint against Sabena, TWA alleges that Sabena’s tariff would allow stopovers on the reduced normal economy fare; although TWA does not serve Belgium, it is concerned about the implications in other U.S.-Europe markets; and if TWA chooses to match liberal stopover tariffs such as Sabena’s, it will incur substantial prorate losses when it hands off its U.S.-Italy traffic to foreign carriers, with the result that there will be continued cross-subsidization between point-to-point and stopover passengers.

In answer to Alitalia’s complaint, National contends that, although Alitalia argues that it should not be allowed to participate in U.S.-Italy traffic by applying the recently reduced fares, if an IATA agreement were in effect there would be no question about its ability to construct Miami-Italy fares at the New York level; National’s filing only provides Florida passengers the opportunity to travel at the reduced New York-Italy fares using routings and construction rules already in effect, which is clearly in the public interest; and Alitalia merely wishes to force all U.S.-Italy traffic to move over routings in which it participates and thus restrain competition.

In answer to the Alitalia and TWA complaints, Sabena’s position is that it considers it has the right to file matching fares to Italy even though the traffic may move via connecting services; if Alitalia presses the point the Board should allow these Alitalia’s fares beyond Italy to third countries; and Sabena is amending its tariff to prohibit all stopovers on the proposed fares, which should meet TWA’s principal objection.

Upon consideration, the Board finds that the complaints do not state facts sufficient to warrant suspension or investigation, and they will therefore be dismissed. The pre-existing U.S.-Italy fares were available on Sabena and National via their respective European gateways, and there is no reason to prevent the new reduced U.S.-Italy fares from being available to the public on these routings, or to prevent carriers from competing for the traffic over thier own routes. The existing IATA fare structure and construction rules allow up to 20-percent circuitry over the direct route mileage at no extra charge and, as Sabena points out, Alitalia itself has numerous fares on file to third countries beyond Italy on services which operate via its country.

Although the Board has expressed its concern with excessive circuitry and stopovers, which is an issue in Docket 27918, North Atlantic Fare Investigation, the U.S.-Italy fares proposed by Sabena and National allow no stopovers, and there is no basis for discrimination against passengers desiring to use the new low U.S.-Italy fares by restricting their availability to only three carriers, especially since other U.S.-Europe fares are generally available on almost any choice of carrier and routing.

In 1971, the Board conditioned the IATA Permanent Effectiveness Resolution to provide that U.S.-Flag carriers be permitted to compete directly with foreign-government ordered fares, using their own on-line services as well as connecting services provided with other carriers. This essential principal of equal opportunity to compete applies equally to all fares whether government-ordered or not.

Accordingly, pursuant to sections 102, 204, 403, and 1002(j) of the Federal Aviation Act,

It is ordered, That: 1. Except to the extent granted here, the complaints of Alitalia-Linee Aeree Italiane, S.p.A., in Dockets 31823 and 31824, and of Trans World Airlines, Inc., in Docket 31816, are dismissed; and


This order will be published in the Federal Register.

By the Civil Aeronautics Board. *

* PHYLIS T. KAYLOR, Secretary.

[FR Doc. 78-277 Filed 1-5-78; 8:45 am]

COMMISSION ON CIVIL RIGHTS

ALASKA ADVISORY COMMITTEE

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Alaska Advisory Committee (SAC) OF the Commission will convene at 6:30 p.m. and will end at 10 p.m. on January 20, 1978 in the Anchorage Westward Hilton, Third at E Street, Anchorage, Alaska 99501.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Northwest Regional Office of the Commission, 915 Second Avenue, Room 2652, Seattle, Wash, 98174.

The purpose of this meeting is to discuss and review preliminary outline of report written from field interviews.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.


JOHN I. BINKLEY, Advisory Committee Management Officer.

[FR Doc. 78-265 Filed 1-5-78; 8:45 am]

IOWA ADVISORY COMMITTEE

Amendment

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a planning meeting.

* All Members concurred.

FEDERAL REGISTER, VOL 43, NO. 4—FRIDAY, JANUARY 6, 1978
of the Iowa Advisory Committee (SAC) of the Commission, a notice previously published in the FEDERAL REGISTER Thursday, December 29, 1977 (FR Doc. 77-37039) on page 64916 is hereby amended.

Persons wishing to attend this open meeting should contact the Committee Chairperson or the Central States Regional Office, instead of the Northeastern Regional Office and the address is 911 Walnut Street, Kansas City, Missouri 64106 instead of 26 Federal Plaza, New York, N.Y. 10007. The date, time and place of the meeting will remain the same.


J O H N  I. BINKLEY,
Advisory Committee
Manager, Officer.

([FR Doc. 78-266 Filed 1-5-78; 8:45 am])

[6325-01]

CIVIL SERVICE COMMISSION
FEDERAL EMPLOYEES PAY COUNCIL

Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the President's Pay Agent announces the following meeting:


DATE AND TIME: January 24, 1978, 2:00 p.m.

PLACE: U.S. Civil Service Commission, 1900 E Street NW., Washington, D.C., Room 5A06A.

TYPE OF MEETING: Open.

CONTACT PERSON:

Claire G. Kline, Committee Management staff for the President's Pay Agent, U.S. Civil Service Commission, 1900 E Street NW., Washington, D.C., Telephone 202-632-5595.

PURPOSE OF COMMITTEE: To make recommendations to the President's Pay Agent with respect to the process and procedures leading to, and amounts of, annual comparability adjustments in Federal white-collar pay.

AGENDA: Discussions on the 1978 comparability adjustment for the statutory pay systems of the Federal Government, which are defined in section 5301 of title 5, United States Code.

For the President's Pay Agent.

RICHARD H. HALL,
Committee Management
Officer for the President's Pay Agent.

([FR Doc. 78-434 Filed 1-5-78; 8:45 am])

NOTICES

DEPARTMENT OF COMMERCE
Bureau of the Census
CENSUS ADVISORY COMMITTEE ON HOUSING FOR THE 1980 CENSUS

Renewal

In accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. I, and Office of Management and Budget Circular A-53 reviewed. It has been determined that the renewal of the Census Advisory Committee on Housing for the 1980 Census is in the public interest in connection with the performance of duties imposed on the Department by law.

The Committee was established in 1976 by the Secretary of Commerce under the Federal Advisory Committee Act (Pub. L. 92-463). Its present charter is scheduled to expire December 31, 1977. The present objective of the Committee is to provide technical advice and guidance in planning the forthcoming decennial census of housing to ensure that the major statistical requirements of decisionmakers are provided by the 1980 Census of Housing program. The Committee provides advice on housing subject-matter concepts, questionnaire content, tabulations, data dissemination plans and other relevant aspects of the overall 1980 census program. The Committee is strictly advisory. In renewing the Committee, no significant change of objectives or emphasis is planned.

The Committee will continue to consist of 13 members including a representative from each of nine major national organizations with different interests, and nine members appointed by the Secretary of Commerce. These representatives are widely regarded and furnished with the major aspects of the Nation's housing. The Chairperson and Chairperson Elect will continue to be elected for a 1-year term by the Committee which will operate in compliance with the Federal Advisory Committee Act.

Copies of the Committee's charter will be filed with the appropriate committees of the Congress.

Inquiries or comments may be addressed to the Committee Control Officer, Mr. Arthur F. Young, Housing Division, Room 303, Scudder Building, Bureau of the Census, Washington, D.C. 20233, telephone 301-763-2803.


DAVID S. NATHAN,
Acting Assistant Secretary for Administration.

([FR Doc. 78-214 Filed 1-5-78; 8:45 am])

[3510-25]

NUMERICALY CONTROLLED MACHINE TOOL TECHNICAL ADVISORY COMMITTEE

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. I (1976 ed.), notice is hereby given that a meeting of the Numerically Controlled Machine Tool Technical Advisory Committee will be held on Monday, January 31, 1978, at 10:00 a.m. in Room 5011, Main Commerce Building, 14th and Constitution Avenue NW., Washington, D.C.

The Numerically Controlled Machine Tool Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974 and January 13, 1977, the Assistant Secretary for Administration approved the recharter and extension of the Committee, pursuant to section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) and the Federal Advisory Committee Act.

The Committee advises the Office of Export Administration with respect to questions involving (A) technical matters, (B) worldwide availability and actual utilization of production technology (C) licensing procedures which may affect the level of export controls applicable to numerically controlled machine tools, including technical data related thereto, and (D) exports of the aforementioned commodities and technical data subject to multilateral controls in which the United States participates including proposed revisions of any such multilateral controls.

The Committee meeting agenda has five parts:

GENERAL SESSION

(1) Opening remarks by the Chairman.
(2) Presentation of papers or comments by the public.
(3) Discussion of industrial robot performance criteria.
(4) Discussion of dimensional inspection machine performance criteria.

EXECUTIVE SESSION

(5) Discussion of matters properly classified under Executive Order 11652, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting is open to the public, at which a limited number of seats will be available. To the extent time permits members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting.

With respect to agenda item (5), the Acting Assistant Secretary of Commerce for Administration, with the concurrence of the delegate of the General Counsel, formally determined
NOTICES

on January 27, 1977, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended by section 5(c) of the Government in the Sunshine Act, Pub. L. 94-409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552(b)(c)(1). Such matters are specifically authorized under criteria established by an Executive Order to be kept secret in the interests of the national defense or foreign policy. All materials to be reviewed and discussed by the Subcommittee during the Executive Session of the meeting have been properly classified under the Executive Order. All Committee members have appropriate security clearances.

Copies of the minutes of the open portion of the meeting will be available upon written request addressed to the Procurement and Export Office, Industry and Trade Administration, Room 3202, U.S. Department of Commerce, Washington, D.C. 20230.

For further information, contact the Assistant Secretary for Administration, approved the recharter and extension of the Committee, pursuant to section 5(c)(1) of the Export Administration Act of 1969, as amended, 59 U.S.C. App. Sec. 2404(c)(1) and the Federal Advisory Committee Act. The Microcircuit Subcommittee was established on December 20, 1977, with the approval of the Assistant Secretary for Industry and Trade, pursuant to the charter of the Committee. The Committee advises the Office of Export Administration with respect to questions involving (A) technical matters, (B) worldwide availability and actual utilization of production technology, (C) licensing procedures which affect the level of export controls applicable to semiconductor products, including technical data or other information related thereto, and (D) exports of the aforementioned commodities and technical data subject to multilateral controls in which the United States participates including proposed revisions of any such multilateral controls. The Microcircuit Subcommittee was formed to study microcircuit devices with the goal of making recommendations to the Department of Commerce relating to the appropriate parameters for controlling exports for reasons of national security.

The Subcommittee will meet only in Executive Session to discuss matters properly classified under Executive Order 11652, dealing with the U.S. and COCOM control program and strategic criteria related thereto. Written statements may be submitted at any time before or after the meeting.

The Acting Assistant Secretary of Commerce for Administration, with the concurrence of the delegate of the General Counsel, formally determined on January 27, 1977, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended by section 5(c) of the Government in The Sunshine Act, Pub. L. 94-409 that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552(b)(c)(1). Such matters are specifically authorized under criteria established by an Executive Order to be kept secret in the interests of the national defense or foreign policy. All materials to be reviewed and discussed by the Subcommittee during the meeting have been properly classified under Executive Order 11652. All Subcommittee members have appropriate security clearances.

For further information, contact Mr. Charles C. Swanson, Director, Operations Division, Office of Export Administration, Industry and Trade Administration, Room 1617M, U.S. Department of Commerce, Washington, D.C. 20230, telephone area code 202-377-4196.

The complete Notice of Determination to close meetings or portions thereof of the series of meetings of the Semiconductor Technical Advisory Committee and of any subcommittees thereof was published in the Federal Register on February 1, 1977, (42 FR 5991).


LAWRENCE J. BRADY,
Acting Director, Office of Export Administration, Department of Commerce.

[FR Doc. 78-294 Filed 1-5-78; 8:45 am]

[3510-25]

MICROCIRCUIT SUBCOMMITTEE OF THE SEMICONDUCTOR TECHNICAL ADVISORY COMMITTEE

Closed Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. I (1976 ed.), notice is hereby given that a meeting of the Microcircuit Subcommittee of the Semiconductor Technical Advisory Committee will be held on Thursday, January 12, 1978, at 9:30 a.m., in Conference Room D, Main Commerce Building, 14th and Constitution Avenue NW., Washington, D.C. The meeting will continue January 13, in Conference Room D, Main Commerce Building, to its conclusion. In view of the urgent need of the Department of Commerce and other agencies advising on January 27, 1977, that it is necessary for this Subcommittee to complete its review of the International List of embargoed commodities as it pertains to semiconductors and related commodities. The review must be completed at the earliest possible date to assure that the U.S. negotiating position for the International List Review negotiations will be tabled on January 27, 1978.

The complete Notice of Determination to close meetings or portions thereof of the series of meetings of the Semiconductor Technical Advisory Committee and of any subcommittees thereof was published in the Federal Register on March 2, 1977 (42 FR 12078).


RAUER H. MEYER,
Director, Office of Export Administration, Bureau of Trade Regulation, U.S. Department of Commerce.

[FR Dec. 78-329 Filed 1-5-78; 8:45 am]

[3510-25]

MATERIALS AND ACOUSTIC WAVE, MEMORY AND PHOTO CONDUCTIVE DEVICE SUBCOMMITTEE OF THE SEMICONDUCTOR TECHNICAL ADVISORY COMMITTEE

Closed Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. I (1976 ed.), notice is hereby given that a meeting of the Materials and Acoustic Wave, Memory and Photo Conductive Device Subcommittee of the Semiconductor Technical Advisory Committee will be held on Thursday, January 12, 1978, at 9:30 a.m., in Conference Room B, Main Commerce Building, 14th and Constitution Avenue NW., Washington, D.C. The meeting will continue January 13, in Conference Room B, Main Commerce Building, to its conclusion. In view of the urgent need of the Department of commerce and other agencies advising on January 27, 1977, that it is necessary for this Subcommittee to complete its review of the International List of embargoed commodities as it pertains to semiconductors and related commodities. This review must
be completed at the earliest possible date to assure that the U.S. negotiating position for the International List Review negotiations will be tabled on time. Therefore, this notice is being published less than 15 days in advance of the meeting.

The Semiconductor Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, and January 13, 1977, the Assistant Secretary for Administration, in accordance with the Federal Advisory Committee Act, approved the recharter and extension of the Committee, pursuant to section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) and (c)(2) and the Federal Advisory Committee Act. The Semiconductor Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, and January 13, 1977, the Assistant Secretary for Administration, in accordance with the Federal Advisory Committee Act, approved the recharter and extension of the Committee, pursuant to section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) and (c)(2) and the Federal Advisory Committee Act. The Semiconductor Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, and January 13, 1977, the Assistant Secretary for Administration, in accordance with the Federal Advisory Committee Act, approved the recharter and extension of the Committee, pursuant to section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) and (c)(2) and the Federal Advisory Committee Act. The Committee advises the Office of Export Administration with respect to questions involving technical matters, (B) worldwide availability and actual utilization of production technology, (C) licensing procedures which affect the level of export controls applicable to semiconductor products, including technical data or other information related thereto, and (D) exports of the aforementioned commodities and technical data subject to multilateral controls in which the United States participates including proposed revisions of any such multilateral controls. The Committee advises the Office of Export Administration with respect to questions involving technical matters, (B) worldwide availability and actual utilization of production technology, (C) licensing procedures which affect the level of export controls applicable to semiconductor products, including technical data or other information related thereto, and (D) exports of the aforementioned commodities and technical data subject to multilateral controls in which the United States participates including proposed revisions of any such multilateral controls. 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under Executive Order 11652. All subcommittee members have appropriate security clearances.

For further information, contact Mr. Charles C. Swanson, Director, Operations Division, Office of Export Administration, Industry and Trade Administration, Room 1617M, U.S. Department of Commerce, Washington, D.C. 20230, telephone area code 202-377-4196.

The complete Notice of Determination to close meetings or portions thereof of the series of meetings of the Semiconductor Technical Advisory Committee and of any subcommittees thereof was published in the Federal Register on March 2, 1977 (42 FR 12078).


RAUER H. MEYER,
Director, Office of Export Administration, Bureau of Trade Regulation, U.S. Department of Commerce.

[FR Doc. 78-344 Filed 1-5-78; 8:45 am]

NOTICES

[3510-03]

Maritime Administration

LYKES BROS. STEAMSHIP CO., INC.
Application for Twenty-Year Operating-Differential Subsidy Agreement

Notice is hereby given that with respect to the application of Lykes Bros. Steamship Co., Inc. (Lykes) for a twenty-year operating-differential subsidy agreement (ODSA), and in consideration of Lykes' application involving major essential trade routes and the operation thereon of vessels, including vessels that may be considered highly technologically advanced vessels, the Maritime Subsidy Board has decided, in the exercise of its discretion, to extend an opportunity for interested parties to present their views on the section 601(a)(4) of the Merchant Marine Act, 1936, as amended, whether the granting of operating-differential subsidy aid sought is necessary to place the proposed operations of the vessel or vessels on a parity with those of foreign competitors or reasonably calculated to carry out effectively the purposes and policy of the Act. The comments will be considered separately from any consideration of the 605(c) issues under Docket No. S-447.

Any person, firm or corporation having an interest in the section 601(a)(4) findings is invited to file written comments by the close of business on February 3, 1978 with the Secretary, Maritime Subsidy Board, Room 3099-B, Department of Commerce Building, 14th and E Streets NW., Washington, D.C. 20230.


By Order Of The Maritime Subsidy Board/Maritime Administration.

ROBERT J. PATTON, JR.,
Assistant Secretary.

[FR Doc. 78-147 Filed 1-5-78; 8:45 am]

STATE STEAMSHIP CO.
Application for Twenty-Year Operating-Differential Subsidy Agreement

Notice is hereby given that with respect to the application of States Steamship Co. (States) for a twenty-year operating-differential subsidy agreement (ODSA), and in consideration of States' application involving major essential trade routes and the operation thereon of vessels, including vessels that may be considered highly technologically advanced vessels, the Maritime Subsidy Board has decided,-

...
NOTICES

PROCUREMENT LIST 1978

Proposed Deletion

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed deletion from procurement list.

SUMMARY: The Committee has received a proposal to delete from Procurement List 1978 military resale items produced by workshops for the blind or other severely handicapped.


ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Va. 22201.

FOR FURTHER INFORMATION CONTACT:

C. W. Fletcher, 703-557-1145.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2), 85 Stat. 77.

It is proposed to delete the following military resale items from Procurement List 1978, November 14, 1977 (42 FR 59015):

- Military Resale Item No. and Name
  - No. 998—Dish, plastic, pet.
  - No. 999—Dish, plastic, pet.

[FR Doc. 78-258 Filed 1-5-78; 8:45 am]

[6820-33]

[3910-01]

DEPARTMENT OF DEFENSE

Department of the Air Force

AIR UNIVERSITY BOARD OF VISITORS

Meeting

The Air University Board of Visitors will hold an open meeting on March 14, 1978, at 1 p.m. in the Air University Conference Room, Austin Hall (Building 800), Maxwell Air Force Base, Ala.

The purpose of this meeting is to give the board an opportunity to present to the Commander, Air University, a report of the findings and recommendations concerning Air University educational programs.

For further information on this meeting contact Dorothy D. Reed, Coordinator, AU Board of Visitors, Office of the Deputy Chief of Staff, Education, Headquarters Air University (EDV), telephone 205-293-7423.

FRANKIE S. ESTEP,
Air Force Federal Register Liaison Officer, Directorate of Administration.

[FR Doc. 78-215 Filed 1-5-78; 8:45 am]
Pursuant to Pub. L. 92-463 notice is hereby given of a public hearing and a meeting of the President's Commission on Military Compensation that will be held on January 18, 1978, in Conference Room B, Departmental Auditorium, Constitution Avenue between 12th and 14th Streets NW., Washington, D.C. The hours for the public hearing are 9 a.m. to 12 noon and for the meeting, 1:30 p.m. to 4:30 p.m.

MEETING

The subject of the meeting will be military retirement. The meeting is open to the public, but observers may not participate in the discussion.

PUBLIC HEARING

The witnesses scheduled for the public hearing, as follows:

9 a.m.—The Honorable Clifford L. Alexander, Jr., Secretary of the Army.
10 a.m.—The Honorable W. Graham Claytor, Jr., Secretary of the Navy.
11 a.m.—The Honorable John P. White, Chief of Naval Operations.
12 noon—General George S. Brown, USAF, Chairman, Joint Chiefs of Staff.
1 p.m.—The Honorable John F. Stroesser, Assistant Secretary of Defense (MRA&I).

Questions on these matters may be addressed to the President's Commission on Military Compensation, 606 11th Street NW., Suite 520, Washington, D.C. 20001.

MAURICE W. ROGHE,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.


[FR Doc. 78-235 Filed 1-5-78; 8:45 am]

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission
[Project No. 469]

CITY OF TACOMA, WASH.

Extension of Time

DECEMBER 27, 1977.

On December 22, 1977, Staff Counsel filed a motion to extend the time for filing a response to the motion filed by the Skokomish Indian Tribe on December 13, 1977, in the above referenced proceeding. The motion states that the city of Tacoma, Wash., does not oppose the requested extension.

NOTICES

[FR Doc. 78-235 Filed 1-5-78; 8:45 am]

NOTICES

Kenneth F. Plum, Secretary.

[FR Doc. 78-235 Filed 1-5-78; 8:45 am]

[FR Doc. 78-235 Filed 1-5-78; 8:45 am]

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission
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DECEMBER 27, 1977.

On December 22, 1977, Staff Counsel filed a motion to extend the time for filing a response to the motion filed by the Skokomish Indian Tribe on December 13, 1977, in the above referenced proceeding. The motion states that the city of Tacoma, Wash., does not oppose the requested extension.

Upon consideration, notice is hereby given that the date for filing responses to the December 13, 1977, motion is extended to and including January 12, 1978.

Kenneth F. Plum, Secretary.

[FR Doc. 78-235 Filed 1-5-78; 8:45 am]

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission
[Project No. 469]

CITY OF TACOMA, WASH.

Extension of Time

DECEMBER 27, 1977.

On December 22, 1977, Staff Counsel filed a motion to extend the time for filing a response to the motion filed by the Skokomish Indian Tribe on December 13, 1977, in the above referenced proceeding. The motion states that the city of Tacoma, Wash., does not oppose the requested extension.

Upon consideration, notice is hereby given that the date for filing responses to the December 13, 1977, motion is extended to and including January 12, 1978.

Kenneth F. Plum, Secretary.

[FR Doc. 78-235 Filed 1-5-78; 8:45 am]
NOTICES

[6740-02] (Docket No. ES78-15)

EL PASO ELECTRIC CO.
Application


Take notice that on December 13, 1977, El Paso Electric Co. (Applicant), filed an application with the Federal Energy Regulatory Commission (Commission), pursuant to section 204 of the Federal Power Act seeking authorization to issue up to 150,000 shares of Common Stock and requesting exemption of such Common Stock from the competitive bidding requirements under the Commission's regulations.

The Applicant states that the Common Stock is to be issued from time to time pursuant to the provisions of the Applicant's Employee Stock Ownership Plan and (Plan), which is intended to qualify as a stock bonus plan under section 403(a) of the Internal Revenue Code of 1954 and as an employee stock ownership plan under section 401(d) of the Tax Reduction Act of 1975. The Applicant further states that the price at which the Common Stock will be issued into the Plan shall be the average of the last bid and asked prices as quoted by the National Association of Securities Dealers' Automated Quotation System for the 20 consecutive trading days immediately preceding the date of transfer to the Plan.

In addition, the Applicant reports that it will realize from the issuance of such Common Stock an additional investment credit against Federal income tax liability equivalent to the value of the Common Stock issued to such Plan. The proceeds in the form of a Federal income tax credit will be used to 'refund a portion of its short term debt.

The Applicant is a Texas corporation with its principal business office at El Paso, Tex., and is engaged in the electric utility business in Texas and New Mexico in an area in the Rio Grande Valley extending approximately 110 miles northwesterly from El Paso to the Cabalo Dam in New Mexico and approximately 120 miles southeasterly from El Paso to Van Horn. The area contains a population of approximately 493,000, of whom 365,000 reside in metropolitan El Paso.

Any person desiring to be heard or to make any protest with reference to such application should on or before January 6, 1978, file with the Federal Energy Regulatory Commission, 825 North Capitol Street, Washington, D.C. 20426, petitions or protests in accordance with the requirements of §§1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's rules.

The application is on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[F.R. Doc. 78-237 Filed 1-5-78; 8:45 a.m.]

FLORIDA GAS TRANSMISSION CO.
Public Conference

DECEMBER 27, 1977.

Take notice that a public conference in the captioned docket will be convened at 9 a.m. on January 16, 1978, in the conference room of the Federal Energy Regulatory Commission, 825 North Capitol Street NE, Washington, D.C. 20426. An administrative law judge to be designated by the chief administrative law judge for that purpose (see delegation of authority, 18 CFR 3.5(d)), shall preside at the conference in this proceeding with authority to establish and change all procedural dates and rule on such matters necessary for the expeditious determination of this proceeding as further provided for in the Commission's rules of practice and procedure.

The purpose of the meeting is to discuss the merits of a proposed compensation plan in connection with the grants of extraordinary relief per the mandate from the United States Court of Appeals for the Fifth Circuit in Fort Pierce Utility Authority of the City of Fort Pierce, et al. v. Federal Power Commission, 526 F.2d 993 (5th Cir. 1976).

Customers and other interested persons will be permitted to attend, but if such persons have not previously been permitted to intervene by order of the Commission or the United States Court of Appeals for the Fifth Circuit, attendance at the conference will not be deemed to authorize intervention as a party in the proceedings.

All parties will be expected to come fully prepared to discuss the merits of all issues concerning the compensation plan and any procedural matters preparatory to a full evidentiary hearing or such other procedures as may be ordered.

KENNETH F. PLUMB,
Secretary.

[F.R. Doc. 78-238 Filed 1-5-78; 8:45 a.m.]

[6740-02] (Docket No. ES78-41)

IOWA PUBLIC SERVICE CO.
Application


Take notice that on December 15, 1977, the Iowa Public Service Co. (Applicant), filed an application pursuant to section 204 of the Federal Power Act for authorization to issue up to 190,000 shares of Class A Preferred Stock (approximately $15 million), via competitive bidding.

The Applicant is incorporated under the laws of the State of Iowa, with its principal business office at Sioux City, Iowa, and is engaged in the electrical utility business in Northwestern, Northcentral, and Eastern Iowa, and a few small communities in South Dakota.

The Applicant proposes to sell the Preferred Stock at competitive bidding in accordance with the applicable requirements of section 34.1a of the Commission's regulations.

The Applicant proposes to use the proceeds from the issuance of the securities to reduce short term loans incurred and to be incurred prior to the sale of the securities and to secure funds for construction purposes.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 5, 1978, file with the Federal Energy Regulatory Commission, 825 North Capitol Street NE, Washington, D.C. 20426, petitions or protests in accordance with the requirements of the Commission's rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's rules. The application is on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[F.R. Doc. 78-238 Filed 1-5-78; 8:45 a.m.]

NORTHERN NATURAL GAS CO.
Extension of Time

DECEMBER 27, 1977.

On December 16, 1977, Staff Counsel filed a motion to extend the date for filing of testimony by supporting intervenors and staff counsel, as re-
NOTICES

On September 7, 1977, Falcon Petroleum Co. (Falcon), filed in Docket No. CIT7-779 a similar petition for a declaratory order, reciting as support therefor the same facts as were included in City's prior filing. The Commission noticed Falcon's petition on September 19, 1977, and established a deadline of October 7, 1977, for filings pursuant to the petition. Petitioners Northern Natural Gas Co. (Northern), filed a timely petition for leave to intervene and answer in Docket No. CIT7-799 on September 28, 1977; on October 21, 1977, for participation in Docket No. C177-799. Falcon Intervenors, Granting Interventions, ON DECEMBER 28, 1977.

On October 1, 1977, pursuant to the provisions of the Department of Energy Organization Act (DOE Act), Pub. L. 95-91, 91 Stat. 568 (August 4, 1977), and Executive Order No. 12009, 42 FR 46267 (September 15, 1977), the Federal Power Commission ceased to exist and its functions and regulatory responsibilities were transferred to the Secretary and the Federal Energy Regulatory Commission (FERC). The City of Perryton, Tex., ET AL.

The joint regulation on October 1, 1977, by the Secretary and the FERC entitled "Transfer of Proceedings to the Secretary of Energy and the FERC," 10 CFR 302, provided that this proceeding would be continued before the FERC. The FERC takes action in this proceeding in accordance with the above mentioned authorities.

On July 22, 1977, the City of Perryton, Tex. (City), filed in Docket No. CIT7-701 a petition for a declaratory order pursuant to section 1.7 of the Commission's rules of practice and procedure (18 CFR 1.7). The petition filed by City was noticed on November 18, 1977, for filing protests and petitions to intervene expired on December 9, 1977.

The "Commission" when used in the context of an action taken prior to October 1, 1977, refers to the FPC when used otherwise, refers to the FERC.

ORDER Consolidating Proceedings, Denying Declaration Order, Setting Matters for Hearing, Adding Respondents, Granting Interventions, and Compounding Show Cause Proceeding

On October 1, 1977, pursuant to the provisions of the Department of Energy Organization Act (DOE Act), Pub. L. 95-91, 91 Stat. 568 (August 4, 1977), and Executive Order No. 12009, 42 FR 46267 (September 15, 1977), the Federal Power Commission ceased to exist and its functions and regulatory responsibilities were transferred to the Secretary and the Federal Energy Regulatory Commission (FERC), which, as an independent commission established by Congress pursuant to the provisions of the Department of Energy Act, as amended (DOE Act), 42 U.S.C. 7151 et seq. and the Natural Gas Act is addressed below.

The "Commission" when used in the context of an action taken prior to October 1, 1977, refers to the FPC when used otherwise, refers to the FERC.

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Falcon and City have submitted petitions for a declaratory order, reciting as support therefor the same facts as were included in City's prior filing. The Commission noticed Falcon's petition on September 19, 1977, and established a deadline of October 7, 1977, for filings pursuant to the petition. Petitioners Northern Natural Gas Co. (Northern), filed a timely petition for leave to intervene and answer in Docket No. CIT7-799 on September 28, 1977; on October 21, 1977, for participation in Docket No. C177-799.

Falcon and City (jointly referred to as Petitioners), seek a declaratory order permitting them to make deliveries to the city of Perryton, Tex. (City), filed in Docket No. C177-701 a petition for a declaratory order, reciting as support therefor the same facts as were included in City's prior filing. The Commission noticed Falcon's petition on September 19, 1977, and established a deadline of October 7, 1977, for filings pursuant to the petition. Petitioners Northern Natural Gas Co. (Northern), filed a timely petition for leave to intervene and answer in Docket No. CIT7-799 on September 28, 1977; on October 21, 1977, for participation in Docket No. C177-799.

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the extent that continued service is unwarranted, or because the present or future public convenience or necessity permit the abandonment. It is apparent that, given the additional gas discovered, abandonment due to depletion is not warranted. So that the question here is whether the present or future public convenience and necessity permit the withdrawal of service to Northern and the transfer of that service to the city of Perryton. We will afford Petitioners herein an opportunity to demonstrate that such a switch is warranted here.

Inasmuch as the separate petitions filed by City in Docket No. C177-701, and by Falcon in Docket No. C177-799 rest on the same facts, we will provide herein that these Dockets will be consolidated.

Based on the allegations made by City and Falcon, it would appear that Amoco may have ceased certificated sales of natural gas in interstate commerce with the first abandonment of service to Northern without FPC authorization; abandonment authorization pursuant to section 7(b) of the Natural Gas Act. We therefore find it necessary to join Amoco and Northern as respondents in these dockets so that they may be afforded the opportunity to show cause why they should not be held in violation of section 7(b) of the Act. Thus, the hearing ordered in this proceeding shall consider the question of possible violations of the Natural Gas Act as well as the abandonment applications. With respect to possible violation the hearing shall consider: First, whether Amoco did cease deliveries to Northern without FPC authorization; secondly, if it did cease such deliveries, whether it was acting in violation of the Act; thirdly, whether Amoco acted as a prudent operator in not deepening its well, as Falcon subsequently did, prior to expiration of its lease and fourthly, whether Northern's failure to notify the Commission of any unauthorized cessation of deliveries constitutes a separate violation. In addition to determine if any violation occurred, the parties shall address themselves to the question of what action, if any, the Commission should take in this matter in the event that it is determined that there has been a violation of the Natural Gas Act, and to what remedies the Commission should adopt.

If it appears on the basis of an administrative proceeding before the Commission, or on the basis of other information available to the Commission, that a violation of the Natural Gas Act has occurred and that the alleged acts or omissions may fall within the sanctions set forth in sections 20 and 21 of the Natural Gas Act, or the Commission's rules, regulations, conditions, restrictions, and orders, the Commission will pursue all available civil and criminal sanctions should it be found that the nature of the violation and the surrounding circumstances thereof warrant such action. In the event that it appears to be a "willful and knowing" violation of either statutes or regulations thereunder, the Commission may refer the case to the Department of Justice for appropriate action or pursue such relief in the Courts.

We set these matters for hearing and will provide that an early prehearing conference be convened.

The Commission orders: (A) The petitions for declaratory order filed in these dockets are denied.
(B) The applications for abandonment authorization filed in Docket No. C177-701 and Docket No. C177-799 are consolidated for all purposes.
(C) Amoco and Northern are joined as respondents in these dockets. Amoco and Northern shall be ordered to show cause why they should not be held in violation of the Natural Gas Act.
(D) Pursuant to the authority set forth in the Natural Gas Act, particularly sections 4, 5, 7, 14, 15, and 16, and the Commission's rules of practice and procedure, a public hearing shall be held in a hearing room of the Federal Energy Regulatory Commission, 825 N. Capitol Street N.W., Washington, D.C. 20462, on the issues presented here.
(E) A presiding administrative law judge shall be designated by the chief administrative law judge for such purpose. Such presiding administrative law judge shall preside at the hearing in this proceeding, with authority to establish and change all procedural dates, and to rule on all motions (with the exception of motions to intervene, consents and motions to dismiss, as provided by the rules of practice and procedure).
(F) The presiding administrative law judge shall preside at a prehearing conference to be held at 9:30 a.m., January 26, 1978, in a hearing room of the Federal Energy Regulatory Commission at the address noted in Ordering Paragraph (C). The presiding administrative law judge shall establish dates for filing evidence and testimony, all of which shall be served upon the presiding administrative law judge, the Commission staff and all parties to this proceeding.
(G) Northern and Transwestern are permitted to intervene in these proceedings subject to the rules and regulations of the Commission: Provided, however, that the participation of such intervenors shall be limited to matters affecting asserted rights and interests as specifically set forth in said petitions for leave to intervene; and Provided, further, That the admission of such intervenors shall not be construed as recognition by the Commission that they might be aggrieved because of any order or orders of the Commission entered in these proceedings.

(H) The Secretary shall cause prompt publication of this order to be made in the Federal Register.

By the Commission.

KENNETH F. PLUMB, Secretary.
would resolve all issues in the captioned proceeding. The settlement proposal is supported by all parties to the proceeding including DOMAC's customers and the commission staff. For the reasons set forth below, the Commission shall approve the settlement agreement.

The instant proceeding was initiated by DOMAC on March 18, 1976, when it filed proposed tariff sheets designed to (1) standardize the rates, terms and conditions under which DOMAC sells and provides its services to 10 gas distribution companies and (2) increases rates by $3.5 million annually. By order issued April 16, 1976, the Federal Power Commission (FPC) accepted the proposed sheets upon the condition that DOMAC eliminate rate-base treatment for the LNG barge Massachusetts and that the filed cost of service be reduced to reflect depreciation reserves accrued through December 31, 1975. The April 16, 1976, order suspended the effectiveness of the filing for a 5-month period. On May 17, 1976, the FPC issued an order in the instant docket which rejected the tariff filings made so as to apply to DOMAC's sales to Boston Gas Co. (Boston Gas). On September 19, 1976, DOMAC's tariff, revised pursuant to the suspension order, became effective subject to refund for all of DOMAC's customers except Boston Gas.

DOMAC, on March 30, 1977, filed with the FPC a substitute gas tariff which incorporated all changes in rates and service pursuant to the proceeding including DOMAC's cus-

The rate levels for the four service and sales classifications provided by DOMAC are set forth in appendix B. These rates are designed to recover the cost of service over estimated annual volumes of 12,810,000 MMBtu.

Article III of the settlement pertains to revenues DOMAC may receive from the terminalling of off-system cargoes. It provides that DOMAC will apportion between itself and its regular customers, such revenues under a three-part formula. The purpose of this provision is to provide an incentive for DOMAC to fully utilize existing terminal capacity while recognizing that the otherwise stipulated rates are designed to recover for DOMAC the full costs of its facilities on the sales and terminalling of only Decartes and Interim volumes (12,810,000 MMBtu). The parties have also agreed to a tariff, Substitute FERC Gas Tariff Original Volume No. 1 as set forth in appendix C to the Settlement Agreement. If approved, the settlement tariff would control the terms and conditions of services and sales by DOMAC to all of its regular customers. The tariff has been in effect for all of DOMAC's customers, including Boston Gas, since the subject to final Commission approval. The Tariff will replace the numerous existing contracts between DOMAC and each of its customers under which DOMAC has previously rendered its sales and services.

In principal part, the settlement tariff provides for the following: (1) A minimum bill provision which can be invoked by DOMAC only upon the tender of gas; (2) A three-tiered rate structure for Rate Schedule TS-1 customers designed to allow DOMAC to recover fixed costs of terminal operation over estimated volumes of 12,810,000 MMBtu, i.e., the first and second tiers of the rate schedule; (3) A provision controlling tender rights which entitles DOMAC to tender 50 percent of LNG volumes in the first 10 days after delivery and the remaining 50 percent thereafter only if the other party or person affected by this order in any proceeding now pending or which may in the future be instituted by or against DOMAC or any other person or party.

The Secretary shall cause prompt publication of this order in the Federal Register.

By the Commission.

KENNETH F. PLUMB, Secretary.

APPENDIX A
Distribs of Massachusetts Corp., Docket No. RP76-73, Settlement Cost of Service

<table>
<thead>
<tr>
<th>Line No. and description</th>
<th>Total</th>
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<tbody>
<tr>
<td>(1)</td>
<td>(2)</td>
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<tr>
<td>Operation and Maintenance Expenses:</td>
<td></td>
</tr>
<tr>
<td>1. Cost of gas withdrawn from storage</td>
<td>$9,590,400</td>
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<tr>
<td>2. Other operation and maintenance expenses</td>
<td>3,355,471</td>
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<tr>
<td>3. Total operation and maintenance expenses</td>
<td>12,945,871</td>
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<tr>
<td>4. Depreciation</td>
<td>1,991,941</td>
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<tr>
<td>5. Taxes other than income taxes</td>
<td>1,075,359</td>
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<tr>
<td>6. Federal income taxes</td>
<td>2,373,763</td>
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<tr>
<td>7. State income taxes</td>
<td>462,093</td>
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<tr>
<td>8. Return</td>
<td>3,318,244</td>
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<td>9. Total cost of service</td>
<td>21,150,633</td>
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</table>

APPENDIX B
Distribs of Massachusetts Corp., Docket No. RP76-73, Settlement Rates

<table>
<thead>
<tr>
<th>Line No. and rate schedule</th>
<th>Rate per MMBtu</th>
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<tbody>
<tr>
<td>1. TS-1 first 6,405,600 MMBtu</td>
<td>$1.05</td>
</tr>
<tr>
<td>2. TS-1 next 6,405,000 MMBtu</td>
<td>.90</td>
</tr>
<tr>
<td>3. TS-1 all other</td>
<td>.89</td>
</tr>
<tr>
<td>4. BO-1 (cents)</td>
<td>70.78</td>
</tr>
<tr>
<td>5. BO-1 (cents)</td>
<td>70.78</td>
</tr>
<tr>
<td>6. SS-1 (cents per MMBtu)</td>
<td>12.5</td>
</tr>
</tbody>
</table>

*In the event that volumes in excess of 12,810,000 MMBtu are received, it has been agreed that a TS
Eastern Shore requested that the proposed tariff sheets be permitted to become effective on January 1, 1977. On December 29, 1976, the FPC accepted the proposed tariff sheets for filing, suspended their effectiveness until June 1, 1977, and set the matter for hearing. The order questioned the cost classification, allocation, and rate design in the filing, which was based on the unmodified Seaboard methodology. Following service of the FPC's staff on April 1, 1977, and settlement discussions between the company and the staff, the only other party to the proceeding, Eastern Shore filed a motion on June 10, 1977, to approve a Stipulation and Agreement. The settlement would resolve all issues in the proceeding.

Prior to the filing of this settlement, Eastern Shore on May 20, 1977, tendered for filing revised rates based upon the settlement cost of service. These rates, which are based on the United method of cost classification, were accepted for filing and permitted by the FPC to become effective, subject to refund, on June 1, 1977, in lieu of those originally filed on November 24, 1976. Public notice of the proposed settlement was issued on July 11, 1977. On July 29, 1977, the staff filed comments recommending that the settlement be approved. The settlement rates are based on a total system cost of service of $5,734,268 of which $4,366,747 is allocated to jurisdictional service as shown in Appendix A. The settlement cost of service includes an overall rate of return of 9.51 percent with a return on common equity of 11.49 percent also as shown in appendix A. Cost classification, allocation, and rate design are based on the United method. The settlement further provides that the jurisdictional portion of demand-charge adjustments received by Eastern Shore from its supplier, Transcontinental Gas Pipe Line Corp., shall be credited to Eastern Shore's jurisdictional customers.

Based on a review of the record in this proceeding the Commission finds that the proposed settlement represents a reasonable resolution of the issues in this proceeding and should be adopted as hereinafter ordered.

The Commission orders: (A) The settlement agreement filed in this proceeding on June 10, 1977, by Eastern Shore is approved and adopted.

(B) Eastern Shore is relieved of refund obligations in this docket, and this proceeding is terminated.

(C) This order is without prejudice to any findings or orders which have been made or which may hereafter be made by the Commission and is without prejudice to any claims or contentions which may be made by the Commission, the staff or any party or person affected by this order in any proceeding now pending or hereinafter instituted by or against Eastern Shore or any other person or party.

(D) The Secretary shall cause prompt publication of this order in the Federal Register.

By the Commission.

KENNETH F. PLUMB,
Secretary.

APPENDIX A
Eastern Shore Natural Gas Co., Docket No. RP77-17, Settlement Cost of Service, 12 months ended June 30, 1976, as adjusted

<table>
<thead>
<tr>
<th>Description</th>
<th>Settlement</th>
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<tbody>
<tr>
<td>Operating expenses</td>
<td>$4,617,459</td>
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<tr>
<td>Depreciation and amortization expenses</td>
<td>231,265</td>
</tr>
<tr>
<td>Taxes other than income taxes</td>
<td>182,345</td>
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<tr>
<td>Federal income tax</td>
<td>40,222</td>
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<tr>
<td>State income tax</td>
<td>323,314</td>
</tr>
<tr>
<td>Return on rate base</td>
<td>3,734,268</td>
</tr>
<tr>
<td>Total cost of service</td>
<td>4,366,747</td>
</tr>
</tbody>
</table>

Allocated jurisdictional cost of service

<table>
<thead>
<tr>
<th>Amount</th>
<th>Rate</th>
<th>Cost</th>
<th>Weighted Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term debt</td>
<td>$1,479,060</td>
<td>28.9</td>
<td>63.8</td>
</tr>
<tr>
<td>Preferred stock</td>
<td>780,940</td>
<td>7.0</td>
<td>46.2</td>
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<tr>
<td>Common equity</td>
<td>3,165,242</td>
<td>63.2</td>
<td>11.49</td>
</tr>
<tr>
<td>Total</td>
<td>5,011,242</td>
<td>100.0</td>
<td>72.8</td>
</tr>
</tbody>
</table>

NOTICES

APPENDIX A—Continued

Eastern Shore Natural Gas Co., Docket No. RP77-17, Settlement Cost of Service, 12 months ended June 30, 1978, as adjusted

CAPITALIZATION AND RATE OF RETURN

<table>
<thead>
<tr>
<th>Overall Rate of Return</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>(PR Doc. 78-232 Filed 1-5-78; 8:45 am)</td>
<td>9.51</td>
</tr>
</tbody>
</table>

[6740-02] [Docket No. ER77-196]

FLORIDA POWER CORP.
Compliance Filing


Take notice that Florida Power Corp. (Florida), on December 14, 1977, tendered for filing, in compliance with the Commission order of December 15, 1977, approving the settlement agreement in the above-noted docket, settlement agreement revisions to the Florida FERC Electric Tariff schedules. Florida indicates that the revised rate schedule sheets are identical to those included in Appendix A of the settlement agreement approved by the Commission.

Any person desiring to be heard or to protest said filing should file a protest with the Federal Energy Regulatory Commission, 285 North Capitol Street, N.W., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10). All such petitions or protests should be filed on or before January 5, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB, Secretary.

[6740-02] [Docket No. ER70-33]

GREEN MOUNTAIN POWER CORP.
Proposed Tariff Agreement


Take notice that on October 25, 1977, Green Mountain Power Corp. (GMPC) tendered for filing the following tariff agreements between Green Mountain and:

1. Village of Morrisville Water & Light Department (VMWLD): The sale of generation from GMP's No. 5 gas turbine plant. VMWLD requested and GMPC agreed to sell capacity from this gas turbine plant. The contract provides that VMWLD will purchase 2.3 MW of capacity and associated energy from the aforementioned plant. By separate contract, included in the rate filing, GMPC will provide transmission services to VMWLD for the power provided under the generation contract and for power furnished by others.

2. Village of Stowe Water & Light Department (VSWLD): The sale of generation from GMP's No. 5 gas turbine plant. VSWLD requested and GMPC agreed to sell capacity from this gas turbine plant. The contract provides that VSWLD will purchase 5.8 MW of capacity and associated energy from the aforementioned plant. By separate contract, included in the rate filing, GMPC will provide transmission services to VSWLD for the power provided under the generation contract and for power furnished by others.

3. Village of Hardwick Electric Department (VHED): The sale of generation from GMP's No. 5 gas turbine plant. VHED requested and GMPC agreed to sell capacity from this gas turbine plant. The contract provides that VHED will purchase 1.7 MW of capacity and associated energy from the aforementioned plant. By separate contract, included in the rate filing, GMPC will provide transmission services to VHED for the power provided under the generation contract and for power furnished by others.

GMPC proposes an effective date of November 1, 1977, and therefore requests waiver of the Commission's notice requirements.

According to GMPC, copies of this filing have been sent to the Vermont Public Service Board and the aforementioned municipal electric system.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 285 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10). All such petitions or protests should be filed on or before January 5, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB, Secretary.

[6740-02] [Docket No. ER78-133]

THE HARTFORD ELECTRIC LIGHT CO.

Proposed Purchase Agreement


Take notice that on December 18, 1977, the Hartford Electric Light Co. (HELCO) tendered for filing a proposed Purchase Agreement with respect to Middletown Station (Purchase Agreement), dated August 25, 1977 between HELCO and Village of Hardwick Electric Department (Hardwick).

HELCO states that the Purchase Agreement provides for a sale to Hardwick of a specified percentage of capacity and energy from four oil-fired steam generating units (Middletown Unit Nos. 1, 2, 3, and 4) during the period from November 1, 1977 to October 31, 1979, together with related transmission service.

HELCO further states that the capacity charge rate for the proposed service is a rate determined on a cost-of-service basis. The monthly transmission charge is equal to one-twelfth of the annual average unit cost of transmission service on the Northeast Utilities (NU) system determined in accordance with Section 13.9 of the New England Power Pool (NEPOOL) Agreement and the uniform rules adopted by the NEPOOL Executive Committee, multiplied by the number of kilowatts of winter capability which Hardwick is entitled to receive.

HELCO indicates that the energy charge is based on Hardwick's portion of the applicable fuel expenses and no special cost-of-service studies were made to derive this charge.

HELCO requests that the Commission waive the thirty-day notice period and permit the rate schedule to become effective on November 1, 1977.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 285 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10). All such petitions or protests should be filed on or before January 5, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB, Secretary.
La. The sale of natural gas for which a Power Co. on- December therein must file petitions to intervene action to be taken but will not considered.

Applicant states that it is seeking certificate authorization for the sale of natural gas by Applicant for a limited term of one year with pregranted abandonment at the end of said limited term to Mid-Louisiana Gas Co. (Mid-Louisiana) from Applicant's interests in the Monroe Field in Ouachita, Union and Morehouse Parishes, La. The sale of natural gas for which a limited term certificate is sought is covered by a contract dated November 23, 1977. The price at which certification is sought is $1.85 per Mcf, subject to adjustments.

Any person desiring to be heard or to make any protest with reference to said application should file a petition with the Federal Energy Regulatory Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file written petitions to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB, Secretary.

[FR Doc. 78-245 Filed 1-5-78; 8:45 am]

NORTHERN STATES POWER CO.

Supplement No. 1 to Manitoba-United States-Winnipeg-Grand Forks 230 KV Interconnection Agreement; Errata

December 29, 1977.

The filing made by Northern States Power Co. on December 8, 1977, and noticed on December 19, 1977, in the above-noted docket, was made pursuant to Section 202(e) of the Federal Power Act. Pursuant to the Department of Energy Organization Act (Pub. L. 95-91) and the Department of Energy Delegation Order No. 0204-4 issued pursuant thereto, the Secretary of Energy delegated the power to administer Section 202(e) of the Federal Power Act to the Administrator of the Economic Regulatory Administration. Hence, this filing made by Northern States Power Co. is not subject to the jurisdiction of the Federal Economic Regulatory Commission. Consequently, the above-noted docket is cancelled.

KENNETH F. PLUMB, Secretary.

[FR Doc. 78-246 Filed 1-5-78; 8:45 am]

SOUTH CAROLINA ELECTRIC & GAS CO.

Application for Use of Project Property


On October 1, 1977, pursuant to the provisions of the Department of Energy Organization Act (DOE Act), Pub. L. 95-91, 91 Stat. 565 (August 4, 1977) and Executive Order No. 12009, 42 FR 46267 (September 15, 1977), the Federal Power Commission (FERC) ceased to exist and its functions and regulatory responsibilities were transferred to the Secretary of Energy and the Federal Energy Regulatory Commission (FERC) which, as an independent commission within the Department of Energy, was activated on October 1, 1977.

The "savings provisions" of Section 705(b) of the DOE Act provide that proceedings pending before the FERC on the date the DOE Act takes effect shall not be affected, and that orders shall be issued in such proceedings as if the DOE Act had not been enacted. All such proceedings shall be continued, and further actions shall be taken by the appropriate component of DOE now responsible for the functions under the DOE Act and regulations promulgated thereunder. The functions which are the subject of this proceeding were specifically transferred to the FERC by Section 402(a)(1) or Section 402(a)(2) of the DOE Act.

The joint regulation adopted on October 1, 1977, by the Secretary of Energy and the FERC entitled "Transfer of Proceedings to the Secretary of Energy and the FERC," 10 CFR 10.8, provides that this proceeding would be continued before the FERC. The FERC takes action in this proceeding in accordance with the above authorities.

Public notice is hereby given that an application was filed on July 28, 1977, under the Federal Power Act, 16 U.S.C. 719a-825r, by the South Carolina Electric & Gas Co. (Applicant) (Correspondence to: Randolph R. Mchan, Esq., South Carolina Electric & Gas Co., P.O. Box 764, Columbia, S.C. 29218; Brian J. McManus, Esq., Reid & Priest, 1701 K Street NW., Washington, D.C. 20006), the license for the Saluda Project, FERC No. 516, requesting authorization to lease project land for the construction of a causeway between an island and the mainland of Lake Murray. The Saluda Project (Lake Murray) is located in Lexington, Newberry, Richland, and Saluda Counties, near the City of Columbia and the Town of Lexington, S.C.

Applicant requests Commission authorization to lease to certain individuals approximately 2,560 square feet of the lake bed at Lake Murray, located approximately 1.1 miles west of the intersection of State Highway 6 and County Road No. 239 in Lexington County, S.C. The 25-foot by 100-foot parcel of lake bed to be leased would be filled in, and a causeway would be constructed thereon to permit the connection of a 1.84-acre tract to the shore land. The volume of fill to be placed is about 800 cubic yards. Construction of the causeway would permit vehicular access to the private-ly-owned island, upon which the owners intend to build a home.

The application is on file with the Commission and is available for public inspection.

Any person desiring to be heard or to make any protest with reference to this application should, on or before February 21, 1978, file with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20425, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR § 1.6 or § 1.10 (1978). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any hearing in the proceeding must file a petition to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB, Secretary.

[FR Doc. 78-246 Filed 1-5-78; 8:45 am]

WESTERN GAS INTERSTATE CO.

Order Approving Pipeline Rate Settlement Agreement


On October 1, 1977, pursuant to the provisions of the Department of Energy Organization Act (DOE Act), Pub. L. 95-91, 91 Stat. 565 (August 4, 1977) and Executive Order No. 12009, 42 FR 46267 (September 15, 1977), the
Federal Power Commission ceased to exist and its functions and regulatory responsibilities were transferred to the Secretary of Energy and the Federal Energy Regulatory Commission (FERC) which, as an independent commission within the Department of Energy, was activated on October 1, 1977.

The “savings provisions” of section 706(b) of the DOE Act provided that proceedings pending before the FPC on the date the DOE Act takes effect shall not be affected and that orders shall be issued in such proceedings as if the DOE Act had not been enacted. All such proceedings shall be continued and further actions shall be taken by the appropriate component of DOE now responsible for the function under the DOE Act and regulations promulgated thereunder. The functions which are subject of this proceeding were specifically transferred to the FERC by section 402(a)(1) or 402(a)(2) of the DOE Act.

The joint regulation adopted on October 1, 1977, by the Secretary and the FERC entitled, “Transfer of Proceedings to the Secretary of Energy and the FERC,” 10 CFR §4.1, provided that this proceeding would be continued before the FERC. The FERC takes action in this proceeding in accordance with the above-mentioned authorities.

On November 28, 1977, the Presiding Administrative Law Judge certified to the Commission a proposed settlement agreement in the captioned proceeding. If approved, the certified settlement agreement would resolve all issues in this proceeding. For the reason set forth below, the Commission finds that the proposed settlement agreement is reasonable and should be approved.

This proceeding was initiated on May 2, 1977, when Western Gas Interstate Co. (Western) tendered for filing tariff sheets designed to produce an annual increase in jurisdictional revenues of $774,452 based upon the base period ending December 31, 1976, as adjusted. Western's tariff filing also proposed to modify Western's purchased gas cost adjustment clause to allow Western: (1) To determine its gas cost adjustment by utilizing estimated annual purchase and sales volumes rather than actual volumes, and (2) to debit or credit its unrecovered purchased gas cost account monthly balance with a 9 percent per annum carrying charge. The May 2 tariff filing became effective subject to refund on November 1, 1977, as a result of the filing of Western of a motion pursuant to section 4(e) of the Natural Gas Act. Subsequently, on November 28, 1977, pursuant to the agreement of the parties and to article II of the proposed settlement agreement, Western filed proposed revised tariff sheets to reflect the currently effective cost of gas as well as the current surcharge adjustment under Western's PGA clause, and to adjust the filed rate under rate schedule T-1 so as to reflect that portion of the settlement cost of service allocated to service under that rate schedule. By letter order of December 15, 1977, the Commission granted Western's request that the November 23 tariffs be accepted and considered effective as of November 1, 1977.

Following the conclusion of settlement discussions among the parties, the proposed settlement agreement was submitted to the Presiding Administrative Law Judge with a request that it be certified to the Commission. Public notice of the certification was issued calling for the filing of comments on or before December 12, 1977. The Commission staff filed timely comments in support of the agreement. There are no other parties to the proceeding.

The settlement rates, as shown in appendix A hereto, are predicated upon a total cost of service of $7,141,133 as set forth in appendix B. The settlement cost of service includes a rate of return on Western's net investment rate base of 10.39 percent, including a return on common equity of 13.25 percent. (See appendix C.) The settlement rates reflect estimated annual sales of 3,880,703 Mcf, 466,400 Mcf, and 187,703 Mcf for the G-N, T-1, and G-S services respectively. Such rates also reflect Western's current cost of gas and the current surcharge from its PGA clause. Finally, the settlement provides that Western shall determine its PGA gas cost adjustment through use of estimated annual sales volumes rather than actual volumes. Western shall not, however, recover carrying charges on the monthly balance in its unrecovered purchased gas cost account.

Article I of the proposed settlement suggests the termination of refund liability associated with the service rendered by Western under its T-2 rate schedule. That service was authorized by the Federal Power Commission by order issued August 29, 1977, in Docket No. CP77-347. The settlement agreement states that, pursuant to the directive in ordering paragraph (D) of that order, the commission staff reviewed the T-2 rate schedule and concluded that the effective rate of 17.13 cents per Mcf is not excessive. The settlement further states that no change in the T-2 rate is required and that the refund condition imposed by the certificate in Docket No. CP77-347 should be terminated. Inasmuch as staff comments dated November 2, 1977, generally support the proposed settlement and suggest nothing inconsistent with the above conclusion, we shall terminate the refund condition established by the August 29, 1977, order in Docket No. CP77-347.

Based upon a review of the record in this proceeding including the settlement agreement itself and the pleadings, evidence, and comments submitted in support thereof, the Commission finds that the proposed settlement represents a reasonable resolution of the issues in this proceeding in the public interest and that the settlement agreement should accordingly be approved and adopted, as hereinafter ordered.

The tariff sheets which would implement the settlement are attached hereto as appendix C. They are identical to the substitute tariff sheets which were filed on November 23, 1977, and which are allowed by our letter order of December 15 to become effective pending our determination in this proceeding. Given this identity, we will approve the proposed settlement agreement without imposing a refund condition or requiring a further filing of compliance tariffs.

By the Commission.

Kenneth F. Plumb,
Secretary.
NOTICES

APPENDIX B—Western Gas Interstate Co., Overall Cost of Service

<table>
<thead>
<tr>
<th>Description</th>
<th>Southern Division</th>
<th>Northern Division</th>
<th>Western Division (Provisional Portion)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas purchased</td>
<td>$250,173</td>
<td>$3,240,659</td>
<td>$2,974,163</td>
</tr>
<tr>
<td>Other gas supply expenses</td>
<td>2,625</td>
<td>624</td>
<td>642</td>
</tr>
<tr>
<td>Operation and maintenance expenses</td>
<td>28,523</td>
<td>228,854</td>
<td>2,410</td>
</tr>
<tr>
<td>Depreciation, depletion and amortization</td>
<td>2,453</td>
<td>71,123</td>
<td>642</td>
</tr>
<tr>
<td>Taxes other than income</td>
<td>1,447</td>
<td>30,694</td>
<td>322</td>
</tr>
<tr>
<td>Federal and State income taxes</td>
<td>2,501</td>
<td>40,076</td>
<td>362</td>
</tr>
<tr>
<td>Return at 10.39 percent</td>
<td>4,654</td>
<td>117,728</td>
<td>740</td>
</tr>
<tr>
<td>Sub-total</td>
<td>27,428</td>
<td>3,842,570</td>
<td>3,032,659</td>
</tr>
<tr>
<td>Field sales deducted from cost of service</td>
<td>5,055</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cost of service</td>
<td>27,428</td>
<td>3,837,615</td>
<td>3,032,659</td>
</tr>
</tbody>
</table>

APPENDIX C—Western Interstate Gas Co., Rate of Return

<table>
<thead>
<tr>
<th>Ratio</th>
<th>Cost of service (Percent)</th>
<th>Weighted return (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term debt</td>
<td>46.58</td>
<td>52.62</td>
</tr>
<tr>
<td>Preferred stock</td>
<td>9.62</td>
<td>8.58</td>
</tr>
<tr>
<td>Common equity</td>
<td>43.80</td>
<td>15.87</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>12.99</td>
</tr>
</tbody>
</table>

(Docket No. ER78-156)

DUKE POWER CO.

Notice of Supplement to Electric Power Contract


Take notice that Duke Power Co. (Duke Power) tendered for filing on December 19, 1977 a supplement to the Company's Electric Power Contract with Piedmont Electric Membership Corp. Duke Power states that this contract is on file with the Commission and has been designated Duke Power Co. Rate Schedule FPC No. 138.

Duke Power further states that the Company's contract supplement, made at the request of the customer and with agreement obtained from the customer, provides for the following increases in designated demand: Delivery Point No. 2, from 7,000 kW to 9,600 kW; Delivery Point No. 5, from 7,000 kW to 9,200 kW; and Delivery Point No. 6, from 6,500 to 6,800 kW.

Duke Power states that this supplement includes an estimate of sales and revenue for December 1977 and for the 12 months immediately succeeding the effective date. Duke Power proposes an effective date of January 20, 1978.

According to Duke Power copies of this filing were mailed to Blue Ridge Electric Cooperative, Inc. and to the South Carolina Public Service Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 3, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make respondents parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

(Docket No. ER78-157)

DUKE POWER CO.

Notice of Supplement to Electric Power Contract


Take notice that Duke Power Co. (Duke Power) tendered for filing on
December 19, 1977, a supplement to the Company’s Electric Power Contract with the Town of Landis. Duke Power states that this contract is on file with the Commission and has been designated Duke Power Co. Rate Schedule FPC No. 230.

Duke Power further states that the Company’s contract supplement, made at the request of the customer and with agreement obtained from the customer, provides for an increase in contract demand from 6,800 kW to 7,200 kW. Duke Power indicates that the supplement also includes an estimate of rate and revenue for the 12 months immediately preceding and for the 12 months immediately succeeding the effective date. Duke Power requests an effective date of January 20, 1978.

According to Duke Power copies of this filing were mailed to the Town of Landis and the North Carolina Utilities Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission and has been filed with the Commission and is available for public inspection. The Chairman is Mr. Hugh D. Guthrie, Department of Energy, Fossil Energy, Washington, D.C. The Chairman is empowered to conduct the meeting in a manner that will facilitate the orderly conduct of business.

Seating will be available on a first-come, first-served basis. Copies of any minutes will be made available following their certification by the Chairman and Program Director/Fossil Energy at the Department of Energy’s Public Document Room, 20 Massachusetts Avenue, Washington, D.C. 20445, upon payment of all charges required by law.


WILLIAM S. HEFFELFINGER,
Director of Administration.

[FR Doc. 78-347 Filed 1-5-78; 8:45 am]

[6503-01] ENVIRONMENTAL PROTECTION AGENCY

MANAGEMENT ADVISORY GROUP TO THE MUNICIPAL CONSTRUCTION DIVISION

Open Meeting

Under Pub. L. 92-463, notice is hereby given that a meeting of the Management Advisory Group to the Municipal Construction Division (MAG) will be held January 23, 1978. The meeting will begin at 9 a.m. and will be held at Waterside Mall, Room 3906-08, 401 M Street SW., Washington, D.C.

The purpose of the meeting is to brief MAG on the provisions of the new Clean Water Act of 1977 that represents the Mid-Course Correction of the Federal Water Pollution Control Act of 1972 (Pub. L. 92-500).

The meeting will be open to the public. Any member of the public wishing to attend the meeting should contact the Executive Secretary, Mr. Harold P. Cahill, Jr., Director, Municipal Construction Division, EPA, Washington, D.C. 20460. The telephone number is area code 202-245-8886.

THOMAS C. JERLING, Acting Assistant Administrator for Water and Hazardous Materials.


[FR Doc. 78-320 Filed 1-5-78; 8:45 am]
FEDERAL DEPOSIT INSURANCE CORPORATION

ADVISORY COMMITTEE ON STATE AND FEDERAL REGULATION OF BANKS

Notice of Meeting

The Federal Deposit Insurance Corporation Advisory Committee on State and Federal Regulation of Banks will meet on Tuesday, January 24, 1978, at 10:30 a.m., in the 6th floor conference room of the Federal Deposit Insurance Corporation Building, 550 17th Street NW, Washington, D.C.

This Committee was established to advise the director, in charge of a major study of State and Federal bank regulation, on the content and direction of the study, and to review sections of the study as they are completed. The Committee consists of nine members broadly representative of groups which are impacted by banking and the regulation of banks. Notice of the establishment of this committee was published in the FEDERAL REGISTER on December 15, 1977 (Vol. 42, No. 241, page 63219).

The agenda for this meeting is: (1) Progress report; (2) Discussion, comments, and suggestions concerning the study plan.

This meeting will be open to the public, with approximately 30 seats available for the public on an unreserved basis. Questions, comments, or statements to the committee may be submitted in writing prior to the opening of the meeting.

Copies of the minutes of the meeting will be available upon written request 30 days after the meeting.

Inquiries may be directed to Dr. Leonard Lapidus, Special Assistant to the Chairman, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, D.C. 20429, telephone 202-389-4213.


For the Federal Deposit Insurance Corporation,

EDWIN C. HOULDSWORTH, Advisory Officer.

[FR Doc. 78-264 Filed 1-5-78; 8:45 am]

FEDERAL RESERVE SYSTEM

NOTICES

[6210-01]

EQUITABLE BANCORPORATION

Proposed Retention of Branch Offices of Equitable Financial Corp.

Equitable Bancorporation, Baltimore, Md. ("Applicant"), has applied, pursuant to §4(c)(6) of the Bank Holding Company Act (12 U.S.C. §1843(c)(6)) and §225.4(b)(2) of the Board's Regulation Y (12 C.F.R. §225.4(b)(2)), for permission to retain eight branch offices of Equitable Financial Corp., located in Glen Burnie, Lutherville, Rockville, and Camp Springs, Md., McLean, Va., Wilmington, Del., and Raleigh and Greensboro, N.C. Such offices were opened without the Board's prior approval.

Notice of the application has been published in newspapers of general circulation in each of the above communities.

Applicant states that the proposed subsidiary would continue to engage in mortgage banking, factoring, finance company activities, and the servicing of loans and other extensions of credit for any person. Such activities have been specified by the Board in §225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of §225.4(b).

Interested persons may express their views on the question whether concentration of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question should be accompanied by a statement summarizing the evidence the person requesting the hearing proposes to submit or to elicit at the hearing and a statement of the reasons why this matter should not be resolved without a hearing.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Richmond.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than January 26, 1978.


GRIFFITH L. GARWOOD, Deputy Secretary of the Board.

[FR Doc. 78-273 Filed 1-5-78; 8:45 am]
[6820-24] NOTICES

[6820-24] GENERAL SERVICES ADMINISTRATION
FEDERAL PROPERTY MANAGEMENT REGULATIONS
[TEMPORARY REGULATION 7-42]
Delegation of Authority

1. Purpose. This regulation delegates authority to the Secretary of Defense to represent the interests of the executive agencies of the Federal Government in a gas, electric, and steam rate increase proceeding.  
2. Effective date. This regulation is effective immediately.  
3. Delegation. (a) Pursuant to the authority vested in me by the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the executive agencies of the Federal Government before the New York Public Service Commission involving the application of the Niagara Mohawk Gas and Electric Corp., for increases in its gas, electric, and steam rates, Case No. 27215, 27216, 27217.  
(b) The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.  
(c) This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

ROBERT T. GRIFFIN,  
Acting Administrator of General Services.

[FR Doc. 77-26 Filed 1-5-77; 8:45 am]

[6820-24] Proposed Intervention in Rate Increase Proceeding; Formal Case No. 7711-1107  
NEW JERSEY BOARD OF PUBLIC UTILITIES; PUBLIC SERVICE ELECTRIC AND GAS CO.

The Administrator of General Services seeks to intervene in a proceeding before the New Jersey Board of Public Utilities concerning an application of the Public Service Electric and Gas Co., for an increase in its tarifed rates for intrastate electric services. The Administrator of General Services represents the interests of the executive agencies of the United States Government, as users of utility services.

Persons desiring to make inquiries concerning this case to GSA should submit them, in writing, to Mr. Spence W. Perry, Assistant General Counsel, Regulatory Law Division, General Services Administration, 18th and F Streets NW., Washington, D.C. 20405, telephone 202-566-0750, on or before February 6, 1978, and refer to this notice number.

Persons making inquiries are put on notice that the making of an inquiry shall not serve to make any persons parties of record in the proceeding.

(Section 210(a)(4), Federal Property and Administrative Services Act, 40 U.S.C. 481(a)(4))


ROBERT T. GRIFFIN,  
Acting Administrator of General Services.

[FR Doc. 77-26 Filed 1-5-78; 8:45 am]

[6820-24] Proposed Intervention Notice 481
C A L I F O R N I A P U B L I C U T I L I T I E S C O M M I S S I O N; PACIFIC GAS AND ELECTRIC CO.

The Administrator of General Services seeks to intervene in a proceeding before the California Public Utilities Commission concerning an application of the Pacific Gas and Electric Co., for an increase in its tariffed rates for intrastate electric services. The Administrator of General Services represents the interests of the executive agencies of the United States Government, as users of utility services.

Persons desiring to make inquiries concerning this case to GSA should submit them, in writing, to Mr. Spence W. Perry, Assistant General Counsel, Regulatory Law Division, General Services Administration, 18th and F Streets NW., Washington, D.C. 20405, telephone 202-566-0750, on or before February 6, 1978, and refer to this notice number.

Persons making inquiries are put on notice that the making of an inquiry shall not serve to make any persons parties of record in the proceeding.

(Section 210(a)(4), Federal Property and Administrative Services Act, 40 U.S.C. 481(a)(4))


ROBERT T. GRIFFIN,  
Acting Administrator of General Services.

[FR Doc. 78-262 Filed 1-5-78; 8:45 am]

FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978

[6210-01] FINANCIAL BANC SHARES, INC.
Formation of Bank Holding Company

Financial Bancshares, Inc., Topeka, Kans., has applied for the Board's approval under §3(a)(1) of the Bank Holding Company Act (12 U.S.C. §1842(a)(1)) to become a bank holding company by acquiring 95.5 percent of the voting shares of the Kansas State Bank in Holton, Holton, Kans. The factors that are considered in acting on the application are set forth in §3(c) of the Act (12 U.S.C. §1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than January 20, 1978.


GRiffTH L. GARWOOD,  
Deputy Secretary of the Board.

[FR Doc. 78-274 Filed 1-5-78; 8:45 am]

[6210-01] SNOWMASS BANCORPORATION
Formation of Bank Holding Company

Snowmass Bancorporation, West Village, Colo., has applied for the Board's approval under §3(a)(1) of the Bank Holding Company Act (12 U.S.C. §1842(a)(1)) to become a bank holding company by acquiring 100 percent of the voting shares of Bank of Snowmass, West Village, Colo. The factors that are considered in acting on the application are set forth in §3(c) of the Act (12 U.S.C. §1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than January 20, 1978.


GRiffTH L. GARWOOD,  
Deputy Secretary of the Board.

[FR Doc. 78-275 Filed 1-5-78; 8:45 am]
NOTICES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Alcohol, Drug Abuse, and Mental Health Administration

ADVISORY COMMITTEES

Filing of Annual Reports

Notice is hereby given that pursuant to section 13 of Pub. L. 92-463 (5 U.S.C. Appendix I), Annual Reports for all Alcohol, Drug Abuse, and Mental Health Administration Committees have been filed with the Library of Congress. These are:

Alcohol Research Review Committee
Alcohol Training Review Committee
Biological Sciences Training Review Committee
Board of Scientific Counselors, NIMH
Clinical Program-Projects Research Review Committee
Clinical Projects Research Review Committee
Clinical Psychopharmacology Research Review Committee
Committee on Mental Health and Illness of the Elderly
Community Alcoholism Services Review Committee
Continuing Education Review Committee
Crime and Delinquency Review Committee
Developmental Problems Research Review Committee
Drug Abuse Demonstration Review Committee
Drug Abuse Prevention Review Committee
Drug Abuse Research Review Committee
Drug Abuse Training Review Committee
Epidemiologic Studies Review Committee
Experimental and Special Training Review Committee
Experimental Psychology Research Review Committee
Interagency Committee on Federal Activities for Alcohol Abuse and Alcoholism
Mental Health Services Research Review Committee
Mental Health Small Grant Committee
Metropolitan Mental Health Problems Review Committee
Minority Advisory Committee, ADAMHA
Minority Group Mental Health Programs Review Committee
National Advisory Council on Alcohol Abuse and Alcoholism
National Advisory Council on Drug Abuse
National Advisory Council on Mental Health
National Panel on Alcohol, Drug Abuse, and Mental Health
Neuropsychology Research Review Committee
Paraprofessional Manpower Development Review Committee
Personality and Cognition Research Review Committee
Preclinical Psychopharmacology Research Review Committee
Psychiatric Nursing Education Review Committee
Psychiatry Education Review Committee
Psychological Sciences Fellowship Review Committee
Psychology Education Review Committee
Rape Prevention and Control Advisory Committee
Research Scientist Development Review Committee
Social Problems Research Review Committee
Social Sciences Research Review Committee
Social Sciences Training Review Committee
Social Work Education Review Committee

Copies are available to the public for inspection at the Library of Congress, Special Forms Reading Room, Main Building, and on weekdays between 9 a.m. and 4:30 p.m., at the Department of Health, Education, and Welfare, Department Library, North Building, room 1436, 330 Independence Avenue SW., Washington, D.C. 20201, 202-245-6791.


GERALD L. KLEIFMAN,
Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 78-194 Filed 1-5-78; 8:45 am]

[4110-03]

Revocation of licenses

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces that all licenses issued for the manufacture of the biological product fibrinogen (human) were revoked as of December 7, 1977, and the sale, barter, or exchange of fibrinogen (human) by any manufacturer was prohibited as of that date. This action was taken at the request of the licensed manufacturers because the effectiveness of fibrinogen (human) is questioned and other products that carry lower risks of transmitting hepatitis may be used in its place. The Commissioner further gives notice that fibrinogen (human) already sold and delivered by the manufacturer may not be resold after July 1, 1978.

DATES: Effective date of revocation of all licenses for the manufacture of fibrinogen (human) was December 7, 1977. Existing stocks of fibrinogen (human) were prohibited from sale, barter, or exchange by the manufacturer as of that date. Fibrinogen (human) in distribution as of that date is prohibited from sale, barter, or exchange by owners or custodians after July 1, 1978.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (Sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 583350) has been filed by American Cyanamid Co., Wayne, NJ 07470, proposing that §175.105 Adhesives (21 CFR 175.105) be amended to provide for the safe use of sulfosuccinic acid 4-ester with polyethylene glycol dodecyl ether disodium salt in the production of food-packaging materials.

Effective date of revocation may be seen in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday.


HOWARD R. ROBERTS,
Acting Director,
Bureau of Foods.

[FR Doc. 78-55 Filed 1-5-78; 8:45 am]
NOTICES

FEDERAL REGISTER, VOL 43, NO. 4—FRIDAY, JANUARY 6, 1978

and Travenol Laboratories, Inc., Hyland Division, establishment license No. 140, for the manufacture of fibrinogen (human) and prohibited the sale, barter, or exchange of fibrinogen (human) by the manufacturers as of December 7, 1977.

Fibrinogen is the component of blood that forms clots. Deficiencies or abnormalities of fibrinogen, whether hereditary or acquired, may lead to poor blood clotting and abnormal bleeding.

Fibrinogen (human) is a biological product that has been licensed since 1947. The product has been recommended for treating patients who are bleeding and have low fibrinogen levels and for prophylaxis in patients with abnormally low fibrinogen levels when a major stress to the blood coagulation system is anticipated. Because the human hemostatic process consists of a series of complex vascular and biochemical reactions, fibrinogen level alone is not always a valid measure of appropriate therapy. In most cases where the administration of fibrinogen is indicated, many abnormalities exist and simple infusion of fibrinogen will not produce normal coagulation.

For this reason, the clinical effectiveness of fibrinogen (human) is difficult to assess, and there are few valid indications for its use.

Fibrinogen (human) is prepared from plasma pooled from a large number of donors. Heat treatment to inactivate hepatitis B virus in fibrinogen (human) will adversely affect the potency of the product. For these reasons, fibrinogen (human) administration is associated with a higher risk of transmitting hepatitis B than products derived from single units of plasma. In those few clinical cases in which fibrinogen replacement is deemed necessary by the attending physician, cryoprecipitated plasma fibrinogen (human) and other products prepared from single units of plasma may be used as a source of fibrinogen. This will diminish the hepatitis risk.

The Advisory Panel of Review of Blood and Blood Derivatives, established pursuant to section 601.25 (21 CFR 601.25), therefore recommended that fibrinogen (human) be withdrawn from the marketplace and that other products, such as cryoprecipitated antihemophilic factor (human), be used as a source of fibrinogen in the few clinical cases in which such therapy is indicated. In response to the panel’s recommendations, all licensed manufacturers of fibrinogen (human) requested that their licenses be revoked and waived the opportunity for a hearing pursuant to section 601.5(a) (21 CFR 601.5(a)).

Accordingly, the Commissioner announces the revocation, effective December 7, 1977, of all product licenses for the manufacture of fibrinogen (human). To facilitate the orderly transition by physicians, hospitals, and blood banks from the use of fibrinogen (human) to other appropriate products used for treatment of clotting problems, and pursuant to section 601(a) of the Public Health Service Act (42 U.S.C. 265(a)), the Commissioner is hereby giving notice that fibrinogen (human) which has already been sold and delivered by licenses may be resold through July 1, 1978, or the expiration date, whichever is earlier.


JOSEPH P. HILE, Associate Commissioner for Compliance.

(FR Doc. 78-54 Filed 1-5-78; 8:45 am)

ROHM & HAAS CO.

Notice of Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Rohm & Haas Co. has filed a petition proposing that the food additive regulations be amended to provide for the use of allyl methacrylate in acrylic and modified acrylic plastics, semirigid and rigid, intended for repeated food-contact use.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1788 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 653172) has been filed by Rohm & Haas Co., Independence Mall West, Philadelphia, Pa. 19106, proposing that the food additive regulations be amended to provide for the use of allyl methacrylate in acrylic and modified acrylic plastics, semirigid and rigid, intended for repeated food-contact use.

The environmental impact analysis report and other relevant material have been reviewed, and it has been determined that the proposed use of the additive will not have a significant environmental impact. Copies of the environmental impact analysis report may be seen in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

[1505-01]

[Docket No. 75N-0223; DSEI 697, 3255, 4661]

CERTAIN ANTIHISTAMINIC DRUGS IN CONTROLLED-RELEASE DOSAGE FORM

Withdrawal of Approval of New Drug Applications

Correction

In FR Doc. 77-29182 appearing at page 54617 in the issue for Friday, October 7, 1977, on page 54618, in the middle column, the center hearing "DESI 3625" should be changed to read "DESI 3285."


HOWARD R. ROBERTS, Acting Director, Bureau of Foods.

(FR Doc. 78-83 Filed 1-5-78; 8:45 am)

[1505-01]

[Docket No. 75N-0377, 76N-0356; DSEI Nos. 7661, 1543]

CERTAIN DRUGS CONTAINING FLUOXYMESTERONE AND ETHINYL ESTRADIOL; DIETHYLSTILBESTROL AND METHYLPERSTEROSE; CHLORDIAZEPXIDINE AND METHYLPERSTEROSE; OR TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE; AND CERTAIN ESTROGEN-CONTAINING DRUGS FOR ORAL OR PARENTERAL USE

Drugs for Human Use; Drug Efficacy Study Implementation; Followup Notice and Opportunity for Hearing; Amendment

Correction

In FR Doc. 77-29312 appearing on page 54621 in the issue for Friday, October 7, 1977, in the second paragraph under "Supplementary Information," in the third line, after the word "preparations," insert "... This was an error in that there were no conjugated estrogen preparations..."

[4110-03]

DERMATOLOGY ADVISORY COMMITTEE

Notice of Renewal

AGENCY: Food and Drug Administration.

ACTION: Notice.


DATE: Authority for this committee will expire on October 31, 1979, unless the Secretary formally determines
NOTICES

that continuance is in the public interest.

FOR FURTHER INFORMATION CONTACT:
Richard L. Schmidt, Committee Management Officer (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.
William F. Randolph, Acting Associate Commissioner for Compliance.

[4110-03]

PANEL ON REVIEW OF ANTIPERSPIRANT DRUG PRODUCTS
Notice of Renewal

AGENCY: Food and Drug Administration.

ACTION: Notice.


DATE: Authority for this committee will expire on December 31, 1978, unless the Secretary formally determines that continuance is in the public interest.

FOR FURTHER INFORMATION CONTACT:
Richard L. Schmidt, Committee Management Officer (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.
William F. Randolph, Acting Associate Commissioner for Compliance.

[FR Doc. 78-195 Filed 1-5-78; 8:45 am]

[4110-03]

PANEL ON REVIEW OF MISCELLANEOUS INTERNAL DRUG PRODUCTS
Notice of Renewal

AGENCY: Food and Drug Administration.

ACTION: Notice.


DATE: Authority for this committee will expire on December 31, 1978, unless the Secretary formally determines that continuance is in the public interest.

FOR FURTHER INFORMATION CONTACT:
Richard L. Schmidt, Committee Management Officer (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.
William F. Randolph, Acting Associate Commissioner for Compliance.

[FR Doc. 78-199 Filed 1-5-78; 8:45 am]

[4110-03]

PANEL ON REVIEW OF CONTRACEPTIVE AND OTHER VAGINAL DRUG PRODUCTS
Renewal

AGENCY: Food and Drug Administration.

ACTION: Notice.


DATE: Authority for this committee will expire on October 31, 1978, unless the Secretary formally determines that continuance is in the public interest.

FOR FURTHER INFORMATION CONTACT:
Richard L. Schmidt, Committee Management Officer (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.
William F. Randolph, Acting Associate Commissioner for Compliance.

[FR Doc. 78-192 Filed 1-5-78; 8:45 am]

[4110-83]

HEALTH RESOURCES ADMINISTRATION
GRADUATE MEDICAL EDUCATION NATIONAL ADVISORY COMMITTEE

Filing of Annual Report

Notice is hereby given that pursuant to section 13 of Pub. L. 92-463, the Annual Report for the following Health Resources Administration Federal Advisory Committee has been filed with the Library of Congress:

GRADUATE MEDICAL EDUCATION NATIONAL ADVISORY COMMITTEE

Copies are available to the public for inspection at the library of Congress, Special Forms Reading Room, Main Building, or weekdays between 9 a.m. and 4:30 p.m. at the Department of Health, Education, and Welfare, Department Library, North Building, Room 1438, 330 Independence Avenue SW, Washington, D.C. 20201, telephone 202-267-8771. Copies may be obtained from Frederick V. Featherstone, M.D., Bureau of Health Manpower, Room 4-42, 3700 East-West Highway, Hyattsville, Md. 20782, telephone 301-456-6430.
James A. Walsh, Associate Administrator for Operations and Management.

[FR Doc. 78-197 Filed 1-5-78; 8:45 am]
Act (Pub. L. 92-463), announcement is

[16x746]vices, Room
[17x466]Bureau of Community Health Ser-
[17x492]other relevant information should
[17x692]Date and time: February
[17x707]Name: Maternal and
[17x720]the month of February
[18x259]Health, Education, and Welfare is
[18x458]5600
[19x164]Assistance have been previously pub-
[19x173]regional Offices of Student Financial
[24x522]to Public Law 92-463.
[24x529]Health Services Administration, pursuant
[24x537]the Determination
[24x545]section 552b(c)(6), Title
[24x554]for the review
[24x560]the review of all research grant applica-
[24x599]the review of grant applications for Feder-
[24x614]Bureau of Community Health Services.
[24x622]and child health administered
[24x638]the review of all research grant applica-
[24x677]Md.
[298x421].the Office of the Principal Regional
[299x730]Office of the Regional Commissioner
[363x421].the Office of the Principal Regional
[365x706]ing issues and educational problems of
[365x714]technical assistance resource In resolv-
[365x741]technical liaison with the HEW ad-
[366x404]source staff in resolving education pro.
[366x430]Provides expert technical assistance to
[366x439]needs of the educational community.
[366x455]ing the views of the regional education
[366x463]effectiveness and in actively determin-
[366x481]officials at State and local levels, in as-
[366x507]of the Principal Regional Official. Acts
[366x516]which are elements of the Office of
[366x526]grams, and directives for the entire
[366x534]interpretation of Federal policies, pro-
[366x543]Provides technical assistance through
[366x552]programs utilizing Federal resources.
[366x569]and alternatives In the initial planning
[366x577]developing new educational strategies
[366x585]and education 'for the Handicapped,
[366x592]elementary and secondary education,
[366x603]knowledge of all Office of Education
[366x612]grams. Through a comprehensive
[366x637]seeking access to an equity in the use
[366x646]all institutions, groups, and Individuals
[366x663]and education 'for the Handicapped,
[366x671]tion, higher and continuing education,
[366x680]occupational education, adult educa-
[366x689]a new, evolving and complex nature In
[366x697]education 'for the Handicapped,
[366x696]education, and education ‘for the Handicapped,
[366x694]an effective pattern
[366x720]vices Division, Office of Public Affairs:
[366x739](EED1PE-EEDXPE).-Serves as
[366x741]technical liaison with the HEW ad-
[366x750]vises as a principal staff resource in cross-
[366x768]ment, the National Institute of Educa-
[366x786]al leadership in resolving educational
[366x794]complex or evolving nature.

Provides coordination with the Office

of the Regional Commissioner

for Federal Student Assistance Programs,

for the review of grant applications for Federal

Grants Review Committee.

Agenda: The Committee will be performing the review of grant applications for Federal assistance. This meeting will be open to the public from 9 to 10 a.m., February 1 for the Opening Remarks. The remainder of the meeting will be closed to the public for the review of grant applications, in accordance with the provisions set forth in section 552b(c)(6), Title 5, U.S. Code and the Determination of Authority of the Department of Health Services Administration, pursuant to Public Law 92-463.

Anyone wishing to obtain a roster of the members, minutes of meeting, or other relevant information should contact Vincent L. Hutchins, M.D., Bureau of Community Health Services, Room 7-59 Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, telephone 301-443-2170.

Agenda items are subject to change as priorities dictate.


WILLIAM H. ASPDEN, JR.,
Associate Administrator for
Management.

(FR Doc. 78-198 Filed 1-5-78; 8:45 am)

[4110-02]

Office of Education

REGIONAL OFFICES OF EDUCATIONAL PROGRAMS

Statement of Organization, Functions, and Delegations of Authority

Part EE.10 of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health, Education, and Welfare is hereby amended to reflect the creation of Regional Offices of Educational Programs as required by the Secretary's reorganization memorandum of July 19, 1977. The Secretary's memorandum abolished the previous Office of Education regional office structures and replaced it with two others. The statements creating the regional Offices of Student Financial Assistance have been previously published at 42 FR 45378 (September 9, 1977).

The specific changes are as follows:

1. Functional statements for the new Offices of Educational Programs are added immediately following the title and statement for the Editorial Services Division, Office of Public Affairs: Office of the Regional Commissioner for Educational Program (EED1PE-EEDXPE)—Serves as a technical assistance resource in resolving issues and educational problems of a new, evolving and complex nature in elementary and secondary education, occupational education, adult education, and education for the Handicapped. Particular emphasis is upon service to all institutions, groups, and individuals seeking access to an equity in the use of Federal resources for the development of improved educational programs. Through a comprehensive knowledge of all Office of Education and Education Division Programs, staff provides expert assistance in developing new educational strategies and alternatives in the initial planning and implementation of educational programs utilizing Federal resources. Provides technical assistance through interpretation of Federal policies, programs, and directives for the entire education community of a region. Through the Regional Commissioner for Educational Programs, the Commissioner of Education and responsible central office program heads with a continuous communication network on the impact of Federal education programs, interpretation of Federal policies, programs, and directives for the entire education community of a region. Provides expert technical assistance to the Office of the Principal Regional Official for Educational Programs and for the entire education community of a region. Provides technical assistance in resolving educational problems of a new, evolving and complex nature in elementary and secondary education, occupational education, adult education, and education for the Handicapped. Particular emphasis is upon service to all institutions, groups, and individuals seeking access to an equity in the use of Federal resources for the development of improved educational programs. Through a comprehensive knowledge of all Office of Education and Education Division Programs, staff provides expert assistance in developing new educational strategies and alternatives in the initial planning and implementation of educational programs utilizing Federal resources. Provides technical assistance through interpretation of Federal policies, programs, and directives for the entire education community of a region. Through the Regional Commissioner for Educational Programs, the Commissioner of Education and responsible central office program heads with a continuous communication network on the impact of Federal education programs, interpretation of Federal policies, programs, and directives for the entire education community of a region.

Division of Educational Dissemination (EED1PD-EEDXPD)—Provides a regional center for the dissemination of information about the program and activities of the agencies in the Education Division and provides such services in a manner consistent with the policies and procedures of the agencies involved. Directs systematic communication activities with the education community of the region on legislation, program priorities, research findings, evaluation results, and policy directions which involve the agencies of the Education Division. Provides leadership in identifying and disseminating proven research findings and validated practices and acts as a catalyst in implementing and diffusing proven practices. Provides dissemination workshops and briefings in the region as a basic responsibility in dissemination services. Identifies exemplary projects and programs in the region and provides assistance in submission for such projects to the Joint Dissemination Review Panel, consistent with policies and procedures. Develops sys-
SUPPLEMENTARY INFORMATION: The Department of Health, Education, and Welfare has initiated a major project called Project Match, to reduce fraud and abuse in the aid to families with dependent children (AFDC) program as administered by DHEW. This project seeks to identify and take action, where appropriate, against those Federal employees who are illegally receiving such benefits. The project uses as its primary source of information data collected by means of a comparison by computer of the entire Federal civilian and military workforce obtained from the Civil Service Commission and the Department of Defense with the AFDC rolls provided by State agencies as the data has been collected all original source computer tapes are promptly returned to the source or destroyed. The records collected by this process will be carefully validated to confirm that each individual identified is or has been in fact employed by the Federal agency and at the same time illegally in receipt of AFDC payments. The new routine use proposed for the system of records investigative files of the Inspector General will facilitate DHEW's disclosure of information about the cases identified to the Federal agency listed as the employing agency in order to validate employment and provide back to HEW information about the employment status and income earned for the period 1974 through 1977.

The minor technical amendments indicate the location where the records maintained in the system of records notice primarily to include records collected by means of computer processing. Dated: December 27, 1977.

CHARLES MILLER, Acting Assistant Secretary for Management and Budget.

[FR Doc. 78-223 Filed 1-5-78; 8:45 am]

NOTICES

Office of the Secretary
PRIVACY ACT OF 1974

New Routine Use and Minor Technical Amendments to Notice of System of Records

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notification of new routine use and minor technical amendments to the notice of systems of records investigatory files of the Inspector General, DHEW, No. 09-90-0003.

SUMMARY: The Department of Health, Education, and Welfare (DHEW) proposes to establish an additional new routine use applicable to the system of records entitled investigatory files of the Inspector General, DHEW under the Privacy Act. The Department also proposes certain minor technical amendments to the system of records notice primarily to include records collected by means of computer processing.

DATES: The routine use and minor technical amendments shall become effective as proposed without further notice on February 5, 1978, unless comments are received on or before February 5, 1978, which would result in a contrary determination.

ADDRESS: Comments should be addressed to Acting Director, Fair Information Practice Staff, Department of Health, Education, and Welfare, 200 Independence Avenue SW., Washington, D.C. 20201. Comments received will be available for inspection in Room H. F. Humphreys Building, at the above address.

FOR FURTHER INFORMATION CONTACT:


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NOTICES

FOOD AND DRUG ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority


Section HF-B, Organization, is amended in paragraph (k), Bureau of Foods (HF), as follows:

(1) Delete paragraph (k-3-3) in its entirety and substitute the following:

(k-3-D Division of Regulatory Guidance (HF/FG). Develops or participates in the development of regulations which implement, interpret, and grant exemptions to those provisions of the laws pertinent to Bureau responsibilities.

Develops and recommends adoption of Agency compliance policy on food, cosmetic, pesticide, and food chemical matters.

Recommends legislation or regulations proposed legislation to solve compliance problems.

Manages the development of controversial or precedent-setting cases; develops and maintains legal guidelines for field use in specific areas and recommends delegations of authority to the field/district offices for direct handling of regulatory actions as necessary.

Reviews and approves or disapproves proposed regulatory actions in areas where authority for direct case handling has not been delegated to the field/district offices; provides guidance to the field/district offices in these areas and provides technical support for case development and contested court cases.
NOTICES

standing with foreign governments to obtain compliance with Federal Food, Drug, and Cosmetic Act requirements for imported food products. Maintains liaison with the Office of Compliance on matters relating to such agreements.

Directs the registration of domestic and foreign low-acid canned food manufacturers and their process filling under the requirements of 21 CFR 108.

Assists field offices, upon request, in the planning and implementation of workshops and seminars for the food, cosmetic, and related industries on current good manufacturing practices and various problem areas.

Assists in the conduct of conferences, seminars, and meetings on specific industry compliance problems and on consumer educational activities in cooperation with the Office of Professional and Consumer Programs (OPCP), and other FDA components, trade associations, and professional and academic groups.

Monitors the implementation of industry quality assurance activities designed to prevent compliance failures, develops plans to help industry improve quality control capabilities.

Develops and issues, with the concurrence of EDRO, OPCP, and OA, consumer education programs for field implementation; coordinates the development and distribution to the field of program support material.

(3) Delete paragraph (k-6-ii) in its entirety and substitute the following:

(k-6-ii) Division of Retail Food Protection (HFPS). Plans, develops, and directs FDA activities to reduce consumer hazards by assisting State and local governments in maintaining effective food protection programs for the retail segment of the food industry including food service, retail food marketing, and food vending.

Develops, revises, and interprets Model Ordinances and guides pertinent to food service, retail food markets, and food vending in cooperation with other components of FDA. Promotes the adoption and uniform application of Model Ordinances by States and municipalities in conjunction with the Executive Director of Regional Operations (EDRO).

Provides technical assistance and advice, as requested, regarding retail food sanitation problems and the development of sanitation standards for food service, retail food market, and food vending equipment.

Assists FDA field offices in maintaining and increasing the competence, uniformity, and consistency of State and local government regulatory work.

Develops model programs and initiatives to assist State and local governments in retail food protection programs.

Provides technical and instructor support to the Cincinnati Training Facility, EDRO in the development and presentation of food training courses for State and local governments; promotes and supports industry training in food protection.

Promotes and coordinates, in cooperation with EDRO, field activities relating to the inspection of food service establishments in Federal buildings under reimbursable agreements with the General Services Administration.

Develops programs for field investigations to solve current and emerging problems of food safety in the retail segment of the industry and evaluates related industry innovations.


CHARLES MILLER,
Acting Assistant Secretary for Management and Budget.

[FR Doc. 78-18 Filed 1-5-78; 8:45 am]

[4110-85]

HEALTH RESOURCES ADMINISTRATION

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HA (Office of the Assistant Secretary for Health) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health, Education, and Welfare (38 FR 18571, July 12, 1973, as amended most recently at 42 FR 61317, December 2, 1977) is amended to reflect the organizational relocation of the Office of Health Information and Health Promotion and the President's Council on Physical Fitness and Sports to the General Services Administration.

Deletes the statement for the Deputy Assistant Secretary for Health Promotion from "(HAS)" to "(HAR)" and removes the Deputy Assistant Secretary for Special Health Initiatives; removes President's Council on Physical Fitness and Sports (HAR-2) with its amended functional statement in its entirety and places under the Office of Special Health Initiatives (HAR).

Change the code designation of Office of Health Information and Health Promotion from "(HAR-1)" to "(HAR-2)" and change that portion of item (5) that reads "Office of Health Policy Analysis and Planning" to read "Office of Health Policy, Research and Statistics" remove Office of Health Information and Health Promotion (HAR-1) with the amended functional statement in its entirety and place under the Office of Special Health Initiatives (HAR).

Amend the statement for Office of Health Programs (HAS) by adding in item (9) the words "reimbursable services," between the words "quality assurance" and "and health care financing," and by deleting item (12) in its entirety. Rename items (13) and (14) to read items (12) and (13) respectively.

Amend the statement for Office of Health Policy, Research and Statistics (HAR) by deleting that portion of item (16) that reads "the Health Information, health promotion.

Delete the statements for the Office of Health Practices Assessment (HASS) and its Division of Policy Development and Research (HASS-1) and Office of Science Technology Transfer (HASS-2) in their entirety and substitute the following:

Office of Health Practice Assessment (HAS). The Office of Health Practice Assessment: (1) Provides scientific, professional, and technical advice and serves as the principal advisor to the Assistant Secretary for Health concerning the assessment of health and medical practice and the assurance of quality of care; (2) has lead responsibility for PHS efforts to assess health technologies (drugs, devices, and procedures) and encourages their appropriate transfer into medical practice; (3) coordinates for the Assistant Secretary for Health PHS activities to disseminate Information to the practicing community and health insurers re-
Division of Health Technology Assessment and Transfer (HAS52). (1) Carries out the responsibilities of the Office of Health Practice Assessment to coordinate PHS efforts regarding health technology assessment and transfer; (2) develops mechanisms and relationships, including approaches for identifying priority issues and developing technical consensus, to facilitate assessment of the effectiveness of drugs, devices, and procedures, and to foster the appropriate adoption of these health technologies by the practicing community; (3) coordinates PHS efforts to disseminate information regarding the effectiveness of medical technologies to the medical profession through Professional Standards Review Organizations and other channels; and (4) coordinates PHS resources required for the Assistant Secretary for Health to provide to HCFA professional advice and recommendations regarding reimbursable (covered) services under the Department's health care financing programs.

Amend the statement for Division of Extramural Research (HAT13) at item (6) by deleting the words "Policy Analysis and" between the words "Office of" and "Program Development."

Amend the statement for Office of Program Support (HAT21) by adding the words "Within guidance and policies provided by the Office of Management," between "(HAT21)" and "directs and conducts."
NOTICES

11662, Battle, Battle No. 1, Big Horse and Diamond lodes;
Secs. 21 and 22, patent No. 34947 as
described by Mineral Survey 14545, Summit
Rgs., T., Rgs., and Secs. 19, 20, and 21 lodes.
Patent No. 35440 as described by Min-
eral Survey 14633, Little Topsy lode, and
Patent No. 37325, as described by Miner-
al Survey 15752, Marie N. lode, exclusive
of areas of these claims within Cripple
Creek Ranches Filing No. 2, as recorded in
plat book F at pages 82 and 83, Office of the
Clerk and Recorder; Teller County, Cripple
Creek, Colo.

T. 5 S., R. 81 W.,
Sec 22, NW¼Sec.
T. 13 S., R. 96 W.,
Sec. 12, SW¼NW¼ and SW¼NE¼.
T. 15 S., R. 93 W.,
Sec. 19, NE¼SE¼ and SE¼SW¼;
Sec. 20, NW¼SW¼ and SW¼NW¼;
Sec. 31, NE¼SW¼ and SE¼;
Sec. 32, SW¼SW¼.
T. 5 S., R. 85 W.,
Sec. 4, E½SW¼.
T. 15 S., R. 97 W.,
Sec. 23, lots 4, 6, 8, 9, SW¼SE¼, W½SE¼,
and SE¼;
Sec. 24, lot 4;
Sec. 25, lot 2, NW¼NW¼, S½N½W¼, and
N½W½S¼;
Sec. 26, NW¼NE¼ and NW¼NW¼.
T. 12 S., R. 101 W.,
A tract of land in Lot 2 Tract 61;
beginning at corner No. 1, identical with
corner No. 1, from corner No. 1, by metes and
bounds, south 89° 58' W., 660 feet to corner No. 2, south
1,319.62 feet to corner No. 3, east 660 feet,
to corner No. 4, identical with the
to corner No. 4, identical with the
true point for corner No. 4 of Tract 61, north
1,320 feet to corner No. 1, the place of
the place of

The areas described aggregate
6,236.57 acres in Mesa, Delta, Monte-
zm, LaPlata, Teller, Montrose, Gar-
field, Moffat, Gunnison, Hinsdale, San
Miguel, and Eagle Counties.

2. The areas described are native
rangeland or scattered in western Colorado. They are being managed,
together with adjoining public lands for
multiple resource use.

3. Subject to valid existing rights,
the provisions of existing withdrawals and the requirements of applicable
law, these lands will be open to oper-
ation of the public land laws, including
the mining laws, chapter 2, Title 30
U.S.C., and the mineral leasing laws
at 10 a.m. on February 2, 1978. All
valid applications received at or prior
to 10:00 a.m. February 2, 1978, shall be
considered as simultaneously filed at
that time. No received thereafter shall be
considered in the order of filing. Mineral interests were not con-
veyed to the United States with the lands described above in T. 36 N., R. 74
W.; T. 61 N., R. 10 W.; T. 81 N., R. 10 W.; T. 39 N., R. 18 W.; Tvpys. 37 and 38 N., R. 20 W.,
New Mexico Principal Meridian; and
T. 75 S., R. 93 W.; T. 13 S., R. 90 W.; T. 15 S., R. 93 W.; T. 5 S., R. 90 W.; Lots 3, 4, and 5 of section 23, T. 15 S., R. 97
W., and T. 12 S., R. 101 W., Sixth Prin-
cipal Meridian.

4. Inquiries concerning the lands
should be directed to the under-
signed, Bureau of Land Management,
700 Colorado State Bank Building,
1600 Broadway, Denver, Colo. 80202.

THOMAS N. HARDIN,
Chief, Branch of Adjudication.
[FR Doc. 78-217 Filed 1-5-78; 8:45 am]

[4310-84]

IDaho

Opportunity for Public Hearing and Republi-
cation of Notice of Proposed Withdrawal

December 30, 1977.
The Fish and Wildlife Service filed
application Serial No. I-4874, on
March 6, 1972, for a withdrawal in re-
lation to the following described lands:

Boise Meridian
T. 11 N., R. 3E,
Sec. 3, lot 7;
Sec. 10, unsurveyed island lying in
SE¼Sec.,
Sec. 15, unsurveyed island lying in
SE¼Sec., unsurveyed island lying in
sections 14 and 15, unsurveyed island
lying in sections 15 and 22.

The area described aggregates
8.2 acres, more or less, in Valley County.
The applicant desires the land for
public purposes, for management of
migrating waterfowl and other wildlife
as a part of the Deer Flat National
Wildlife Refuge.

A notice of the proposed withdrawal
was published in the Federal Register
on April 5, 1972, page 6675, volume No.
36, document No. 72-5165.

Pursuant to section 204(h) of the
Federal Land Policy and Management
Act of 1976, 90 Stat. 2754, notice is
hereby given that an opportunity for a
hearing is afforded in connection with
the pending withdrawal application.
All interested persons who desire to hear
on the proposed withdrawal must file a
document for a hearing with the State
Director, Bureau of Land Management,
Federal Building, 550 West Fort Street,
Box 042, Boise, Idaho 83724.

WILLIAM E. IRELAND,
Acting Chief, Branch of Lands
and Minerals Operations.
[FR Doc. 78-218 Filed 1-5-78; 8:45 am]

[4310-84]

Wyoming

Application

December 30, 1977.
Notice is hereby given that pursuant
to section 28 of the Mineral Leasing
Act of 1920, as amended (30 U.S.C.
185), the Cities Service Gas Co. of
Oklahoma City, Okla., filed an applica-
tion for a right-of-way to construct a
4 inch natural gas pipeline for the
purpose of transporting natural gas across
the following described public lands:

Sixth Principal Meridian, Wyoming
T. 23 N., R. 94 W.,
Sec. 28, NW¼NW¼.

The proposed pipeline will extend from the Cheyenne 450 wellhead loc-
cated in the SW¼ of section 21, T. 23
N., R. 94 W., and will connect with Cities Service Co.'s existing gather-
ing line located in the SW¼ of sec-
tion 29, T. 23 N., R. 94 W., Sweetwater
County, Wyo.

The purpose of this notice is to
inform the public that the Bureau will
be proceeding with consideration of
whether the application should be
approved, and if so, under what terms
and conditions.

Interested persons desiring to ex-
press their views should do so promptly.
Persons submitting comments
should include their name and address

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and send them to the District Manager, Bureau of Land Management, 1300 Third Street, P.O. Box 670, Rawlins, Wyo. 82301.

LARRY L. STEWARD, Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-219 Filed 1-5-78; 8:45 am]

NOTICES

[1505-01]

JOINT BOARD FOR THE ENROLLMENT OF ACTUARIES

ADVISORY COMMITTEE ON JOINT BOARD ACTUARIAL EXAMINATIONS

Meeting

Correction

In FR Doc. 77-36853 appearing at page 64747 in the issue for Wednesday, December 28, 1977, in the first paragraph, the date of the meeting now reading "January 15, 1978" should have read "January 25, 1978".

[4510-30]

DEPARTMENT OF LABOR

Employment and Training Administration

EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATIONS UNDER THE RURAL DEVELOPMENT ACT

Notice of Applications

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the Consolidated Farm and Rural Development Act, as amended, 7 U.S.C. 1924(b), 1932, or 1942(b).

The Act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate or subsidiary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the intention of closing down an operating facility.

The Act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production of goods, materials, or commodities, or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing competitive enterprises in the area.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.

2. Employment trends in the same industry in the local area.

3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.

4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).

5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within two weeks of publication of this notice to: Deputy Assistant Secretary for Employment and Training, 601 D St., NW., Washington, D.C. 20213.

Signed at Washington, D.C. this 30th day of December 1977.

ERNEST G. GREEN, Assistant Secretary for Employment and Training.

APPLICATIONS RECEIVED DURING THE WEEK ENDING DECEMBER 30, 1977

Name of Applicant, Location of Enterprise, and Principal Product or Activity

Laurels Country Club Inc., Thompson, N.Y., Resort hotel complex.


[FR Doc. 78-73 Filed 1-5-78; 8:45 am]
The investigation was initiated on March 28, 1977 in response to a worker petition received on March 24, 1977 which was filed by the United Rubber Workers of America on behalf of workers and former workers producing polyvinyl chloride (PVC) film and sheeting and PVC compound at Atlantic Tubing and Rubber Co., Cranston, R.I.

The Notice of Investigation was published in the FEDERAL REGISTER on April 12, 1977 (42 FR 11212). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Atlantic Tubing and Rubber Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, the U.S. Department of the Treasury, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

2. That sales or production, or both, of such firm or subdivision have decreased absolutely;

3. That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

4. That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is importantly but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

The Department's investigation revealed that the products manufactured by Atlantic Tubing and Rubber Co., Cranston, R.I. included PVC film and sheeting, PVC compound, plastic garden hose, and floor tile (vinyl and tile asbestos). The largest proportion of Atlantic's sales (approximately 75 percent in 1976) consisted of PVC sheet and film and PVC compound.

Customers surveyed who purchased PVC compound from Atlantic indicated that they did not purchase imported PVC compound. The majority of PVC sheet and film customers surveyed either decreased import purchases or bought no imports at all during 1976 and the first six months of 1977. Customers surveyed who decreased purchases from Atlantic indicated they did not increase purchases from foreign sources.
 principally from officials of Dana Corp., Spicer Transmission Division, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (3) has not been met.

In the Department's previous investigation (TA-W-872) workers at Dana's Toledo, Ohio plant engaged in employment related to the production of truck transmissions and parts who became separated on or after April 20, 1975 and before April 2, 1976 were certified eligible to apply for adjustment assistance. The termination date was included because of declining imports in 1975. Imports of truck transmissions declined 48.7 percent from 1975 to 1976 and declined 20.3 percent in the first half of 1977 compared to the same period in 1976. The ratio of imports to domestic production declined from 3.5 percent in 1975 to 1.5 percent in 1976 and again dropped in the first half of 1977 to 1.5 percent compared to 2.0 percent for the same period in 1976.

Imports of transfer cases were negligible in 1976 and 1977 according to industry and government sources.

Conclusion

After careful review of the facts obtained in the investigation I conclude that increases of imports of articles like or directly competitive with heavy duty truck transmissions and transfer cases produced by the Toledo, Ohio plant of Dana Corp., Spicer Transmission Division did not contribute importantly to the decline in sales or production or separations of workers of that firm as required in Section 222 of the Trade Act of 1974. The petition is, therefore, denied.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2115: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on June 1, 1977 in response to a worker petition received on May 31, 1977 which was filed by the Amalgamated Clothing and Textile Workers Union on behalf of workers and former workers producing men's, boys' and ladies' slacks at Dury Clothing Co., Inc., West Pittston, Pa. During the course of the investigation it was revealed that Dury Clothing Co. also produces men's and women's shorts and that Dury does not produce boys' slacks.

The notice of investigation was published in the Federal Register on June 17, 1977, (42 FR 30858). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Dury Clothing Co., Inc., its manufacturers, the customers of the manufacturers, the National Cotton Council of America, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The investigation revealed that all of the above criteria have been met.

Significant Total or Partial Separations

Average employment of production workers increased 2 percent from 1974 to 1975, declined 8 percent from 1975 to 1976 and then declined 23 percent in the first five months of 1977 when compared to the same period in 1976. The plant was closed for lack of work during the last week in July 1976 and the first week of August 1976.

Sales or Production, or Both, Have Decreased Absolutely

Total sales of Dury Clothing, Inc. increased 2 percent from 1974 to 1975, declined 23 percent from 1975 to 1976 and then declined 44 percent in the first five months of 1977 when compared to the same period in 1976. Total company production of men's and women's slacks and shorts, in quantity, increased 6 percent from 1974 to 1975, declined 28 percent from 1975 to 1976 and then declined 47 percent in the first five months of 1977 when compared to the same period in 1976.

Increased Imports

Imports of men's and boys' dress and sport trousers and shorts declined in absolute terms, from 1972 to 1974 and increased from 1974 to 1975. Imports increased 33 percent from 1975 to 1976 and declined 17 percent in the first six months of 1977 compared to the same period in 1976. The ratio of imports to domestic production and consumption increased from 34.1 percent and 26.4 percent, respectively, in 1975 to 41.9 percent and 29.5 percent, respectively, in 1976.

Imports of women's, misses' and children's slacks and shorts declined in absolute terms, from 1972 to 1974 and increased from 1974 to 1975. Imports increased 10 percent from 1976 to 1977 and increased 4 percent in the first six months of 1977 compared to the same period in 1976. The ratio of imports to domestic production and consumption increased from 35.2 percent and 26.0 percent, respectively, in 1975 to 36.4 percent and 26.7 percent, respectively, in 1976.

Contributed importantly

The Department's investigation revealed that Dury Clothing Co., Inc. produces men's and women's slacks and shorts on a contract basis for other manufacturers. The Department's survey of manufacturers representing 78-percent of Dury's sales in 1975, 70 percent in 1976 and 100 percent in the first five months of 1977, revealed that none of the six manufacturers with
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which Dury contracted switched orders from Dury to offshore contractors. However, the survey revealed that retail customers of manufacturer (manufacturers which represented 53 percent of Dury’s sales in 1975, 28 percent in 1976 and 7 percent in 1977), decreased purchases from the manufacturers and increased purchases of imported men’s slacks. As a result of this switch by retail customers to imported men’s slacks, the manufacturer reduced contracts with Dury from 1975 to 1976 and then stopped contracting with Dury for the production of men’s slacks in 1977. The reduced contracts for men’s slacks lead to a change in the product mix as men’s slacks and shorts accounted for 80 percent of Dury’s production in 1975 and 1976 and 60 percent in the first five months of 1977. The reduced contracts and the change in the product mix in turn resulted in the decline in Dury’s sales and production from 1975 to 1976 and in the first five months of 1977 when compared to the same period in 1976.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with men’s and women’s slacks and shorts produced by Dury Clothing Co., Inc., West Pittston, Pa. contributed importantly to the absolute decline in sales of the workers of that firm. In accordance with the provisions of the Act, I find that the following conditions were met with respect to the workers at Dury Clothing Co., Inc., West Pittston, Pa. who became totally or partially separated or were threatened to become totally or partially separated:

1. That a significant number or proportion of the workers in the firm’s or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;
2. That sales or production, or both, of such firm or subdivision have decreased absolutely;
3. That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and
4. That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important but not necessarily more important than any other cause.

The investigation has revealed that all four of the above criteria have been met with respect to open die forged engine parts. The investigation further revealed that criterion (4) has not been met with respect to steel forgings.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of hourly workers Ellwood City Forge Inc. increased 1 percent from 1974 to 1975 and then declined 14 percent from 1975 to 1976. The average number of hourly workers increased 2 percent in the third quarter of 1976, and increased 3 percent in the fourth quarter of 1976, when compared to the previous quarters. The average number of hourly workers declined 9 percent in the first quarter of 1977 compared to the first quarter of 1976.

SALES OR PRODUCTION OR BOTH, HAVE DECREASED ABSOLUTELY

Total company sales declined 5 percent, in quantity, from 1974 to 1975 and then increased 3 percent from 1975 to 1976. Total company sales declined 29 percent, in quantity, in the first quarter of 1977 compared to the first quarter of 1976.

The above data was not available by product line. All forgings are produced according to customers’ orders, therefore, production is equivalent to sales.

INCREASED IMPORTS

Imports of steel forgings increased 1 percent from 1972 to 1973, increased 50 percent from 1973 to 1974 and increased 18 percent from 1974 to 1975. Imports then declined 47 percent in 1975 to 57.1 thousand short tons, the lowest level of imports for the five year period.

Imports of open die forged engine parts increased by 13.2 percent from 1975 to 1976, and by 18.1 percent in January-September 1977 compared to the same period in 1976.

CONCLUDED IMPORTANTLY

Imports of open die forged engine parts have increased absolutely from 1972 to 1976. Imports of open die forged engine parts have increased by 13.2 percent from 1975 to 1976. There has been an 18.1 percent increase in engine parts from January-September 1976 compared to the same period in 1977.

Ellwood’s largest customers of a particular engine part were surveyed regarding their purchases of crankshafts. All of these customers purchased imported crankshafts. One of the customers who reduced purchases from Ellwood and increased purchases of imported crankshafts represented 6 percent of Ellwood’s crankshaft sales in 1975 and 11 percent in 1976.

Conclusively, or steel forgings increased absolutely in each year from 1972 through 1975. Imports then declined 47 percent from 1975 to 1976. In the first quarter of 1977, imports increased 9 percent compared to the first quarter of 1976. The ratio of imports to domestic production and consumption declined from 5.7 percent and 5.6 percent, respectively, in 1975 to 3.3 percent and 3.2 percent, respectively in 1976.

During the investigation, Ellwood’s customers were surveyed by OTAA regarding their purchases of steel forgings. The representative sample of firms contacted either did not purchase imported steel forgings in 1976 and 1977 or decreased purchases from all sources.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of steel forgings like or directly competitive with steel forgings, not engine parts, produced at Ellwood City Forge Corp., Ellwood City, Pa. did not contribute importantly to the absolute decline in sales or production and to the total or partial separation of workers at that
In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;
2. That sales or production, or both, of such firm or subdivision have decreased absolutely;
3. That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and
4. That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important, but not necessarily more important than any other cause.

Without regard to whether the other criteria have been met, the investigation has revealed that the first criterion has not been met with respect to all petitioning plants with the exception of the Lima, Ohio, engine plant (TA-W-2055). The investigation has revealed that all of the criteria have been met with respect to the Lima engine plant.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

The average number of hourly workers employed at the Lima, Ohio, engine plant declined 5.7 percent in the April 1976-March 1977 period compared to the April 1975-March 1976 period.


SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Adjusted sales of parts produced for use in subcompact cars at the Lima, Ohio, engine plant declined 39.7 percent in the April 1976-March 1977 period compared to the April 1976-March 1976 period.

INCREASED IMPORTS

Imports of subcompact cars increased from 1,393.4 thousand units in MY 1974 to 1,437.9 thousand units in MY 1975 and then declined to 1,325.4 thousand units in MY 1976. In the first quarter of MY 1977, imports numbered 390.3 thousand units, up from 381.2 thousand units in the first quarter of MY 1976.

The ratio of imports to domestic production increased from 108.6 percent in MY 1974 to 180.8 percent in MY 1975 and then fell to 142.9 percent in MY 1976. The ratio of imports to domestic production increased steadily from 101.4 percent in the first quarter of MY 1976 to 260.8 percent in the first quarter of MY 1977.

CONTRIBUTED IMPORTANTLY

In a previous Department of Labor investigation (TA-W-1937-1939), it was determined that increased imports of subcompact cars contributed importantly to the separation of workers at three Ford Motor Co. assembly plants producing such cars.

The Department's investigation revealed that during the period April 1976-March 1977, the Lima, Ohio, engine plant produced a substantial proportion of its output for use in subcompact cars and therefore was integrated into the production of those cars.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with Ford Motor Co. subcompact cars contributed importantly to the decrease in sales and to the total or partial separation of workers producing parts for such Ford cars at the Lima, Ohio, engine plant (TA-W-2055) of the Ford Motor Co.

I further conclude that a significant number or proportion of workers at the remaining six (6) petitioning auxiliary plants of the Ford Motor Co. did not become totally or partially separated as required for certification under section 222 of the Trade Act of 1974.

In accordance with the provisions of the Act, I make the following certification:

All workers of the Ford Motor Co., Lima, Ohio, engine plant (TA-W-2056), engaged in employment related to the production of parts for use in Ford subcompact cars who became totally or partially separated on or after March 28, 1976, and before August 8, 1977, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974. All workers separated on or after August 8, 1977 are denied eligibility.
Signed at Washington, D.C., this 22nd day of December 1977.

JAMES P. TAYLOR,
Director, Office of Management, Administration, and Planning.

[4510-28]

[FEDERAL REGISTER, VOL 43, NO. 4—FRIDAY, JANUARY 6, 1978]

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Threatened to become totally or partially separated

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-1937-1939: Investigation regarding certification of eligibility to apply for worker adjustment assistance prescribed in section 222 of the Act.

The investigation was initiated on March 31, 1977, in response to a worker petition received on March 31, 1977, which was filed by the International Union, United Automobile, Aerospace & Agricultural Implement Workers of America (UAW) on behalf of workers and former workers engaged in the production of subcompact cars at the Metuchen, N.J., Dearborn, Mich., and San Jose, Calif., assembly plants of the Ford Motor Co., Dearborn, Mich.

The notice of investigation was published in the Federal Register on April 15, 1977 (42 FR 19937). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Ford Motor Co., the U.S. Department of Commerce, the U.S. International Trade Commission, the Motor Vehicle Manufacturers Association, Automotive News, Ward's Automotive Reports, industry analysts, and Department files.

In order to make an affirmative determination and issue a certificate of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;
2. That sales or production, or both, of such firm or subdivision have decreased absolutely;
3. That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and
4. That the increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important, but not necessarily more important than any other cause.

Significant Total or Partial Separations


The average number of hourly workers engaged in relation to the production of subcompact cars at the San Jose, Calif., plant declined 53.9 percent from MY 1974 to MY 1975, increased 4.9 percent from MY 1975 to MY 1976, declined 23.2 percent from the first half of MY 1976 to the first half of MY 1977, and declined 17.1 percent in the period April 1976-March 1977 compared to the April 1975-March 1976 period.

The average number of hourly workers employed at the Metuchen, N.J., plant declined 19 percent from MY 1974 to MY 1975, and 31.2 percent in the first half of MY 1977 compared to the last half of MY 1976. Average hourly employment declined 27.1 percent in the period April 1976-March 1977 compared to the April 1975-March 1976 period.

The average number of hourly workers employed at the Dearborn, Mich., San Jose, Calif., and San Jose, Calif., assembly plants of the Ford Motor Co., Dearborn, Mich., and San Jose, Calif., assembly plants of the Ford Motor Co., Dearborn, Mich., and San Jose, Calif., were 11.1 percent, 22.3 percent, and 51 percent of all subcompact car production respectively.

The ratio of imports to domestic production increased from 108.6 percent in MY 1974 to 180.8 percent in MY 1975 and then fell to 142.9 percent in MY 1976. The ratio of imports to domestic production increased steadily from 101.4 percent in the first quarter of MY 1976 to 250.8 percent in the first quarter of MY 1977.

Imported Subcompact car imports are produced by American-based companies, primarily in Canada, and by foreign-based companies, in countries other than Canada. In MY 1976, 19 percent of subcompact imports were built in Canada and 81 percent were built overseas. The cars produced in Canada are indistinguishable from the same make and model cars produced at U.S. plants.

Ford's imports of subcompact cars from Canada increased 47.1 percent from MY 1975 to MY 1976 and then declined 36.1 percent in the first half of MY 1977 compared to the same period of MY 1976.

Imports of subcompact cars from Canada by Ford, indistinguishable from those produced at the Metuchen and San Jose plants, decreased from 29.1 percent of Ford's domestic market for these cars in the first half of MY 1976 to 41.5 percent in the first half of MY 1977.

Imports have penetrated the domestic market for subcompact cars to the extent that during MY 1974-1976 more than 50 percent of all subcompacts sold domestically were imported. From the first quarter of MY 1976 to the first quarter of MY 1977 the share of the domestic subcompact market held by imports rose steadily from 51 percent to 61.6 percent. During the same period, the market share held by domestically built subcompacts decreased from 22.3 percent to 15.9 percent and the share held by other domestically built subcompacts fell from 25.7 percent to 22.5 percent.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with subcompact cars produced at the Metuchen, N.J., Dearborn, Mich., and San Jose, Calif., assembly plants of the Ford Motor Co. contributed importantly to the decline in production and to the total or partial separation of the workers at such plants. In accordance with the provisions of the Trade Act of 1974, I make the following certifications:

All workers of the Ford Motor Co., Metuchen, N.J., assembly plant (TA-W-1937) who became totally or partially separated on or before March 24, 1977, and before August 8, 1977, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974. All workers separa-
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TA-W-2244: Investigation Regarding Eligibility To Apply for Worker Adjustment Assistance

GREAT EASTERN TEXTILE PRINTING CO.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2244: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on August 8, 1977 in response to a worker petition received on August 3, 1977 which was filed on behalf of workers and former workers producing printed textile fabrics at Great Eastern Textile Printing Co., Mahwah, N.J.

At the initiation of the investigation, Great Eastern Textile Printing Co., Mahwah, N.J., a division of Eastern Textile Printing Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any other criteria have been met, criterion (4) has not been met.

Great Eastern produces printed textile fabric exclusively for two converters. A survey of clothing manufacturers who decreased their purchases of finished fabric from these two converters revealed that the manufacturers did not shift their orders of printed textile fabric from the two converters to imports.

Imported wearing apparel cannot be considered to be like or directly competitive with printed and dyed fabric. Imports of all types of finished fabric must be considered in determining import injury to workers producing printed and dyed fabric at Great Eastern Textile Printing Company. Aggregate imports of finished fabric declined in each quarter of 1976 compared to the respective previous quarters and declined in the first half of 1977 compared to the first half of 1976. The ratio of imports to domestic production remained at two percent or less since 1975.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that imports of articles like or directly competitive with those produced by the Great Eastern Textile Printing Co., Mahwah, N.J., did not contribute importantly to the decline in sales or to the total or partial separations of workers at that firm, as required for certification under section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 23rd day of December 1977.

JAMES F. TAYLOR, Director, Office of Management, Administration, and Planning.

[FR Doc. 78-228 Filed 1-5-78; 8:45 am]

TA-W-2190: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on July 5, 1977 in response to a worker petition received on July 1, 1977 which was filed by former workers producing coated cloth, paper, and plastic film at the Lincoln, R.I., plant of the Holliston Mills, Inc.

The Notice of Investigation was published in the Federal Register on July 15, 1977 (42 FR 36313). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Holliston Mills, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

The Department contacted a representative sample of former coated paper and cloth customers of the Lincoln, R.I. plant. None of these had purchased any imported products similar to those formerly produced at the Lincoln, R.I. plant.

Moreover, trade and industry analyses by the Department indicated negligible imports of those products.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that imports of articles, like or directly competitive with coated cloth, paper and film at the Lincoln, R.I. plant of Holliston Mills, Inc. did not contribute importantly to the total or partial separations of workers at the plant as required for certification in section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 3rd day of December 1977.

JAMES F. TAYLOR, Director, Office of Management, Administration, and Planning.

[FR Doc. 78-228 Filed 1-5-78; 8:45 am]
Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2191: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on July 5, 1977, in response to a worker petition received on July 1, 1977, which was filed by former workers producing coated cloth, paper, and plastic film at the Lincoln, R.I., plant of the Holliston Mills, Inc., on behalf of workers at the Hyannis, Mass., office of the same company.

The notice of investigation was published in the Federal Register on July 15, 1977 (42 FR 36513). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Holliston Mills, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in such workers’ firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;
2. That sales or production, or both, of such firm or subdivision have decreased absolutely;
3. That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and
4. That increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in such workers’ firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;
2. That sales or production, or both, of such firm or subdivision have decreased absolutely;
3. That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and
4. That increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

The investigation was initiated on July 5, 1977, in response to a worker petition received on July 1, 1977, which was filed by former workers producing coated cloth, paper, and plastic film at the Lincoln, R.I., plant of the Holliston Mills, Inc., on behalf of workers at the Hyannis, Mass., office of the same company.

The information upon which the determination was made was obtained principally from officials of Holliston Mills, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles, like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

4. That increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

The investigation was initiated on July 5, 1977, in response to a worker petition received on July 1, 1977, which was filed by former workers producing coated cloth, paper, and plastic film at the Lincoln, R.I., plant of the Holliston Mills, Inc., on behalf of workers at the Kingsport, Tenn., plant.

The notice of investigation was published in the Federal Register on July 15, 1977 (42 FR 36513). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Holliston Mills, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles, like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

4. That increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

The investigation was initiated on July 5, 1977, in response to a worker petition received on July 1, 1977, which was filed by former workers producing coated cloth, paper, and plastic film at the Lincoln, R.I., plant of the Holliston Mills, Inc., on behalf of workers at the Kingsport, Tenn., plant.

The notice of investigation was published in the Federal Register on July 15, 1977 (42 FR 36513). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Holliston Mills, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.
apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 23, 1977, in response to a worker petition received on March 23, 1977, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing women's dresses at the Nanticoke, Pa., plant of Holly Dress Co.

The notice of investigation was published in the FEDERAL REGISTER on April 12, 1977 (42 FR 19176). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Holly Dress Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

2. That sales or production, or both, of such firm or subdivision have decreased absolutely;

3. That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

4. That such increased imports have contributed importantly to the separations, or threatens thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important but not necessarily more important than any other cause.

Without regard to whether the other criteria have been met, the fourth criterion has not been met.

Evidence developed during the course of the investigation revealed that the impact of imports in the domestic market for women's and misses' dresses has been small and did not change appreciably from 1975 to 1976 or in the first nine months of 1977 compared to the first nine months of 1976. From 1975 to 1976 the ratio of imports to domestic production remained constant at 4.5 percent while imports increased by only 2.3 percent in absolute terms. Imports fell by 12.8 percent in the first nine months of 1977 compared to the first nine months of 1976.

Holly Dress produced women's dresses under one manufacturer which accounted for almost 100 percent of the subject firm's production in 1976 and the first six months of 1977. A survey of the manufacturer's customers indicated no significant switch in purchases to imported dresses.

CONCLUSION

After careful review of the facts obtained in the investigation, it is concluded that increased imports like or directly competitive with dresses produced at the Nanticoke, Pennsylvania plant of Holly Dress Co. did not contribute importantly to the decrease in production or to the total or partial separations of workers at that plant.

Signed at Washington, D.C., this 23rd day of December 1977.

HARRY GRUBER, Director, Office of Foreign Economic Research.

[FR Doc. 78-292 Filed 1-5-78; 8:45 am]

[4510-28]

[TA-W-1727]

HOLLY SUGAR CORP.

Correction of Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In FR Doc. 77-28885 appearing at page 55510 in the FEDERAL REGISTER of September 30, 1977, the impact date on which total or partial separations began was inaccurate. Data obtained in the original investigation was in error with respect to certain workers separated on or before the plant closing. Reevaluation of the data revealed that workers were separated prior to the March 1, 1977, impact date. Therefore, the following change should be made:

1. The 3rd column, 5th paragraph, 4th line is corrected by changing March 1, 1977 to February 11, 1977.

Signed at Washington, D.C., this 23rd day of December 1977.

HARRY GRUBER, Director, Office of Foreign Economic Research.

[FR Doc. 78-293 Filed 1-5-78; 8:45 am]

[4510-28]

[TA-W-1851]

KENNETH MANUFACTURING CO.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of Trade Act of 1974, the Department of Labor herein presents the results of TA-W-1851: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 22, 1977, in response to a worker petition received on March 22, 1977, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing women's and misses' dresses at the Kenneth Manufacturing Co., Wilkes-Barre, Pa.

The notice of investigation was published in the FEDERAL REGISTER on April 5, 1977 (42 FR 18156). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Kenneth Manufacturing Co., its customer, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

2. That sales or production, or both, of such firm or subdivision have decreased absolutely;

3. That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

4. That such increased imports have contributed importantly to the separations, or threatens thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important but not necessarily more important than any other cause.

Without regard to whether the other criteria have been met, criterion (4) has not been met.

Evidence developed during the Department's investigation revealed that Kenneth Manufacturing Co. is a contractor for women's and misses' dresses for one manufacturer. Sales of Kenneth Manufacturing Co.'s manufacturer increased in 1976 compared to 1975 and in the first 9 months of 1977 compared to the first 9 months of 1976. This manufacturer's purchases of imported dresses are negligible.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that imports of articles like or directly competitive with women's and misses' dresses produced at Kenneth Manufacturing Co., Wilkes-Barre, Pa., have not contributed importantly to the decline in sales or production of the firm compared to the total or partial separations of workers of that firm as required for certification under section 222 of the Trade Act of 1974.
Signed at Washington, D.C., this 23rd day of December 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

(FR Doc. 78-294 Filed 1-5-78; 8:45 am)

[4510-28]

TA-W-1859

MANER SPORTSWEAR, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-1859: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 22, 1977, in response to a worker petition received on that date which was filed by the International Ladies' Garment Workers Union on behalf of workers and former workers producing women's dresses, suits, and pant suits at Maner Sportswear, Inc., Sugar Notch, Pa., Paterson, N. J.

The Notice of Investigation was published in the FEDERAL REGISTER on April 5, 1977 (42 FR 18156). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Maner Sportswear, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

Imports of women's, misses and children's suits, and pant suits decreased from 412 thousand dozen in 1975 to 408 thousand dozen in 1976 and declined from 178 thousand dozen in the first half of 1976 to 168 thousand dozen in the first half of 1977. Imports of women's and misses' dresses decreased from 395 thousand dozen in the first half of 1976 to 346 thousand dozen in the first half of 1977.

Maner Sportswear is a clothing contractor, producing women's dresses, suits, and pant suits for clothing manufacturers. A survey of clothing manufacturers, who represented over 56 percent of dollar sales by Maner Sportswear in 1976, indicated that these clothing manufacturers did not purchase any women's dresses, suits, or pant suits.

Dollar sales and employment at Maner Sportswear increased 158 percent and 46 percent, respectively, from 1975 to 1976. Temporary layoffs occurred at the plant in August 1976, when a major customer, Maner Sportswear decided to start in-house production of women's sportswear. The plant employment at Maner Sportswear in the first half of 1977 were 127 percent and 49 percent higher than respective levels in the first half of 1976.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with women's dresses, suits, and pant suits produced by Maner Sportswear, Inc., Sugar Notch, Pa., did not contribute importantly to sales declines or to separations of workers of that firm, as required for certification under section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 22nd day of December 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

(FR Doc. 78-295 Filed 1-5-78; 8:45 am)

[4510-28]

ITA-W-2161

PERENNIAL PRINT WORKS, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2161: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on June 20, 1977, in response to a worker petition received on June 16, 1977, which was filed by the Machine Printers and Engravers Association on behalf of workers and former workers engaged in the printing of fabric at Perennial Print Works, Inc., Paterson, N. J.

The notice of investigation was published in the FEDERAL REGISTER on June 28, 1977 (42 FR 32853). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Perennial Print Works Inc., fabric converters who are customers of Perennial, customers of the fabric converters, The National Cotton Council, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important, but not necessarily more important than any other cause.

The Department's investigation has revealed that without regard to any of the other criteria, criterion four (4) was not met.


Fabric converters, who represented 100 percent of Perennial's sales in 1976 were surveyed by the Department concerning their purchases of finished fabric. Over fifty percent of the converters surveyed responded. Of these, only one converter shifted purchases of finished fabric from Perennial to imports in 1976 or in 1977.

In addition, apparel manufacturers, who are customers of the fabric converters, were also surveyed concerning purchases of finished fabric. In general these customers did not shift purchases of finished fabric from domestic sources to imports.
Inasmuch as all types of finished fabric, flocked, dyed, and printed, are generally interchangeable and substitutable in their end uses, all types of finished fabric may be considered like or directly competitive with the fabric printed at Perennial Print Works.


Imports of finished fabric declined in each quarter of 1976 when compared to the previous quarter. Imports declined 38 percent in the first six months of 1977 compared to the like period of 1976.

Since 1973 the ratio of imports to domestic production has not exceeded 2.0 percent.

**CONCLUSION**

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with fabric printed at Perennial Print Works, Inc., Paterson, N.J. did not contribute importantly to the decline in sales or production and to the total or partial separation of workers of that plant.

Signed at Washington, D.C., this 23rd day of December 1977.

JAMES P. TAYLOR, Director, Office of Management, Administration, and Planning.

[FR Doc. 78-297 Filed 1-5-78; 8:45 am]

[4510-28]

ITA-W-23453

Plesco Products, Inc.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-23453: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 223 of the Act.

The investigation was initiated on September 14, 1977 in response to a worker petition received on September 13, 1977 which was filed on behalf of workers and former workers producing disposable hospital garments at the St. Petersburg, Fla. plant of Plesco Products, Inc. The notice of investigation was published in the Federal Register on October 4, 1977 (42 FR 54031). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Plesco Products, Inc. and its sales agent, customers of the sales agent, the U.S. Department of Commerce, the U.S. International Trade Commission, the U.S. Customs Service, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision, have become totally or partially separated, or are threatened to become totally or partially separated.
2. That sales or production, or both, of such firm or subdivision have decreased absolutely.
3. That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production.
4. That the ratio of imports to domestic production has not exceeded 2.0 percent.

**SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS**

The average number of workers at the St. Petersburg plant increased from October 1976 (when the plant opened) through February 1977, remained fairly stable through September 1977 and then began to decline. Most workers were laid off by October 1977 when the plant closed.

**SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY**

Sales at Plesco Products, Inc., in terms of unadjusted value, increased 86 percent in the fiscal year ending February 28, 1977 compared to the fiscal year ending February 28, 1976. Sales increased 17 percent in the seven month period ending September 1977 compared to the same period ending September 1976. Sales declined 24 percent in the July-September 1977 period compared to the July-September 1976 period.

The St. Petersburg plant was opened for approximately one year, from October 1976 to October 1977.

Sales, at the St. Petersburg plant, in terms of unadjusted value, increased in each of the four quarters in which the plant was operating, compared to the respective previous quarter.

Production at the St. Petersburg plant, in terms of quantity, increased in each of the first three quarters in which the plant was operating and then declined in the fourth quarter, compared to the respective previous quarter.

All production and sales ceased in October 1977 when the plant closed.

**INCREASED IMPORTS**

Imports of disposable apparel, linens, and accessories (non-wovens) for hospital and medical use, which includes caps and shoe covers increased in absolute terms in each year from 1972 through 1976. Imports increased 49 percent from 1975 to 1976 and increased 11 percent in the first seven months of 1977 compared to the same period in 1976. Information on domestic production and consumption of these products is confidential.

**CONTRIBUTED IMPORTANTLY**

The disposable garments industry is highly labor-intensive. Many domestic firms have found it profitable to have a twin plant in Mexico to sew, assemble, and pack their products. The Mexican firm ships the finished products back to the U.S. where they are sterilized and then sold. These imports from Mexico enter under Tariff Provision 407,00.

Plesco sells most of its production through its sales agent (over 70 percent in the first six months of FY 1977). The remainder is sold outside, mostly to government agencies. Plesco's sales agent indicated that a substantial portion of their business was lost when their own customers began purchasing imports. The sales agent also indicated that many of Plesco's competitors were manufacturing offshore.

Customers of the sales agent confirmed that they began purchasing disposable hospital garments from firms that maintained offshore facilities, and accordingly, reduced purchases from firms that produced solely domestically.

**CONCLUSION**

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with disposable hospital garments (caps and shoe covers) produced at the St. Petersburg, Fla. plant of Plesco Products, Inc. contributed importantly to the total or partial separations of the workers of that plant.

In accordance with the provisions of the Act, I make the following certification:

All workers at the St. Petersburg, Fla. plant of Plesco Products, Inc. who became totally or partially separated from employment on or after September 1, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 23rd day of December 1977.

HARRY GRUBERT, Director, Office of Foreign Economic Research.

[FR Doc. 78-298 Filed 1-5-78; 8:45 am]

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Sales or Production, or Both Have Decreased Absolutely

Sales at Plesco Products, Incorporated, in terms of unadjusted value, increased 66 percent on the fiscal year ending February 28, 1976. Sales increased 16 percent in the seven month period ending September 13, 1977 compared to the same period ending September 1976. Sales declined 24 percent in the July-September 1977 period compared to the July-September 1976 period.

Sales by the Worcester plant, in terms of unadjusted value, increased 66 percent in the fiscal year ending February 28, 1977 compared to the fiscal year ending February 28, 1976. Sales declined 43 percent in the eight month period ending October 1977 compared to the same period ending October 1976.

Production at the Worcester plant, in terms of quantity, declined 23 percent in the first ten months of 1977 compared to the same period in 1976.

Increased Imports

Imports of disposable apparel, linens, and accessories (non-wovens) for hospital and medical use, which includes caps and shoe covers, increased in absolute terms in each year from 1972 through 1976. Imports increased 23 percent from 1975 to 1976 and increased 11 percent in the first seven months of 1977 compared to the same period in 1976. Information on domestic production and consumption of these products is confidential.

Contributed Importantly

The disposable garments industry is highly labor-intensive. Many domestic firms have found it profitable to have a twin plant in Mexico to sew, assemble, and package products. The Mexican firm ships the finished products back to the U.S. where they are sterilized and then sold. These imports from Mexico enter under Tariff Provisin 907.00.

Plesco sells most of its production through its sales agent (over 70 percent in the first six months of FY 1977). The remainder is sold outside, mostly to government agencies. Plesco's sales agents indicated that the substantial portion of their business was lost when their own customers began purchasing imports. The sales agent also indicated the many of Plesco's competitors were manufacturing offshore.

Customers of the sales agent confirmed that they began purchasing disposable hospital garments from firms that maintained offshore facilities, and accordingly, reduced purchases from firms that produced solely domestically.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with disposable apparel garments (caps and shoe covers) produced at the Worcester, Mass. plant of Plesco Products, Inc. contributed importantly to the total or partial separations of the workers of that plant. In accordance with the provisions of the Act, I make the following certification:

All workers at the Worcester, Mass. plant of Plesco Products, Inc. who became totally or partially separated from employment on or after February 1, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C. this 23d day of December, 1977.

HARRY GRUBER,
Director, Office of Foreign Economic Research.

[TAR Doc. 78-299 Filed 1-5-78; 8:45 am]
(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and
(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

This investigation has revealed that all four of the above criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATION

The average number of production workers employed by Reid Stevens, Inc. decreased during the last six months of 1976 compared to the same period in 1975, and decreased during the first seven months of 1977 compared to the same period in 1976.

The average number of weekly hours worked by production workers decreased during the last six months of 1976 compared to the same period in 1975, and decreased during the first seven months of 1977 compared to the same period in 1976.

SALES, PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Sales of ladies' coats manufactured by Reid Stevens, Inc. decreased during the last six months of 1976 compared to the same period in 1975, and decreased during the first seven months of 1977 compared to the same period in 1976.

INCREASED IMPORTS

United States imports of women's, misses' and children's coats and jackets were recorded at 1,769 thousand dozen in 1972, increased to 1,807 thousand dozen in 1973, decreased to 1,478 thousand dozen in 1974, increased in 1975 to 1,517 thousand dozen, increased in 1976 to 2,252 thousand dozen, and increased to 1,231 thousand dozen during the first six months of 1977 compared to 951 thousand dozen for the same period in 1975.

The imports to domestic production ratio for women's, misses' and children's coats and jackets decreased from 39.3 percent in 1972 to 37.3 percent in 1973, decreased to 30.9 percent in 1974, increased in 1975 to 38.9 percent, and increased in 1976 to 57.5 percent.

CONTRIBUTED IMPORTANTLY

A survey of Reid Stevens, Inc. sole manufacturer revealed that the manufacturer increased its imports of ladies' coats during the first three quarters of 1977 compared to the same period in 1976, while at the same time decreasing its utilization of Reid Stevens.

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CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with ladies' coats produced by Reid Stevens, Inc., Commack, New York contributed importantly to the total or partial separation of the workers at the Plant. In accordance with the provisions of the Act, I make the following certification:

All workers at Reid Stevens Inc., Commack, N.Y., who became totally or partially separated from employment on or after July 8, 1976 are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Trade Act of 1974.

Signed at Washington, D.C., this 23rd day of December 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-300 Filed 1-5-78; 8:45 am]

[4510-28]

ITAW-2196

ROCKWELL INTERNATIONAL ADMIRAL GROUP

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TAW-2196: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on July 7, 1977, in response to a worker petition received on July 1, 1977, which was filed by the International Brotherhood of Electrical Workers on behalf of workers and former workers producing television yokes and tuners at the McHenry, Ill., plant of Rockwell International, Admiral Group.

The notice of investigation was published in the Federal Register on July 15, 1977 (42 FR 36513). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Rockwell International, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important, but not necessarily more important than any other cause.

The investigation has revealed that all four of the above criteria have been met.

Average weekly employment at the McHenry, Ill., plant decreased in 1976 compared to 1975. The McHenry plant closed permanently on November 11, 1976. All workers were separated at this time.

Production of television components at the McHenry, Ill., plant decreased in 1976 compared to 1975.

Imports of monochrome televisions increased 45.5 percent in 1976 compared to 1975. Imports of monochrome televisions dominate the black and white television market, with 90.9 percent of these imports coming from Asia. The ratio of imports to domestic production increased from 193.8 percent in 1975 to 311.3 percent in 1976.

Imports of color televisions increased 179.8 percent in 1976 compared to 1975. The ratio of imports to domestic production increased from 23.4 percent in 1975 to 55 percent in 1976.

The McHenry, Ill., plant supplied television components to the Harvard, Ill., television assembly plant that was certified eligible for trade adjustment assistance benefits on May 16, 1977 (TA-W-1571). This integrated affiliation with the Harvard plant makes the level of television component production at the McHenry plant contingent upon the sales and/or production of televisions by the Admiral Group or by the Harvard plant.

Admiral Group sales of color televisions and monochrome televisions decreased 21 percent and 28 percent, respectively, in quantity in 1976 compared to 1975.

Production of color televisions and monochrome televisions at the Harvard, Ill., plant decreased 19 percent and increased 18 percent, respectively in quantity in 1976 compared to 1975.

The proportion of Rockwell International's total company sales in quantity of color televisions which were completed in Taiwan in 1976 was almost double the proportion in 1975. The very high proportion of company sales of monochrome televisions completed in Taiwan remained unchanged in 1976 compared to 1975.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude...
that increases of imports of articles like or directly competitive with color and monochrome televisions produced at the Harvard, Ill., plant of Rockwell International (Admiral Group) contributed importantly to the separations of workers at the McHenry, Ill., plant of Rockwell International (Admiral Group). In accordance with the provisions of the Act, I make the following certification:

All workers at the McHenry, Ill., plant of Rockwell International (Admiral Group) who became totally or partially separated from employment on or after June 25, 1976, and before November 28, 1976, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974. All workers separated on or after November 28, 1976 are denied eligibility.

Signed at Washington, D.C., this 23rd day of December 1977.

HARRY GRUBEK,
Director, Office of Foreign Economic Research.

[FR Doc. 78-301 Filed 1–5–78; 8:45 am]

ROCKWELL INTERNATIONAL, GRAPHIC SYSTEMS GROUP, GOSS DIVISION

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-1927: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 30, 1977, in response to a worker petition received on March 29, 1977, which was filed by supervisory personnel formerly engaged in the production of web-fed letter printing presses at the Graphic Systems Group, Goess Division plant of Rockwell International in Cicero, Ill. On April 28, 1977, a petition was received which was filed by the International Association of Machinists and Aerospace Workers on behalf of production workers employed at that plant.

The notice of investigation was published in the Federal Register on April 12, 1977 (42 FR 19178). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Rockwell International and its customers, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in such workers’ firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;
2. That sales or production, or both, of such firm or subdivision have decreased absolutely;
3. That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

Evidence developed in the Department’s investigation revealed that the utilization of web-fed letter presses is being phased out in favor of web-fed offset presses which offer superior technological advantages. By late 1976, according to industry analysts, this conversion process had reached more than three-fourths of all domestic newspaper printing plants, the principal users of web-fed printing presses. The domestic production of web-fed letter presses was sharply reduced in response to this technological shift. No imported web-fed letter presses had been purchased by any of the customers surveyed during the course of the Department’s investigation nor had any customers indicated that imported web-fed offset presses were purchased in replacement of letter presses. Customers furthermore indicated that web-fed offset presses manufactured in the United States have a technological and serviceability advantage over foreign made presses and, in most instances, a price advantage.

CONCLUSION

After careful review of the facts obtained in the investigation, it is concluded that increases of imports of articles like or directly competitive with the web-fed letter presses produced at the Graphic Systems Group, Goess Division plant of Rockwell International in Cicero, Ill., contributed importantly to the decline in sales and production and to the total or partial separations of the workers from that plant as required for a certification under section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 23rd day of December 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-302 Filed 1-5-78; 8:45 am]

ROTH TRANSFER PRINT, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2362: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on September 19, 1977, in response to a worker petition received on September 15, 1977, which was filed on behalf of workers and former workers producing print fabric at Roth Transfer Print, Inc., Fair Lawn, N.J.

The notice of investigation was published in the Federal Register on October 4, 1977 (42 FR 54032). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Roth Transfer Print, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

1. That a significant number or proportion of the workers in such workers’ firm, or an appropriate subdivision thereof have become totally or partially separated, or are threatened to become totally or partially separated;
2. That sales or production, or both, of such firm or subdivision have decreased absolutely;
3. That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important, but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (4) has not been met.

Evidence developed in the Department’s investigation revealed that
NOTICES

Roth Transfer Print, Inc., is a commissioned printing firm which prints fabric for converters and manufacturers. The single plant company was founded to transfer print from paper to cloth using a heat transfer process.

A survey of customers accounting for 90 percent of Roth Transfer Print, Inc.'s sales in the first three quarters of 1977, revealed the customers switched to other domestic sources and did not switch to imports.


Imports of finished fabric declined in each quarter of 1976 compared to the respective previous quarters and declined 38 percent in the first half of 1977 compared to the first half of 1976.

The ratios of imports of finished fabric to domestic production and consumption reached a peak in the most recent five year period at 2.2 percent in 1972. Since 1972, the ratios have been 2 percent or less.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that imports of articles like or directly competitive with printed fabric produced at Roth Transfer Print, Inc., Fair Lawn, N.J., have not contributed importantly to the decline in sales or production of the firm or to the total or partial separations of workers at that firm as required in section 222 of the Act.

The petition is, therefore, denied.

Signed at Washington, D.C., this 23rd day of December 1977.

JAMES P. TAYLOR, Director, Office of Management, Administration, and Planning.

[FR Doc. 78-303 Filed 1-5-78; 8:45 am]

TOY-MARK CORP.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2618: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on November 17, 1977, in response to a worker petition received on November 2, 1977, which was filed by the company president of the Toy-Mark Corp., on behalf of workers and former workers of the corporation who were engaged in the retail sale of earth shoes and plumbing fixtures and fittings at the Earth Shoe Store, Providence, R.I.

Without regard to whether any of the other criteria have been met, criterion (1) has not been met.

Toy-Mark Co. is a manufacturer of plumbing fittings and has been in this business since 1889. The Wilmington, Delaware plant is the company's only manufacturing facility and also serves as its headquarters. Toy-Mark Co. makes plumbing fixtures such as kitchen and bathroom faucets, and shower fittings primarily for residential use.

Average annual employment increased 11 percent in 1976 compared to 1975 and increased 27 percent in the first six months of 1977 compared to the first six months of 1976.

Sales at the Toy-Mark Co. increased 8 percent in 1976 compared to 1975. Sales increased 18 percent in the first half of 1977 compared to the like period in 1976. The increasing sales at the Toy-Mark Co. indicate that there is no current threat of separations of workers.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that a significant number or proportion of the workers at the Wilmington, Del., plant of the Speakman Co. have not become totally or partially separated, as required for certification in section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 22nd day of December 1977.

JAMES P. TAYLOR, Director, Office of Management, Administration, and Planning.

[FR Doc. 78-304 Filed 1-5-78; 8:45 am]

[TA-W-2134]

[FR Doc. 78-304 Filed 1-5-78; 8:45 am]

[TA-W-2134]

TOY-MARK CORP.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2618: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on November 17, 1977, in response to a worker petition received on November 2, 1977, which was filed by the company president of the Toy-Mark Corp., on behalf of workers and former workers of the corporation who were engaged in the retail sale of earth shoes and plumbing fixtures and fittings at the Earth Shoe Store, Providence, R.I.

The Notice of Investigation was published in the Federal Register on December 13, 1977 (42 FR 62556). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Toy-Mark Corp., and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (1) has not been met.

Toy-Mark Co. is a manufacturer of plumbing fittings and has been in this business since 1889. The Wilmington, Delaware plant is the company's only manufacturing facility and also serves as its headquarters. Toy-Mark Co. makes plumbing fixtures such as kitchen and bathroom faucets, and shower fittings primarily for residential use.

Average annual employment increased 11 percent in 1976 compared to 1975 and increased 27 percent in the first six months of 1977 compared to the first six months of 1976.

Sales at the Toy-Mark Co. increased 8 percent in 1976 compared to 1975. Sales increased 18 percent in the first half of 1977 compared to the like period in 1976. The increasing sales at the Toy-Mark Co. indicate that there is no current threat of separations of workers.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that a significant number or proportion of the workers at the Wilmington, Del., plant of the Speakman Co. have not become totally or partially separated, as required for certification in section 222 of the Trade Act of 1974.

Signed at Washington, D.C., this 22nd day of December 1977.

JAMES P. TAYLOR, Director, Office of Management, Administration, and Planning.

[FR Doc. 78-304 Filed 1-5-78; 8:45 am]

[TA-W-2618]

TOY-MARK CORP.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2618: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on November 17, 1977, in response to a worker petition received on November 2, 1977, which was filed by the company president of the Toy-Mark Corp., on behalf of workers and former workers of the corporation who were engaged in the retail sale of earth shoes and plumbing fixtures and fittings at the Earth Shoe Store, Providence, R.I.

The Notice of Investigation was published in the Federal Register on December 13, 1977 (42 FR 62556). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Toy-Mark Corp., and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

The Toy-Mark Corp., was the sole franchise holder in the state of Rhode
NOTICES

Island for the sale of "earth shoes" manufactured by Kalso Systemet Inc. They operated one store, Earth Shoe Store, at 311 Westminster Ave., Providence, R.I. 02903.

The Earth Shoe Store opened on or about October 1, 1976, and closed permanently in the first week of September 1977. There was no corporate or other financial relationship between Toy-Mark Corp., and Kalso Systemet Inc., the franchisor.

The Department of Labor has previously determined that the performance of services is not included within the term "articles" as used in section 222 (3) of the Act. See Notice of Negative Determination in Pan American World Airways, Inc. (TA-W-153; 40 FR 54639).

The employees of the Toy-Mark Corp., were engaged in the retail sales of earth shoes. The Toy-Mark Corp., was not involved in the production of an article within the meaning of section 222 (3) of the Act.

CONCLUSION

After careful review of the issues, I have determined that the services provided by Toy-Mark Corp., are not articles within the meaning of section 222 (3) of the Trade Act of 1974 and that workers should therefore be denied eligibility to apply for adjustment assistance.

Signed at Washington, D.C., this 23rd day of December 1977.

HARRY GRUBERT, Director, Office of Foreign Economic Research.

[FR Doc. 78-306 Filed 1-5-78; 8:45 am]

[4510-28]

[TA-W-2659]

VULCAN MOLD AND IRON, INC.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2659: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on November 23, 1977, in response to a worker petition received on November 14, 1977, which was filed by three workers on behalf of workers and former workers producing ingot molds at the Trenton, Mich., plant of Vulcan Mold and Iron, Inc.

The Notice of Investigation was published in the Federal Register on December 6, 1977 (42 FR 61695). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Vulcan Mold and Iron, Inc., the U.S. Department of Commerce, the U.S. International Trade Commission, Industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (3) has not been met.

The evidence developed in a survey of consumers of ingot molds conducted by the Department revealed that imports of ingot molds are negligible. The product, ingot molds, is not listed as a separate item on any U.S. Tariff Schedule.

Vulcan Mold and Iron produces ingot molds principally for the steel industry where they are used in the production of steel. The production of ingot molds is directly dependent upon the production of steel which is currently at depressed levels.

Imports of ingot molds are not "like or directly competitive" with steel products within the meaning of section 222 (3) of the Trade Act of 1974.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that articles like or directly competitive with the ingot molds produced at the Trenton, Mich., plant of Vulcan Mold and Iron have not increased as required for certification in section 222 of the Trade Act of 1974 and that the workers at the plant should therefore be denied eligibility to apply for adjustment assistance benefits.

Signed at Washington, D.C., this 23rd day of December 1977.

HARRY GRUBERT, Director, Office of Foreign Economic Research.

[FR Doc. 78-306 Filed 1-5-78; 8:45 am]

[4510-28] [TA-W-2055]

WAKEFIELD INDUSTRIES, INC.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2055: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on May 18, 1977, in response to a worker petition received on May 16, 1977, which was filed on behalf of workers and former workers producing modular and console stereo units at the Norwich, Conn., plant of Wakefield Industries, Inc.

The Notice of Investigation was published in the Federal Register on May 24, 1977 (42 FR 26481-2). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Wakefield Industries, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, Industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Without regard to whether any of the other criteria have been met, criterion (3) has not been met.

The evidence developed in a survey of consumers of ingot molds conducted by the Department revealed that imports of ingot molds are negligible. The product, ingot molds, is not listed as a separate item on any U.S. Tariff Schedule.

Vulcan Mold and Iron produces ingot molds principally for the steel industry where they are used in the production of steel. The production of ingot molds is directly dependent upon the production of steel which is currently at depressed levels.

Imports of ingot molds are not "like or directly competitive" with steel products within the meaning of section 222 (3) of the Trade Act of 1974.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that articles like or directly competitive with the ingot molds produced at the Trenton, Mich., plant of Vulcan Mold and Iron have not increased as required for certification in section 222 of the Trade Act of 1974 and that the workers at the plant should therefore be denied eligibility to apply for adjustment assistance benefits.

Signed at Washington, D.C., this 23rd day of December 1977.

HARRY GRUBERT, Director, Office of Foreign Economic Research.

[FR Doc. 78-306 Filed 1-5-78; 8:45 am]

FEDERAL REGISTER, VOL 43, NO. 4—FRIDAY, JANUARY 6, 1978
NOTICES

[4510-28]

ITA-W-2243J

WENTWORTH MANUFACTURING CO.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2243: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on August 6, 1977, in response to a worker petition received on August 5, 1977, which was filed by the International Ladies' Garment Workers Union, on behalf of workers and former workers producing junior, misses, and half size pantsuits and dresses at the Lake City, S.C. production facility of Wentworth Manufacturing Co. The investigation was expanded to include company sales offices in New York, N.Y.

The notice of investigation was published in the Federal Register on August 23, 1977 (42 FR 42397). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Wentworth Manufacturing Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements section 222 of the Trade Act of 1974 must be met:

(1) That a significant number or proportion of the workers in such workers’ firm, or an appropriate subdivision thereof have become totally or partially separated, or are threatened to become totally or partially separated;

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That articles like or directly competitive with those produced by the firm or subdivision are being imported in increased quantities, either actual or relative to domestic production; and

(4) That such increased imports have contributed importantly to the separations, or threat thereof, and to the decrease in sales or production. The term “contributed importantly” means a cause which is important, but not necessarily more important than any other cause.

The investigation has revealed that all four of the above criteria have been met.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

Employment at the Lake City, S.C. plant of the Wentworth Manufacturing Co. increased 1 percent in 1976 compared to 1975 and decreased 93 percent in the first six months of 1977 compared to the first eight months of 1976. All production workers were laid off on January 31, 1977.

Employment at the New York, N.Y. sales office increased 4 percent in 1976 compared to 1975 and decreased 88 percent in the first six months of 1977 compared to the first six months of 1976. All sales operations at the New York, N.Y. sales office were terminated in June 1977.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Total sales by Wentworth Manufacturing Co. decreased by less than one percent from 1975 to 1976 and declined 81 percent in the first half of 1977 compared to the first half of 1976. Wentworth ceased sales operations in June 1977.

Production at the Wentworth Manufacturing Co. decreased 7 percent in 1976 compared to 1975 and decreased 70 percent in January 1977 compared to January 1976. All production operations were permanently terminated on January 31, 1977.

INCREASED IMPORTS

Imports of women’s and misses’ dresses increased from 613 thousand dozen in 1974 to 645 thousand dozen in 1975 and to 659 thousand dozen in 1976.

CONTRIBUTED IMPORTANTLY

Customers accounting for 38 percent of total sales in 1976 indicated in a survey that they increased purchases of imported junior, missy, and half size dresses while decreasing purchases from Wentworth during the same time period.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with modular and console stereo units produced by Wakefield Industries, Inc., located in New York, N.Y., are eligible to apply for worker adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 23d day of December 1977.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

(FR Doc. 78-307 Filed 1-5-78; 8:45 am)
The investigation has revealed that all four criteria have been met by workers engaged in the production of disposable operating room gowns. Furthermore, the investigation revealed that criterion two has not been met by workers engaged in the production of surgical face masks.

SIGNIFICANT TOTAL OR PARTIAL SEPARATIONS

Production workers are not separately identifiable by product line in company employment records. The average number of production workers declined 23.8 percent in 1975 compared to 1974 and declined 19.4 percent in 1976 compared to 1975. Employment declined 1.4 percent in the first three quarters of 1977 compared to the first three quarters of 1976.

SALES OR PRODUCTION, OR BOTH, HAVE DECREASED ABSOLUTELY

Since Berkowitz produces only on order, plant sales and production are the same.

Plant production of operating room gowns declined 38.9 percent in 1975 compared to 1974 and declined 12.8 percent in 1976 compared to 1975. Plant production of operating room gowns declined 10.6 percent in the first three quarters of 1977 compared to the first three quarters of 1976. Plant production of surgical face masks declined 4.7 percent in 1976 compared to 1975 and declined 2.9 percent in 1976 compared to 1975. In the relevant time period under investigation, from May 1976 to the present, production of surgical masks at the Unlontown plant increased. Production increased 10 percent in the May-December 1976 period when compared to the same period in 1975. Plant production of surgical face masks increased 26 percent in the first three quarters of 1977 compared to the first three quarters of 1976. Plant production of surgical face masks increased in each quarter from the third quarter of 1976 through the third quarter of 1977 when compared to the like quarters of the preceding year.

INCREASED IMPORTS

The value of imports of disposable apparel, linens, and accessories (non-wovens) for hospital and medical use was $6,966 thousand dollars in 1972 and increased to $10,363 thousand dollars and $14,323 thousand dollars, respectively, in 1973 and 1974. The value of imports increased to $14,405 thousand dollars and $16,213 thousand dollars, respectively, in 1975 and 1976. The value of imports increased from $14,671 thousand dollars in the first seven months of 1976 to $16,213 thousand dollars in the first seven months of 1977.
cable law. This determination follows
consultation with the Committee Man-
gagement Secretariat, pursuant to the
Federal Advisory Committee Act and
OMB Circular No. A-63, Revised.
Name of committee: Advisory Com-
mittee for International Programs.
Purpose: To provide advice, recom-
mendations, and oversight concerning
support for activities related to inter-
national scientific and technical coop-
eration.
Effective date of establishment and
duration: The establishment of the
Committee is effective upon filing the
charter with the Director, NSF, and
the standing committees of Congress
having legislative jurisdiction of the
NSF. The Committee will operate on a
continuing basis contingent upon its
renewal every 2 years.
Membership: Membership of the
Committee shall be fairly balanced in
the terms of the point of view repre-
sented and the Committee's functions.
The Committee will consist of approxi-
mately 12 persons selected from the
U.S. scientific and foreign affairs com-
munities. Members of the Committee
will be chosen so that they will reason-
ably represent the scientific areas and
international scientific and technologi-
cal interests of the Division of Inter-
national Programs (INT), the differ-
ent types and sizes of U.S. institutions
having scientific programs of interest
to INT, the sexes, minority scientists,
and geographical regions of the
United States.
Operation: The Committee will oper-
ate in accordance with provisions of
the Federal Advisory Committee Act
(Pub. L. 92-463); NSF policy and pro-
cedures, OMB Circular No. A-63, Re-
vised, and other directives and instruc-
tions issued in implementation of the
Act.

RICHARD C. ATKINSON, 
Director.


[FR Doc. 78-250 Filed 1-5-78; 8:45 am]

[7555-01]

SUBCOMMITTEE ON POPULATION BIOLOGY
AND PHYSIOLOGICAL ECOLOGY
Meeting

In accordance with the Federal Advi-
sory Committee Act, as amended, Pub.
L. 92-463, the National Science Foun-
dation announces the following meet-
ing:

SUBCOMMITTEE ON POPULATION BIOLOGY
AND PHYSIOLOGICAL ECOLOGY OF THE ADVISORY
COMMITTEE ON ENVIRONMENTAL BIOLOGY
Date and time: January 23 and 24, 1978; 8:30
a.m. to 5 p.m. each day.
Place: Room 338, National Science Foun-
dation, 1800 G Street, NW., Washing-
ton, D.C. 20550.
Type of meeting: Closed.
Contact person: Dr. Donald W. Kaufman,
Associate Program Director, Population

Biology and Physiological Ecology Pro-
gram, Room 336, National Science Foun-
dation, Washington, D.C. 20550, telephone
202-355-5781.

Purpose of subcommittee: To provide advice
and recommendations concerning support for
research in population biology and
physiological ecology.

Agenda: To review and evaluate research
proposals as part of the selection process for
awards.

Reason for closing: The proposals being re-
viewed include information of a pro-
prietary or confidential nature, including
technical information: financial data, such
as salaries; and personal information con-
cerning individuals associated with the
proposals. These matters are within ex-
ceptions (4) and (5) of 5 U.S.C. 552(b)(c),
Government In the Sunshine Act.

Authority to close meeting: This determina-
tion was made by the Committee Manage-
ment Officer pursuant to provisions of
section 10(d) of Pub. L. 92-463. The Com-
mittee Management Officer was delegated
the authority to make such determina-
tions by the Acting Director, NSF, on Feb-
uary 18, 1977.

M. REBECCA WINKLER,
Acting Committee
Management Officer.


[FR Doc. 78-248 Filed 1-5-78; 8:45 am]

[7555-01]

FEDERAL SCIENTIFIC AND TECHNICAL
INFORMATION MANAGERS
Meeting

The next meeting of the Federal Sci-
etic and Technical Information Man-
gers will be held on Wednesday,
January 11, 1978, from 9:30 a.m. to 12
noon, at the National Science Foun-
dation, Conference Room 540, 1800 G
Street NW., Washington, D.C. The
theme of this meeting will be "New
Information Technologies: Prospects
and Impacts."

These meetings, sponsored by the
National Science Foundation, provide
a forum for the interchange of in-
formation concerning common problems
and coordination in the areas of Fed-
eral scientific and technical informa-
tion and communications.

These meetings are designed solely
for the benefit of Federal employees
and officers, and do not fall under the
provisions of the Federal Advisory
Committee Act (Pub. L. 92-463). How-
ever, this meeting is believed to be of
sufficient importance and interest to
the public to be announced in the Fed-
eral Register.

Any persons wishing to attend this
meeting or requiring further informa-
tion should contact me, Division of
Science Information, National Science
Foundation, Washington, D.C. 20550,
telephone 202-355-5624.

LEE G. BURCHINAL,
Director, Division of
Science Information.


[FR Doc. 78-249 Filed 1-5-78; 8:45 am]
noted that the crank was in the wrong position. He immediately retracted the source into its shielded container and called his supervisor. From re-enactments, it is estimated the fingers of his left hand were in close proximity to the source for 3-5 seconds.

Data from a film badge worn by the individual, re-enactment of the incident and additional dosimetry are consistent with the estimate that this individual received a whole body dose of approximately 0.6 rem and a dose to the fingers of his left-hand of 300-600 rems.

The consequences of this type of incident are limited to the individual involved. At the licensee's instigation, the exposed individual was hospitalized briefly after the incident for medical observation. The licensee has retained a medical consultant to follow the case.

Cause or causes—The direct cause of this incident was the failure of the radiographer to retract the sealed source into its safe, shielded position. Contributing to the cause was the failure of the radiographer to conduct a complete survey of the area at the conclusion of the radiographic exposure to ensure that the source had been completely retracted into its shield.

Actions Taken to Prevent Recurrence

Licensee.—The licensee initiated a new formal management audit system to augment the present program of internal audits. These audits will be performed by an individual with extensive experience in radiographic operations who is not a member of the licensee's radiography staff. The details of this incident will be discussed with all of the licensee's radiographers during retraining. In addition, the licensee plans to conduct retraining of each radiographer and to confirm each radiographer's level of comprehension with written tests and observation of on-the-job activities.

NRC—The NRC has conducted an inspection on November 14, 15, 22, and 23, 1977. The NRC staff met with the licensee's management on November 17, 1977, to express concern about this overexposure and review the licensee's planned corrective and preventive actions. Appropriate enforcement action is being planned.

Dated at Washington, D.C. this 30th day of December, 1977.

For the Nuclear Regulatory Commission.

John C. Hoyte, Assistant Secretary of the Commission.

[FR Doc. 78 200 Filed 1-5-78; 8:45 am]

NOTICES

[7590-01]

DRAFT ENVIRONMENTAL STANDARD REVIEW PLANS, PART III

Availability of Draft for Public Comment

The Nuclear Regulatory Commission is developing Environmental Standard Review Plans for the purpose of directing the NRC staff's environmental review of applications for nuclear power plant construction permits. When completed, these plans will serve to inform interested parties of the nature of the technical portion of the environmental review and the basis for the various technical conclusions made.

The first group of draft Environmental Standard Review Plans, NUREG-0158 Part I, was issued in January 1977. The second group of plans, NUREG-0158 Part II, was issued in May 1977. The notices of availability of the plans were published in the FEDERAL REGISTER on February 10, 1977 (42 FR 8443) and May 31, 1977 (42 FR 27702). Public comment was invited on the plans at that time. At this time a third group of plans, NUREG-0158 Part III, is available for review and comment. This completes the preparation of the draft Environmental Standard Review Plans, and after a period for analysis of comments, the Commission will issue final Environmental Standard Review Plans.

Interested persons may submit comments on the draft Environmental Standard Review Plans for the Commission's consideration. Comments on this group of plans are due by January 31, 1978. Comments should be addressed to the Director, Division of Site Safety and Environmental Analysis, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.


Dated at Bethesda, Md. this 23rd day of December 1977.

For the Nuclear Regulatory Commission.

Wm. H. Reagan, Jr.,
Chief, Environmental Projects Branch 2, Division of Site Safety and Environmental Analysis.

[FR Doc. 78 208 Filed 1-5-78; 8:45 am]

[7590-01]

[DOCKET NO. 50-3066]

FLORIDA POWER & LIGHT CO. (ST. LUCIE PLANT, UNIT 2)

Order

On October 19, 1977, the Commission decided to review ALAB-420, and requested briefing on questions set out in the order of that date. The Commission will hear oral argument in this case on Thursday, January 12, 1978, at 11 a.m., in the Commission's conference room, 11th floor, 1717 H Street NW., Washington, D.C. The parties should be prepared to address whether and how licensing boards might take into account the lateness of a request for an antitrust hearing in: (1) determining the scope of the hearing, and (2) granting relief. The parties should also discuss whether the Licensing Board, in view of the lateness of the request for hearing, should have looked behind the allegations contained in the Florida Cities affidavits filed with the Board in determining whether good cause existed to have a late antitrust hearing. The order and time limits for argument will be as follows:

Florida Power & Light Co., 20 minutes.

The Florida Cities', 20 minutes.

NRC Staff and U.S. Department of Justice, 20 minutes—to be divided by agreement. If there is no agreement, then divided equally.

Each party may elect to reserve a portion of its allotted time for rebuttal. It is so ordered.

Dated at Washington, D.C. on this 29th day of December, 1977.

By the Commission.

Samuel J. Chilk,
Secretary of the Commission.

[FR Doc. 78-196 Filed 1-5-78; 8:45 am]

[17590-011

[DOCKET NO. 50-389A]

MAIN YOURAN ATOMIC POWER CO.

Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued amendment No. 32 to Facility Operating License No. DPR-36, issued to Maine Yankee Atomic Power Co. (the Licensee), which revised technical specifications for operation of the Maine Yankee Atomic Power Co. (the Facility) located in Lincoln County, Maine. The "Florida Cities" is the collective name used in this litigation for twenty-one Florida municipalities and utility commissions and the Florida Municipal Utilities Association. The individual names have been specified in previous filings before the Commission and in Commission orders.
Maine. The amendment is effective as of its date of issuance.

The amendment to the technical specifications grants an extension for submitting the report on the 5-year nonradiological environmental monitoring program.

The Commission has made the amendment to the Technical Specifications dealing with respiratory protection and environmental impact appraisal. The amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated August 25, 1977, and (2) amendment No. DPR-36. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. and at the Wiscasset Public Library, High Street, Wiscasset, Maine. A copy of item (2) may be obtained upon request addressed to the Director, Division of Operating Reactors, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Md., this 27th day of December 1977.

For the Nuclear Regulatory Commission.

ROBERT W. REID, Chief, Operating Reactors Branch No. 4, Division of Operating Reactors.

[FR Doc. 78-201 Filed 1-5-78; 8:45 am]

[7590-01] (Docket No. 50-289)

METROPOLITAN EDISON CO., ET AL.

Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 35 to Facility Operating License No. DPR-50, issued to Metropolitan Edison Co., Jersey Central Power & Light Co. and Pennsylvania Electric Co. (the licensees), which revised Technical Specifications for operation of the Three Mile Island Nuclear Station, Unit No. 1 (the facility) located in Dauphin County, Pa. The amendment becomes effective December 29, 1977.

This amendment deletes the requirements of the Technical Specifications dealing with respiratory protection and environmental impact appraisal. The amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated November 15, 1977, (2) Amendment No. 35 to License No. DPR-50, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. and at the Government Publications Section, State Library of Pennsylvania, Box 1601 (Education Building), Harrisburg, Pa.

A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Md., this 29th day of December 1977.

For the Nuclear Regulatory Commission.

ROBERT W. REID, Chief, Operating Reactors Branch No. 4, Division of Operating Reactors.

[FR Doc. 78-202 Filed 1-5-78; 8:45 am]

[7590-01] (Docket No. 27-39)

NUCLEAR ENGINEERING COMPANY, INC.

Receipt of Application for License Amendment and Request for Exemption; Notice of Opportunity for Public Comment

Nuclear Engineering Co., Inc. (NECO), 9200 Shelbyville Road, Suite 526, P.O. Box 7246, Louisville, Ky. 40207, has asked for approval of additional compacted fill burial trenches, in particular "Trench 15", within the currently licensed 20.45 acres at the existing low-level waste burial facility located near Sheffield, Illinois, operated by NECO. The 20.45 acre site has been used for low-level waste since 1968, and is owned by the State of Illinois. Because preparation of an Environmental Impact Statement for the site is in progress, the staff has informed NECO that it will allow use of Trench 15 only after a review following the criteria in 10 CFR 30.11(b). In addition to the regular safety and health review. NECO has requested permission to use Trench 15 prior to the completion of the overall environmental review under 10 CFR Part 51 of the license renewal and site expansion applications (see 42 FR 61522, December 5, 1977), based upon satisfactory consideration and balancing of the criteria in 10 CFR 30.11(b). These criteria are:

1. Whether conduct of the proposed activities will give rise to a significant adverse impact on the environment and the nature and extent of such impact, if any
2. Whether redress of any adverse environmental impact from conduct of the proposed activities can reasonably be effected which is necessary
3. Whether conduct of the proposed activities would foreclose subsequent adoption of alternative ways
4. The effect on the public interest. During the period of any exemption granted pursuant to this paragraph (b), any activities conducted shall be carried out in such a manner as will minimize or reduce their environmental impact.

A licensing decision on Trench 15 is needed by early February, 1978 if NECO is to continue to bury radioactive wastes at the Sheffield, Illinois, facility. Any interested person may comment concerning the staff's approach for authorizing the use of Trench 15 and on the four criteria as applied to Trench 15. Comments should be filed by January 31, 1978 with the Secretary of the Commission, United States Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Section, or may be delivered to the Commission's Public Document Room, 1717 H Street NW., Washington, D.C.

Dated at Silver Spring, Md., this 30th day of December 1977.

For the Nuclear Regulatory Commission.


[FR Doc. 78-199 Filed 1-5-78; 8:45 am]
NOTICES

For the Nuclear Regulatory Commission, ROBERT W. REID, Chief, Operating Reactors Branch No. 4, Division of Operating Reactors.

Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission), has issued Amendment No. 17 to Facility Operating License No. DPR-7, issued to Pacific Gas and Electric Co. (the licensee), which revised Technical Specifications for operation of the Humboldt Bay Power Plant, Unit No. 3 (the facility), located near Eureka, Calif. The amendment becomes effective December 29, 1977.

This amendment: (1) Adds the requirement that the Monthly Operating Report include a narrative summary of operating experience; (2) deletes the requirement for an Annual Operating Report while retaining the requirement that occupational exposure data be reported on an annual basis; and (3) deletes the Respiratory Protection Program from the Technical Specifications.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement, or negative declaraton and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated November 4, 1977, (2) the Commission's letter to the licensee dated July 28, 1977, (3) Amendment No. 17 to License No. DPR-7, and (4) the Commission's Related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., and at the Humboldt County Library, 636 F Street, Eureka, Calif. A copy of items (2), (3), and (4) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Md., this 29th day of December 1977.

U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Md., this 29th day of December 1977.

For the Nuclear Regulatory Commission, ROBERT W. REID, Chief, Operating Reactors Branch No. 4, Division of Operating Reactors.

Issuance of Amendment to Facility Operating License

The Nuclear Regulatory Commission (the Commission), has issued Amendment No. 42 to Facility Operating License No. DPR-28 issued to Vermont Yankee Nuclear Power Corp. (the licensee), which revised Technical Specifications for operation of the Vermont Yankee Nuclear Power Station (the facility), located near Vernon, Vt. The amendment becomes effective on December 29, 1977.

The amendment revises the Technical Specifications to allow the use of a modified Monthly Operating Report format, deletes the requirement for an Annual Operating Report, and deletes the requirements concerning respiratory protection which are now stipulated in 10 CFR 20.103.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application dated November 22, 1977, (2) the Commission's letter to the licensee dated August 4, 1977, (3) Amendment No. 42 to License No. DPR-28, and (4) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., and at the Brooks Memorial Library, 224 Main Street, Brattleboro, Vt. A copy of items (2), (3), and (4) may be obtained upon request addressed to the Commission.

Dated at Bethesda, Md., this 29th day of December 1977.

FRED J. EMERY, Director of the Federal Register. DECEMBER 29, 1977.
NOTICES

[Release No. 20350]
COLUMBIA GAS SYSTEM, INC., ETC.

Proposal by Subsidiary To Issue Common Stock to Parent Holding Company; Issuance of Installment Notes by Subsidiary and Acquisition Thereof by Parent Holding Company; Short Term Advances by Parent to Subsidiary


In the matter of The Columbia Gas System, Inc., 20 Montchanin Road, Wilmington, Del. 19807, and Columbia Gas of Maryland, Inc., Columbia Gas of West Virginia, Inc., and Columbia Gas of Texas, Inc., filed a post-effective amendment to an application-declaration previously filed with this Commission pursuant to the Public Utility Holding Company Act of 1935 ("Act"), designating Sections 6(b), 9, 10, 12(b), and 12(f) of the Act and rules 43, 45, and 50(a)(3) promulgated thereunder as applicable to the proposed transactions. All interested persons are referred to the post-effective amendment, which is summarized below, for a complete statement of the proposed transactions.

By orders dated April 22, 1977, October 17, 1977, and November 23, 1977 (HCA Nos. 19996, 20219 and 20290), Columbia and certain of its subsidiary companies, including Columbia of Maryland and Columbia of West Virginia, were authorized to engage in intrasystem financing to enable the subsidiaries to meet projected expenditures for construction programs and gas supply projects and working capital requirements. Columbia of Maryland and Columbia of West Virginia now estimate that their capital expenditures and working capital requirements will exceed those projected in the application-declaration and that additional intrasystem financing will be required. The increases in expenditures are estimated as follows:

<table>
<thead>
<tr>
<th></th>
<th>Gross and noncash capital additions</th>
<th>Net salvage items</th>
<th>Net capital expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Columbia of Maryland</td>
<td>$829,000</td>
<td>$589,000</td>
<td>$743,000</td>
</tr>
<tr>
<td>Original estimate</td>
<td></td>
<td>$174,000</td>
<td>$200,000</td>
</tr>
<tr>
<td>Increase</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amended estimate</td>
<td>1,003,000</td>
<td>60,000</td>
<td>943,000</td>
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<tr>
<td>Columbia of West Virginia</td>
<td>4,384,000</td>
<td>639,000</td>
<td>3,745,000</td>
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<tr>
<td>Original estimate</td>
<td></td>
<td>815,000</td>
<td>702,000</td>
</tr>
<tr>
<td>Increase</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amended estimate</td>
<td>5,199,000</td>
<td>902,000</td>
<td>4,097,000</td>
</tr>
</tbody>
</table>

The increased construction activity is due to the need to replace more pipelines which were damaged due to last winter's severe cold weather. In addition to funds required due to higher construction costs, Columbia of West Virginia requires additional funds to make refunds to its customers in accordance with an order of the Public Service Commission of West Virginia in a recent rate case.

It is therefore proposed that Columbia of Maryland will issue an additional $200,000 principal amount of installment notes to Columbia and Columbia of West Virginia will issue and sell an additional 200,000 shares of common stock, par value $25 per share, to Columbia for an aggregate sale price of $5,000,000. It is also proposed that Columbia will make additional short term advances of up to $500,000 to Columbia of Maryland to enable the subsidiary to meet state excise taxes which have been accelerated by the State of Maryland.

The purchase of additional installment notes from and the short term advances to Columbia of Maryland and the purchase of additional common stock equity from Columbia of West Virginia shall be subject to the same terms and conditions as the original transactions authorized by the Commission's Order in this file dated April 22, 1977 (HCA No. 19996).

The fees and expenses to be incurred in connection with the proposed transactions are estimated at $1,000. The sale of common stock by Columbia of West Virginia has been authorized by the Public Service Commission of West Virginia. It is stated that no other State commission and no Feder-
In accordance with section 19(b) of the Act and rule 19b-4 thereunder, notice of the proposed rule change was published in the Federal Register (42 FR 57966, November 7, 1977), and the public was invited to comment thereon. Notice of the filing and an invitation for comments also appeared in Securities Exchange Act Release No. 34-14107, October 27, 1977. No letters of comment were received. The Commission has reviewed the proposed rule change and finds that it is consistent with the requirements of the Act and the rules and regulations thereunder applicable to registered clearing agencies. It is therefore Ordered, pursuant to section 19(b)(2) of the Act, That the proposed rule change contained in File No. SR-DTC-77-9 be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons, Secretary.

[FR Doc. 78-178 Filed 1-5-78; 8:45 am]

[8010-01]

MUNICIPAL SECURITIES RULEMAKING BOARD
Order Approving Proposed Rule Change

In the matter of Municipal Securities Rulemaking Board, Suite 587, 1150 Connecticut Avenue NW, Washington, D.C. 20036 (SR-MSBK-77-13). On September 28, 1977, the Municipal Securities Rulemaking Board filed with the Commission, pursuant to Section 19(b) of the Securities Exchange Act of 1934 (the “Act”), as amended by the Securities Acts Amendments of 1975, and Rule 19b-4 thereunder, copies of a proposed rule change which would specify the minimum scope and frequency of periodic compliance examinations of municipal securities brokers and municipal securities dealers. Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by publication of a Commission Release (Securities Exchange Act Release No. 14053 (October 18, 1977)) and by publication in the Federal Register (42 FR 56656 (October 27, 1977)). Interested persons were invited to submit written data, views and arguments concerning the proposal by November 17, 1977. One commentator expressed the view that all municipal securities brokers and municipal securities dealers should be subject to an annual examination cycle. The Commission believes, however, that the minimum twenty-four month cycle established by Rule G-16 will offer self-regulatory and regulatory organizations maximum flexibility in the conduct and scheduling of their examination programs and will be sufficient to ensure compliance with applicable regulations. The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the Municipal Securities Rulemaking Board, and in particular, the requirements of Section 15b and the rules and regulations thereunder.

It is therefore ordered, Pursuant to section 19(b)(2) of the act, that the above-mentioned proposed rule change be, and it hereby is, approved.

By the Commission.

GEORGE A. FITZSIMMONS, Secretary.

[FR Doc. 78-179 Filed 1-5-78; 8:45 am]

[8010-01]

AMERICAN STOCK EXCHANGE, INC.
Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78ss(b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on December 16, 1977 the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

EXCHANGE’S STATEMENT OF TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

The American Stock Exchange, Inc. (“Amex”) proposes to amend Exchange Rule 950(c), the text of the proposed amendment is set forth below (italics indicate new language):

Rule 950. (a) Rules of General Applicability

Rule 950. (c) The provisions of Rule 125, with the exception of subparagraphs (a) and (b) thereof, shall apply to Exchange option transactions and the following additional commentary shall also apply: Commentary

01 When a member holding a spread or straddle order and bidding or offering

1The standard established in the rule is a minimum standard, and examining authorities may establish for themselves more stringent standards consistent with the rule. Furthermore, examining authorities should continue to conduct examinations as frequently as necessary and as circumstances require.
NOTICES

PROPOSED RULE CHANGE

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 16 U.S.C. 78s(b)(1) as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on December 21, 1977, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows (Additions are italicized):

EXCHANGE'S STATEMENT OF THE TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

Rule 8.1 Interpretation and Policies

.01 Options transactions effected on the Exchange which result from orders transmitted from off the floor of the Exchange by a Market-Maker shall be deemed to be initiated on the floor of the Exchange and shall count as Market-Maker transactions for the purposes of this Chapter and Rule 3.1 provided that (i) at the time such orders are transmitted to the floor of the Exchange the Market-Maker is temporarily absent from the floor and (ii) such orders result in options transactions which provide a bona fide hedge of options positions previously opened by the Market-Maker in and Exchange transaction effected by the Market-Maker while on the floor of the Exchange.

.02 For the purposes of Interpretation .01, a bona fide hedge shall occur when an adverse change in the market price of the initial option position would be reasonably anticipated to be offset by a countervailing change in the market price of the subsequent options position, provided that such subsequent position respects the same underlying security as the initial options position.

EXCHANGE'S STATEMENT OF BASIS AND PURPOSE

The purpose of the proposed rule change is to allow Market-Makers to effect a limited number of options transactions from off the Exchange.
floor, which transactions hedge previously established options positions, when such Market-Makers are temporarily absent from the Exchange floor. This proposed interpretation recognizes that since Rule 8.1 requires that Market-Makers be individuals who are either individual members or nominees of member organizations, such persons must necessarily be absent from the Exchange floor from time to time for brief periods. As such, it provides Market-Makers with the capability of reducing the market risk inherent in those options positions previously established pursuant to their obligations under Chapter VIII of the Exchange Rules at times when the Market-Maker must be absent for short periods from the trading floor.

In addition, this proposed interpretation should result in greater on-floor adherence to Market-Maker obligations, for Market-Makers able to anticipate a temporary absence will not feel compelled to limit the size of their options positions during the time prior to the commencement of such absence. It is understood that previously many Market-Makers who knew they would be away from the Exchange for a short time often performed in a way that left them with no open positions during their absence. Consequently, Market-Makers, under this proposal, can more vigorously respond to their continuous obligation to provide liquid markets during the time preceding planned absences, since they will have the ability to protect such options positions during such absences, if necessary. This then should also lead to greater competition among Market-Makers.

Moreover, this proposal will also give Market-Makers the capability to compete more effectively with the specialist units on other exchanges which trade the same options as those traded on CBOE. Specialist units with their interchangeable personnel, unlike CBOE Market-Makers, are subject to maintain a constant presence on the floors of the exchanges of which they are members. By enabling Market-Makers to offset, to a certain extent, previously established options positions with options orders directed off from the Exchange floor, Market-Makers may engage in greater on-floor competition with the specialists of such other exchanges through establishing larger positions in multiple traded options and quoting tighter and deeper markets.

The basis under the Act for the proposed rule change are sections 6(b)(5) and 11A(a)(5) of the Act. The proposed change will promote just and equitable principles of trade and protect investors and the public interest, for it will encourage greater competition among Market-Makers and facilitate the performance of Market-Maker obligations. Such circumstances will produce deeper, tighter, more liquid options markets on the Exchange. In addition, enabling Exchange Market-Makers to compete more effectively with specialists on other exchanges in multiple traded options is consistent with, and in furtherance of, the objectives stated in Congress in section 11A(a)(5) of the Act.

Comments were not solicited nor were comments received regarding this proposed rule change.

The Exchange, as stated more fully above, believes this proposed rule change will enhance competition not only on the Exchange floor, but between the Exchange and other exchange markets as well.

By February 10, 1978, or within such longer period (I) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (II) as to which the Exchange continues to maintain that the question of extending self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons desiring to make written submissions concerning the foregoing, requests to withdraw from consideration the bracketed portion of Rule 319(c) which was deferred by the Commission when it approved amendments to this filing by Release No. 34-15977 on May 27, 1977, because it had not yet taken action on another filing (SR-NYSE—77-13) wherein the bracketed portion is proposed to be defined.

Exchange's Statement of Purpose of Proposed Rule Change

Upon reevaluation, the Exchange feels that the question of extending fidelity bonding requirements to "persons in a securities or kindred business in which the member or member organization has a controlling interest" can be more appropriately addressed in its restructuring of rules relevant to the affiliates and subsidiaries. The Exchange continues to maintain that the extension of fidelity bonding to certain other areas of a member organization's business is necessary to insure adequate protection for investors where the potential risk to the member or member organization is significant. However, these major areas of concern to the Exchange are now being reviewed in a much broader context.

By February 10, 1978, or within such longer period (I) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (II) as to which the Exchange continues to maintain that the question of extending self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

NEW YORK STOCK EXCHANGE, INC.

Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78o(b)(1), as amended by Pub. L. No. 94-29 (June 10, 1975), notice is hereby given that on December 19, 1977, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

TEXT OF PROPOSED RULE CHANGE

FIDELITY BONDS

Rule 319 • • •

(c) Members and member organizations subject to this rule are required to maintain basic and specific coverages, which apply both to Stockbrokers Partnership Bond and Brokers Blanket Bond, in amounts not less than those prescribed in this Rule. Where applicable, such coverage must also extend to limited partners as employees, (persons in a securities or kindred business in which the member or member organization has a controlling interest,) outside organizations providing electronic data processing services and the handling of U.S. government securities in bearer form.

The New York Stock Exchange, Inc., requests to withdraw from consideration the bracketed portion of Rule 319(c) which was deferred by the Commission when it approved amendments to this filing by Release No. 34-15977 on May 27, 1977, because it had not yet taken action on another filing (SR-NYSE—77-13) wherein the bracketed portion is proposed to be defined.

Exchange's Statement of Purpose of Proposed Rule Change

Upon reevaluation, the Exchange feels that the question of extending fidelity bonding requirements to "persons in a securities or kindred business in which the member or member organization has a controlling interest" can be more appropriately addressed in its restructuring of rules relevant to affiliates and subsidiaries. The Exchange continues to maintain that the extension of fidelity bonding to certain other areas of a member organization's business is necessary to insure adequate protection for investors where the potential risk to the member or member organization is significant. However, these major areas of concern to the Exchange are now being reviewed in a much broader context.
Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons desiring to make written submissions should file 6 copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and all written submissions will be available for inspection in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number referred to in the caption above and should be submitted on or before January 27, 1978.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS, Secretary.


(Release No. 34-14314; File No. SR-NYSE-77-35)

NEW YORK STOCK EXCHANGE, INC.

Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on December 14, 1977, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

TERMS OF SUBSTANCE OF THE PROPOSED CONSTITUTIONAL AND RULE CHANGES

(a) The Exchange may deny, limit or revoke its approval of a member or member organization’s telephonic or electronic communication with the Exchange whenever it determines that such communication is inconsistent with the public interest, the protection of investors or the maintenance of a fair and orderly market.

(b) Such denial, limitation or revocation shall be in accordance with the procedural requirements set forth in proposed Rule 475, which is referenced in the rule filed herein and which is the subject of a separate filing with the Commission. Such action shall not be taken unless (i) notice and an opportunity to be heard on the specific grounds is given to the person subject to such action, and any such action is supported by a statement setting forth the specific grounds on which such action is based, or (ii) the grounds for summary action, as set forth in Section 6(d)(3) of the Securities Exchange Act of 1934, exist and the person subject to such summary action is promptly afforded an opportunity to be heard.

(c) The provision which allows the Exchange to deny a member access to the Floor based on the knowledge of entry or filing against such member of any legal process which does not affect the membership is being rescinded. The Exchange may deny a member access to the Floor if the conditions set forth in the rule exist and provided such action is pursuant to the hearing procedure in proposed Rule 475 as outlined in (b) above.

(d) The rule which allows the Exchange to discontinue at any time, any means of communication in or between the offices of a member or member organization, is being rescinded.

(e) The rule requiring that a non-member enter into an agreement with the Exchange whenever it establishes or maintains a communication system with a member for the transmission of electronic data, and which each such member report the continued existence of such arrangements to the Exchange annually, is being rescinded.

PURPOSE OF PROPOSED RULE CHANGE

The proposed amendments would rescind the regulatory requirements that a non-member enter into an agreement with the Exchange whenever it establishes or maintains a communication system with a member for the transmission of Exchange continuous quotations, and that each such member report the continued existence of such arrangements to the Exchange annually. The Exchange does retain a proprietary interest in bid-asked quotations and last sale price information, and is entitled to impose charges for the privilege of receiving such information. These interests are protected by the Exchange’s contracts with vendors and subscribers, including member organizations.

BASIS UNDER THE ACT FOR PROPOSED RULE CHANGE

The proposed amendments to Article III, Section 6, Rules 36 and 303, and the rescission of Rules 356 and 359 are consistent with sections 6(b), 6(d), and 11A of the Act as follows:

The proposed rule changes carry out the purposes of the Act by facilitating competition and providing for a procedure for limiting any member’s access to services. The Exchange’s authority to require physical or electronic access to a member, subject to notice and an opportunity for a hearing, is consistent with the Exchange’s obligation to prevent fraudulent and manipulative practices, to promote just and equitable principles of trade and to protect investors and the public interest, by eliminating certain restrictions on a member organization’s means of communication by...
NOTICES

PHILADELPHIA STOCK EXCHANGE, INC.

Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on December 19, 1977, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

PHILADELPHIA STOCK EXCHANGE, INC. ("PHLX's")

STATEMENT OF TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

The Philadelphia Stock Exchange, Inc. (PHLX), proposes an amendment to Bylaw 3-2 whereby the date of the Exchange's annual meeting and election will be moved from the first Monday in March to the second Monday in March. At such annual meeting there shall be elected, by ballot, a Chairman of the Board of Governors and two Vice-Chairmen of the Board of Governors for the term of 3 years. Beginning with the annual meeting in 1977, and at every third annual meeting thereafter, there shall also be elected by ballot one Public Governor for the term of three years. At each annual meeting there shall also be elected by ballot Governors to fill vacancies in the Board of Governors which may have occurred during the preceding year. In the election of Governors, due regard will be given to the provisions of article IV, section 4-1, of the bylaws with respect to the composition of the Board of Governors of the Corporation.

PHSLX'S STATEMENT OF BASIS AND PURPOSE

The basis and purpose of the foregoing proposed rule amendments is as follows:

The proposed amendment is consistent with the fair administration of the Exchange and by expanding the time period within which members can submit their votes, facilitates under section 6(b)(3) of the Act, assurance of a fair representation of the Exchange's members in the selection of its directors and the administration of its affairs. PHLX states that no comments have been received from members or others on the proposed rule change and believes no burden on competition will be imposed by the proposed amendment.

The foregoing rule change has become effective, pursuant to section 19(b)(3) of the Securities Exchange Act of 1934. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

Interested persons are invited to submit views, data, and arguments concerning the foregoing. Persons desiring to make written submissions should file six (6) copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organizations. All submissions should be made to the number referenced in the caption above and should be submitted by January 27, 1978.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS, Secretary.


[FR Doc. 78-4813 Filed 1-5-78; 8:45 am]

[8010-01]

(PHILADELPHIA STOCK EXCHANGE, INC. ("PHLX"), STATEMENT OF TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE)

The Philadelphia Stock Exchange, Inc. (PHLX), proposes an amendment to Bylaw 3-2 whereby the date of the Exchange's annual meeting and election will be moved from the first Monday in March to the second Monday in March. At such annual meeting there shall be elected, by ballot, a Chairman of the Board of Governors and two Vice-Chairmen of the Board of Governors for the term of 3 years. Beginning with the annual meeting in 1977, and at every third annual meeting thereafter, there shall also be elected by ballot one Public Governor for the term of three years. At each annual meeting there shall also be elected by ballot Governors to fill vacancies in the Board of Governors which may have occurred during the preceding year. In the election of Governors, due regard will be given to the provisions of article IV, section 4-1, of the bylaws with respect to the composition of the Board of Governors of the Corporation.

PHSLX'S STATEMENT OF BASIS AND PURPOSE

The basis and purpose of the foregoing proposed rule amendments is as follows:

The proposed amendment is consistent with the fair administration of the Exchange and by expanding the time period within which members can submit their votes, facilitates under section 6(b)(3) of the Act, assurance of a fair representation of the Exchange's members in the selection of its directors and the administration of its affairs. PHLX states that no comments have been received from members or others on the proposed rule change and believes no burden on competition will be imposed by the proposed amendment.

The foregoing rule change has become effective, pursuant to section 19(b)(3) of the Securities Exchange Act of 1934. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

Interested persons are invited to submit views, data, and arguments concerning the foregoing. Persons desiring to make written submissions should file six (6) copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organizations. All submissions should be made to the number referenced in the caption above and should be submitted by January 27, 1978.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS, Secretary.


[FR Doc. 78-4813 Filed 1-5-78; 8:45 am]
NOTICES

The Philadelphia Stock Exchange, Inc. (PHLX), proposes to amend its listing fee schedule for securities listed on the Exchange. The supplemental listing fee for additional shares or warrants is to be increased from $500 to $1,000 where 100,000 or more shares or warrants are involved. The annual maintenance fee, involving stocks and warrants, is to be increased from $500 to $750 for one issue, and from $100 to $150 for each additional issue. The complete listing fee schedule is attached as exhibit 3 for purposes of information.

PHLX'S STATEMENT OF BASIS AND PURPOSE

The purpose of the change is partially to offset rising administrative costs by an increase in a fixed charge. The new fees are comparable to charges made by other exchanges for similar services. The listing fee change is consistent with equitable allocation of reasonable dues, fees, and charges among members, issuers, and other persons using the facilities of the Exchange, as contemplated by section 6(b) of the Act.

PHLX states that no comments have been received from members or issuers on the proposed change and believes that no burden on competition will be imposed by the proposed amendment.

By February 10, 1978, or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the above-mentioned self-regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or
(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons are invited to submit, written data, views and arguments concerning the foregoing. Persons desiring to make written submissions should file 6 copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number referenced in the caption above and should be submitted by January 27, 1978.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978
sunshine act meetings

This section of the FEDERAL REGISTER contains notices of meetings published under the “Government in the Sunshine Act” (Pub. L. 94–409, 5 U.S.C. 552b)(3).

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[6351-01]
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[6714-01]
2
FEDERAL DEPOSIT INSURANCE CORPORATION.

BROADWAY BANK, a proposed new bank to be located at 151 South Broadway, Chicago, Ill., for Federal deposit insurance.

ORLAND PARK PLAZA BANK, a proposed new bank to be located at 153d Street and LaGrange Road, Orland Park, Ill., for Federal deposit insurance.

AMHERST SAVINGS BANK, an operating uninsured mutual savings bank located in Amherst, Mass., for Federal deposit insurance.

RANDOLPH BANK & TRUST CO., a proposed new bank to be located at 175 North Fayetteville Street, Asheboro, N.C., for Federal deposit insurance.

UNITED SAVINGS BANK, mutual, to be located in Salem, Oreg., for Federal deposit insurance coincident with the conversion of the First Federal Savings and Loan Association of Salem, Salem, Oreg., into a mutual savings bank.

REQUEST FOR AN EXTENSION OF TIME IN WHICH TO ESTABLISH A BRANCH:

First Vermont Bank and Trust Company, Brattleboro, Vt., for an extension of time to December 4, 1978, in which to establish a branch on the east side of Route 100 in Waterbury, Vt.

RECOMMENDATIONS REGARDING THE LIQUIDATION OF ASSETS ACQUIRED BY THE CORPORATION IN ITS CAPACITY AS RECEIVER, LIQUIDATOR, OR LIQUIDATING AGENT OF THOSE ASSETS:

Case No. 43,299—NR, United States National Bank (Addendum) San Diego, Calif.

RECOMMENDATIONS WITH RESPECT TO PAYMENT FOR LEGAL SERVICES RENDERED AND EXPENSES INCURRED IN CONNECTION WITH RECEIVERSHIP AND LIQUIDATION ACTIVITIES:

Bronson, Bronson & McKinnon, San Francisco, Calif., in connection with the receivership of United States National Bank, San Diego, Calif.

Schall, Bouvrie & Gore, Inc., San Diego, Calif., in connection with the receivership of United States National Bank, San Diego, Calif.

Bronson, Bronson & McKinnon, San Francisco, Calif., in connection with the liquidation of First Bank of Northern California, San Leandro, Calif.

Sidley & Austin, Chicago, Ill., in connection with the liquidation of First Bank of Northern California, San Leandro, Calif.


Kaye, Scholer, Fierman, Hays & Handler, New York, N.Y., in connection with the receivership of American Bank & Trust Company, New York, N.Y.

Kaye, Scholer, Fierman, Hays & Handler, New York, N.Y., in connection with the liquidation of Franklin National Bank, New York, N.Y.

Sahn, Shapiro & Epstein, New York, N.Y., in connection with the liquidation of Franklin National Bank, New York, N.Y.

J. Imprim Peter, Miag Corporation, S.C., in connection with the liquidation of American Bank & Trust, Orangeburg, S.C.

(124 pages)
SUNSHINE ACT MEETINGS

FDIC Building located at 550 17th Street NW., Washington, D.C.

CONTACT PERSON FOR MORE INFORMATION:
Alan R. Miller, Executive Secretary, 202-359-4446.

[8:13-78; Filed 1-4-78; 2:45 pm]

FEDERAL DEPOSIT INSURANCE CORPORATION


PLACE: Board Room, 6th Floor, FDIC Building, 550 17th Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Applications for Federal deposit insurance:

Bank of the Sierra, a proposed new bank to be located at 90 North Main Street, Porterville, Calif., for Federal deposit insurance.

Aledo State Bank, a proposed new bank to be located at Farm Road 5, Aledo, Tex., for Federal deposit insurance.

Associated Bank of Appleton, a proposed new bank to be located at 720 East Northland Avenue, Appleton, Wis., for Federal deposit insurance.

Application for consent to change a main office location:

Bank of Lake Helen, Lake Helen, Fla., for consent to move its main office from 121 Lakeview Avenue to the northwest corner of the intersection of Summit Avenue and Main Street, both locations within Lake Helen, Fla.

Application for consent to establish branches:

The Islamorada Bank, Unincorporated Monroe County (P.O. Islamorada), Fla., for consent to establish a branch at the northeast quadrant of the intersection of U.S. Highway 1 and Ocean Bay Drive, Unincorporated Monroe County (P.O. Key Largo), Fla.

Total Bank, Miami, Fla., for consent to establish a branch at 765 East 9th Street, in the LeJeune Plaza Shopping Center, Hialeah, Fla.

Capital Bank of North Bay Village, North Bay Village, Fla., for consent to establish a branch at 5900 Northwest 37th Street, Virginia Gardens, Fla.

Banco Popular de Puerto Rico, San Juan (Hat0 Rey), P.R., for consent to establish a branch at Insular Road No. 9, Kilometer 10.5 and Ignacio Arzuaga Street, Carolina, P.R.

Request for modification of a condition previously imposed in connection with the approval of a branch application:

First Marine Bank & Trust Company of the Palm Beaches, Riviera Beach, Fla., for modification of a condition previously imposed in connection with approval of the bank's application for consent to exercise the powers of executor, administrator, trustee, guardian, committee, agent, custodian, corporate trustee, and corporate agent.

Applications for or requests pursuant to section 19 of the Federal Deposit Insurance Act for the Corporation's consent to service of persons convicted of an offense involving dishonesty or a breach of trust as directors, officers, or employees of insured banks:

Names of persons and of banks authorized to be exempt from disclosure pursuant to the provisions of subsection (e)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6)).

Application for consent to exercise limited powers:

Bank of Springfield, Springfield, Ill., for consent to exercise limited trust powers, namely, to exercise the powers of executor, administrator, trustee, guardian, committee, agent, custodian, corporate trustee, and corporate agent.

Recommendations with respect to the initiation or termination of cease-and-desist proceedings or termination of insurance proceedings against certain insured banks:

Names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (e)(8) and (e)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8) and (c)(9)(A)(ii)).

Memorandum proposing the conduct of an investigation, pursuant to section 10(c) of the Federal Deposit Insurance Act, of the activities of certain persons as they relate to the liquidation of a closed insured bank:

Names of persons and of bank authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(10), (c)(9)(B), and (c)(10)).

NAME OF INSURED BANK

Case No. 43,328-SR—The Peoples Bank of the Virginia Islands, Charlotte Amalie, St. Thomas, V.I.

Case No. 43,332-L—The Monroe Bank and Trust Co., Monroe, Conn.

Case No. 43,304-L—Shawville National Bank, Shawville, Ill.

Case No. 43,312-L—The Peoples Bank of New York, N.Y.

Case No. 43,308—Bank of New York, N.Y.

Case No. 43,311—American City Bank & Trust Co., National Association, Milwaukee, Wis.

Case No. 43,318—American City Bank & Trust Co., National Association, Milwaukee, Wis.

Case No. 43,327-L—American City Bank & Trust Co., National Association, Milwaukee, Wis.

FEDERAL REGISTER, VOL. 43, NO. 4—Friday, January 6, 1978
SUNSHINE ACT MEETINGS

II. PRODUCER MATTERS

A. Producer Certificates

CI-1.--Docket No. CP77-719, South Louisiana Production Co., Inc. (operator), et al.

CI-2.--Docket No. CP77-720, Consolidated Gas Pipeline Co., Inc. (operator), et al.


CI-4.--Docket No. CP74-322 et al.; Michigan Gas Storage Co., et al.

CI-5.--Reserved.

CI-6.--Reserved.

CI-7.--Reserved.

B. Producer Rates

CI-8.--Pennzoil Co., FPC Gas Rate Schedule No. 10.

CI-9.--Reserved.

CI-10.--Reserved.

CI-11.--Reserved.

C. Special Relief


III. PIPELINE CERTIFICATE MATTERS

A. Pipeline Certificates

CP-1.--Docket No. CP74-394, Secretary of the Army v. Cities Service Gas Co.

CP-2.--Docket No. CP77-477, Panhandle Eastern Pipe Line Co.

CP-3.--Docket No. CP77-527, Transcontinental Gas Pipe Line Corp.

CP-4.--Reserved.

CP-5.--Reserved.

CP-6.--Reserved.

B. Liquefied Natural Gas


CP-8.--Reserved.

CP-9.--Reserved.

CP-10.--Reserved.

C. Curtailments

CP-11.--Docket No. RP72-59, Transcontinental Gas Pipe Line Corp.


GAS AGENDA, 47TH MEETING, JANUARY 11, 1978, REGULAR MEETING

I. PIPELINE RATE MATTERS

A. Pipeline Rates (PGA)

RP-1.--RF72-149 (PGA77-103) Mississippi River Transmission Corp.

RP-2.--Reserved.

RP-3.--Reserved.

RP-4.--Reserved.

B. Pipeline Rates


RP-6.--Docket Nos. RP73-3 (PGA76-21) RP73-69 and RP72-99 (PGA76-3), Transcontinental Gas Pipe Line Corp.

RP-7.--Docket No. RP71-140, Consolidated Gas Supply Corp.

RP-8.--Docket Nos. RP71-71 (remand); RP78-104, RP73-107, RP74-90 and RP75-91, Consolidated Gas Supply Corp.

RP-9.--Docket No. RP76-198, North Penn Gas Co.

RP-10.--Docket No. RP77-3, Northern Natural Gas Co.

RP-11.--Docket Nos. RP77-56, RP71-107 (PGA78-1), Northern Natural Gas Co.

RP-12.--Docket No. RP75-9, Columbia Gas Transmission Corp.

RP-13.--Docket No. RP76-140, Natural Gas Pipeline Co. of America; Docket No. RP77-4, Tennessee Gas Pipeline Co., a division of Tenneco Inc.
SUNSHINE ACT MEETINGS

Information, 202-523-5830; recorded message, 202-523-3806.
[S-16-78 Filed 1-4-78; 3:47 pm]

[6750-01]

7
FEDERAL TRADE COMMISSION.
TIME AND DATE: 10 a.m., Tuesday, January 10, 1978.
STATUS: Closed.
MATTERS TO BE CONSIDERED:
Nonadjudicative Matters:
(1) Approval of Minutes of Nonadjudicative Matters Considered at Meetings of November 4, and December 13, 1977.
(2) Consideration of initiation of a consumer redress civil action and/or issuance of an investigational resolution authorizing compulsory process in Las Animas Ranch, Inc., Docket No. C-2877.
Adjudicative Matters Under Part 3 of the Rules of Practice:
(1) Approval of Minutes of Adjudicative Matters Considered at Meeting of December 13, 1977.
CONTACT PERSON FOR MORE INFORMATION:
Wilbur T. Weaver, Office of Public Information, 202-523-3830; recorded message, 202-523-3806.
[S-15-78 Filed 1-4-78; 3:47 pm]

[7030-01]

8
INDIAN CLAIMS COMMISSION.
PLACE: Room 600, 1730 K Street NW., Washington, D.C.
STATUS: Closed to the Public.
FOR MORE INFORMATION:
[S-9-78 Filed 1-4-78; 9:56 am]

[4910-58]

9
NATIONAL TRANSPORTATION SAFETY BOARD.
“FEDERAL REGISTER” CITATION OF PREVIOUS ANNOUNCEMENT:

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: Thursday, January 5, 1978, 9:30 a.m. [NM-78-11]
CHANGE IN THE MEETING: The following item (Item No. 1) has been removed from the agenda:
A majority of the Board has approved this change by recorded vote, and no earlier announcement was possible.

[S-17-78 Filed 1-4-78; 3:47 pm]

[7590-01]

10
NUCLEAR REGULATORY COMMISSION.
“FEDERAL REGISTER” CITATION OF PREVIOUS ANNOUNCEMENT: (to be published).

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, January 4, 1978, 1:30 p.m.
CHANGES IN THE MEETINGS: Time reserved for FY 1978 domestic safeguards technical assistance and research contractual projects is cancelled. Affirmation of proposed rule on avoidance of contractor organizational conflict of interest is cancelled.

CONTACT FOR MORE INFORMATION:
Walter Magee, 202-634-1410.
WALTER MAGEE,
Chief, Operations Branch, Office of the Secretary.

[S-11-78 Filed 1-4-78; 2:45 pm]

[7910-01]

11
RENEGOTIATION BOARD.
PREVIOUSLY ANNOUNCED DATE AND TIME OF MEETING: Tuesday, January 10, 1978; 10 a.m.
CHANGES IN MEETING: Addition of matters 6 through 9 to the previously announced agenda.
MATTERS TO BE CONSIDERED:

FEDERAL REGISTER, VOL. 43, NO. 6.—Friday, January 6, 1978

STATUS: Matters 6 through 9 are open to public observation.

CONTACT PERSON FOR MORE INFORMATION:


GOODWIN CHASE
Chairman

[S-10-78 Filed 1-4-78; 12:44 pm]

[8010-01]

12
SECURITIES AND EXCHANGE COMMISSION.

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of January 9, 1978, in room 825, 500 North Capitol Street, Washington, D.C.

An open meeting will be held on Tuesday, January 10, 1978, at 10 a.m. A closed meeting will be held immediately following the open meeting.

The Commissioners, their legal assistants, the Secretary of the Commission and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meeting may be so considered pursuant to one or more of the exemptions set forth in 5 U.S.C. 552(b)(4), (8), (9)(A), and (10) and 17 CFR 200.402(a) (8), (9)(l), and (10).

Chairman Williams, Commissioners Loomis, Pollack, Evans, and Karmel determined to hold the aforesaid meeting in closed session.

The subject matter of the open meeting scheduled for Tuesday, January 10, 1978, at 10 a.m., will be:

1. Consideration of the adoption of rules defining the term "common trust fund" so as to exempt from the Federal securities laws, common trust funds for constituent banks of a bank holding company to the same extent that common trust funds are exempt for single banks.


3. Discussion of the recommendations for Commission consideration from the Advisory Committee on Corporate Disclosure.

The subject matter of the closed meeting scheduled for Tuesday, January 10, 1978, immediately following the open meeting, will be:

Referral of files to Federal, State, or self-regulatory authorities.

Formal orders.

Institution of injunctive actions.

Settlement of injunctive actions.

Institution of administrative proceedings of an enforcement nature.

Settlement of administrative proceedings.

Freedom of Information Act appeal.

Opinions.

Other litigation matters.

FOR FURTHER INFORMATION CONTACT:
Michael Blount at 202-755-1224 or Katherine A. Malfa at 202-376-8004.


[S-5-78 Filed 1-4-78; 9:56 am]

[7905-01]

13
U.S. RAILROAD RETIREMENT BOARD.


CHANGES IN THE MEETING: Additional items to be considered at the portion of the meeting closed to the public:

(8) Appeal from referee's denial of disability annuity application, Eddie Bailey.

(9) Appeal from referee's denial of child's insurance annuity application, Marion P. Russell.

CONTACT PERSON FOR MORE INFORMATION:
R. F. Butler, Secretary of the Board, COM No. 312-751-4920, FTS No. 387-4920.

[S-9-78 Filed 1-4-78; 12:37 pm]
Department of Health, Education, and Welfare

Food and Drug Administration

OTC Topical Antimicrobial Products

Over-the-Counter Drugs Generally Recognized as Safe, Effective and Not Misbranded
[4110–03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration [21 CFR Part 333]
[Docket No. 75N–0183]

OVER-THE-COUNTER DRUGS GENERALLY RECOGNIZED AS SAFE, EFFECTIVE AND NOT MISBRANDED

OTC Topical Antimicrobial Products

AGENCY: Food and Drug Administration.

ACTION: Tentative Final Order.

SUMMARY: This tentative final monograph would establish conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) products such as antibacterial soaps, surgical scrubs, skin cleansers and first-aid preparations. The monograph is based on the recommendations and findings of the OTC Antimicrobial I Panel and a proposal by the Commissioner of Food and Drugs; in accordance with procedures for the agency's ongoing review of OTC drug products.

DATE: Objections and/or requests for oral hearing before the Commissioner by February 6, 1978.

ADDRESS: Written objections and/or requests for hearing to the Hearing Clerk, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFZ–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, 301–443–4686.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 13, 1974 (39 FR 33103), the Commissioner issued a proposal, pursuant to the OTC drug review procedures in §330.10 (a)(6) (21 CFR 330.10(a)(6)), to establish a monograph for OTC topical antimicrobial products for repeated daily human use, together with the report of the OTC Antimicrobial I Panel, which is the advisory review panel responsible for evaluating data on drugs in that category. Interested persons were invited to submit comments on the proposal within 60 days—on or before November 12, 1974. Reply comments in response to comments filed during the initial 60-day period were allowed until December 12, 1974.

The Commissioner advises that some of the labeling terminology proposed in this document, especially those terms relating to broad spectrum of opinion, may not yet be fully informative to some persons. The Commissioner invites further public comment on the present content and format of the labeling required by the tentative final monograph so that all interested persons may have an opportunity to submit their views and the agency has the benefit of as broad a spectrum of opinion as possible on this aspect of the proposal.

All comments and the proposed labeling will be carefully evaluated, and any changes deemed necessary will, if appropriate, be made in the final monograph.

Numerous comments requested extension of the deadlines for comments and reply comments because of the complexity of the Panel report, the monograph and because the information evaluated by the Panel would not, in accordance with §330.10(a)(2) of the OTC drug review procedures, be available until 30 days after publication. The Commissioner granted the request and issued a notice in the Federal Register of October 3, 1974 (39 FR 25675) granting a 30-day extension of the deadline for comments until December 15, 1974, and the reply comment period was extended until January 1, 1975. The data and information considered by the Advisory Review Panel were put on public display 30 days after publication, i.e., on October 13, 1974, in the office of the Hearing Clerk, Food and Drug Administration, after deletion of a small amount of trade secret information.

In response to the proposal, 66 comments and reply comments were received from 16 trade associations, 45 drug manufacturers, 1 consumer group, 24 consumers, and 4 professional or scientific associations.

The Commissioner has reviewed the report and proposed monograph and all the comments and reply comments. The Commissioner has decided, for clarity, to divide his conclusions in this document in the following sections:

1. The Commissioner's conclusions on the panel's recommendations and conclusions.
2. The Commissioner's restatement of the panel's recommendations and conclusions for Category II (not generally recognized as safe and effective) and Category III (available data insufficient for classification) and the Category III testing guidelines.
3. The Commissioner's conclusions and tentative final monograph.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact statement is on file with the Hearing Clerk, Food and Drug Administration.

1. THE COMMISSIONER'S CONCLUSIONS ON THE COMMENTS AND REPLY COMMENTS

A. GENERAL COMMENTS

1. Several comments contended that the agency does not have the authority under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to establish a maximum other than by formal rule making.

This subject was dealt with in detail in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drugs, published in the Federal Register of May 11, 1972 (37 FR 9464, 9471–9472), and the Commissioner re-affirms the conclusions stated there.

2. One comment contended that the Commissioner's secret information relating to the question of whether long-term use of antimicrobial bar soaps alters the normal balance of microorganisms on the body, published in the Federal Register of September 13, 1974 (39 FR 33103) is a "disclaimer that contravenes paragraph 74 of the May 11, 1972, preamble to the procedures for classification of OTC drugs, published in the Federal Register of May 11, 1972 (37 FR 9464, 9471–9472), which rejected as unnecessary a suggestion that the OTC drug procedures specifically state that the Commissioner is not bound by a Panel's monograph.

The cited paragraph, which stated the Commissioner's conclusion that a boiler-plate explanation of the function of an advisory committee need not be included in the OTC drug procedures, cannot reasonably be interpreted as meaning that the Commissioner's right to comment on a Panel report, to explain or highlight a particular problem, or to emphasize that controversial Panel decisions are subject to additional public procedure and do not represent the final judgment of the agency. The Commissioner will identify areas of controversy or doubt in future Panel reports when, in his judgment, to do so will stimulate maximum public response to these documents.

That long-term use of antimicrobial soaps may alter the normal balance of gram-negative and gram-positive organisms on the body was plainly recognized by the OTC Antimicrobial I Panel's report as a hypothesis, not a proven fact. However, the contrary impression may have been created by the emphasis that the news media gave this one section of the report. The Commissioner therefore included a statement in the preamble designed to bring the matter into perspective and encourage debate on the scientific merits of both sides.

3. One comment stated that "the Panel's duty was to evaluate antimicrobial ingredients, but it made recommendations clearly extending to non-antimicrobial ingredients." The comment...
claimed that such recommendations exceed the legal boundaries of the Panel's responsibility. The comment requested that "the Commissioner modify the monograph to make it clear that the issue is limited to products with antimicrobial ingredients."

Some products that have been traditionally considered first-aid for minor skin wounds are also designed to protect against infection, either by chemical or physical means. These products contain ingredients intended to exclude contamination by microbes, together with antimicrobial ingredients to inhibit the growth of the microbes. These differing functions are interdependent and logically can be considered together as part of a total system aimed at excluding harmful microorganisms from wounds in the human body. The Commissioner believes that consideration of all the ingredients in such a system is within the charge of the Antimicrobial I Panel.

4. Some objected to the degree of testing recommended by the Panel. They argued that such testing was unnecessary and a waste of time, resources, and money. This conclusion was predicated on the belief that ingredients listed in Category III have been used safely and effectively for many years. The comments called upon FDA to issue a financial impact statement. The costs of such testing for these ingredients would be some products, it was contended, and, according to one comment, such products would be withdrawn from the market in spite of marketable medicinal uses. The comment suggested that the cost of required testing be underwritten by the government rather than by manufacturers.

In performing the task it was assigned, the Panel used its best judgment about what testing requirements are required for ingredients placed in Category III. The OTC drug review regulations and the historical evidence negate the generality that longtime use of an ingredient indicates that it is necessary to prove safety and effectiveness that is demanded by current scientific standards. The Commissioner does not intend to create testing regimens more burdensome than needed to prove safety and effectiveness, as required by law. The fact that testing must be scientifically valid and adequate to reach reliable conclusions, and therefore may be costly, is a product of the statutory standard as applied by experts to the principles of drug investigation. The Commissioner does not believe that such testing will place undue burden on the industry and the research community. Although the cost of testing a product may be a factor in the decision as to whether FDA regulations may in exceptional cases exceed the sales of a product in any given year, it is improbable that such cost would exceed sales over a significant period of time. The market life of a product. The financial impact statement requested by these comments is on file in the office of the Hearing Clerk, Food and Drug Administration.

The Commissioner is alert to the need to conduct self-tests in an economical manner and without unnecessary duplication of effort. However, the public must be assured that marketing of products with Category III ingredients, claims is permitted only on condition that appropriate testing is concurrently carried out to resolve issues that have been identified by the Panel concerning safety and effectiveness. Testing required by the Commissioner and the research community. Although the Commissioner does not believe that such testing will be withdrawn from the market in some than-needed to prove safety and effectiveness, the generality that longtime use of an ingredient is limited to products with antimicrobial ingredients. The Panel and to participate in preparing the tentative final and final monographs. Employees who have worked with the Panel best understand its reasoning and deliberations. Those best qualified to review comments on the Panel's report. Of course, the comments on the proposed monograph are reviewed not just by those individuals who served on the Panel, but by many others who have worked with the agency. Consequently, the views of those persons who assisted the Panel will not prevail unless they are scientifically reasonable and sustainable on the record.

6. Several comments stated that FDA "bears the burden of proving the statutory solution" with respect to OTC drug regulations, and that the agency must demonstrate a preponderance of the evidence that a drug is not generally recognized as safe and effective."

It is not clear what was intended by these statements. The comments mean that the agency must establish a basis and purpose for the regulations issues, they are correct. Section 4 of the OTC monograph (21 CFR § 101) requires that the agency incorporate in each regulation a concise general statement of its basis and purpose. As noted above (paragraph A.1.), the legal status of OTC drug monographs is discussed elsewhere.

7. A comment stated that "If each and every company must submit active ingredients, vehicle and total product tests recommended by the Panel this would be tantamount to a pre-clearance requirement on every product. It is our understanding that FDA chose the OTC Drug Review route to avoid this."

The Commissioner will not require every company to test and will ordinarily not require testing of the active ingredient, vehicle, and total product. However, within the broad and varied class of OTC drugs there may possibly be circumstances in which review and testing of individual products is the only way to determine whether the statutory and regulatory criteria are met. While this may result in more extensive testing for a very few classes of OTC products than was envisioned at the beginning of the OTC drug review, the requirements applicable to these products will be nowhere near as extensive and detailed as the new drug application (NDA) requirements. For certain product classes in this monograph, where safety and irritancy are of importance, data will have to be submitted on active ingredients, vehicles, and/or total products. These ingredients or product classes will be delineated in appropriate testing guidelines.

8. A comment claimed that "there is no provision in the law for Category III."
The list of the comment is that Category III status is incompatible with continued lawful marketing of a product without an approved NDA.

This issue is currently the subject of litigation in the U.S. District Court for the District of Columbia. Health Research Group v. Kennedy, Civ. Action No. 77-0734. The Commissioner's position on the matter will be explained in that forum.

9. One comment suggested that all Category III products should bear the label statement "WARNING * * * the safety of this product has not been determined."

Products in Category III have been on the market for many years. Classification in this category permits them to remain on the market for a longer period while evidence is developed to permit their final classification into either Category I or Category II. A product may be in Category III for a number of reasons having nothing to do with safety, including questions about its effectiveness. To require all Category III products to bear a safety-related warning for a brief period of time may be confusing to consumers who are not interested in the questions involved. The warning as phrased is, moreover, misleading even for products that have been placed in Category III to obtain more safety data. It implies a complete absence of information supporting the safety of products for which there will ordinarily be a lengthy history of safe use and a considerable body of experience that the new drug application would support. The Commissioner advises that drugs are not placed in Category III if currently available data serious concerns about their safety. Such drugs are either placed in Category II or sub-
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jected to expedited regulatory action out-
side the OTC Drug Review procedures,
depending on the reliability and conclu-
siveness of the data and the degree of
harm the drug might cause.

10. Numerous comments objected to
the 1-year limit for testing products with
claims based on Category III ingredients,
primarily because of the large number of
products in Category III that require
testing under regulatory schemes of
bottleneck personnel and laboratory facilities
that would make it impractical to carry out
the required safety and stability tests
within the 1-year period.

The Commissioner concludes that
because of the extensive testing require-
ments and the many ingredients in Cate-
ogy III, a 2-year testing period would be
appropriate. He therefore considers that
Category III conditions should be
permitted to remain in use for 2 years
after the date of publication of the final
monograph in the Federal Register.

11. A number of comments suggested
that the Panel appears to have set standards
contrary to the concept that OTC drugs are
generally symptom-oriented, in contrast
to prescription drugs, which are disease-
oriented, and, therefore, that the Panel
exceeded its charge.

The Panel was charged with judging
the scientific merit of claims for safety
and effectiveness of OTC products con-
taining antidermal ingredients for
topical human use, which include soaps,
surgical scrubs, skin washes, skin
 cleaners and first-aid preparations, pur-
ges of the report should have made it

12. A comment expressed concern over
the theoretical existence of the normal
flora balance. The Commissioner agrees that
the normal flora balance, if disrupted,
can involve certain gram-positive
organisms, such as Staphylococcus, but
is not relevant to the Commissioner in judging
whether or not the consumer is receiving
what he is paying for in terms of a par-
ticular claim made for a product.

Although the Commissioner recogn-
izes that OTC drugs are generally
symptom-oriented rather than disease-
oriented, he is aware of several areas in
which OTC products are used to treat
disease, e.g., athlete's foot and acne. Since
the difference between symptom and dis-
ease is not well defined, each OTC drug
ingredient claim will be judged on its
own merit for safety and effectiveness
regardless of whether the claim is di-
rected to a disease condition or symptom.

13. There was comment from authors
of papers describing the use of antimic-
robial soaps on patients isolated in hos-
pital “life island” facilities. It was said
that Panel statements about the papers
do not clearly distinguish between the
authors’ and the Panel’s opinions. The
authors wished to make it clear that the
work shows major reduction of bacte-
rical-colony-forming units on all body
sites tested, including reductions in
gram-negative bacterial counts. The
comment, further discussing bacterial
reduction, stated that the bacteriostatic
soap preparations used in these studies
were “certainly equivalent to prepara-
tions containing hexachlorophene.”

The Commissioner agrees that the lan-
guage of the reports should not make it
clear that the Panel was stating its own
analyses and conclusions rather than
those of the authors of the cited scien-
tific papers.

14. Comments criticized the composi-
tion of the Panel, which included no
surgeons, because surgeons routinely rec-
ommend and use antimicrobial cleansing
products.

The Commissioner recognizes that
antimicrobial ingredients are contained
in marketed surgical scrubs that are
used by surgeons, but does not believe
that including surgeons on the Panel
would have improved the reliability of the
advice rendered. Judg-
ments about the safety and effective-
ness of antimicrobials are made on the
basis of microbiological, toxicological,
epidemiological, and biostatistical data.
The Panel members were qualified to
judge such data in fact cited scientific
literature published by surgeons. In addi-
tion, the procedures employed for de-
veloping the monograph include oppor-
tunities for surgeons to express their
views. The Panel itself requested advice
from the appropriate committee of the
American College of Surgeons, but re-
ceived no response.

15. Numerous comments referred to
the hypothesis that elimination of gram-
positive skin bacteria is inevitably fol-
lowed by shifts in environmental pres-
ence and dominance of gram-negative
bacteria. They contended that the concept is not
supported by a preponderance of exis-
ting evidence, and that, therefore, the
danger that might exist from the postu-
lated phenomenon is speculative. Com-
ments cited scientific literature to sup-
port the claim that gram-negati-
v bacterial overgrowth after use of an
antimicrobial soap is a risk not yet
expected not verified by experience. The
existence of an unsubstantiated hypothe-
sis provides no scientific or legal justifi-
cation for banning the normal household
use of antimicrobial soap, the comments
argued.

The Panel statements did not imply
the inevitability stressed in the com-
ments, but rather were intended to call
attention to the published literature in-
dicating such a potential and to encour-
age studies of the normal flora balance.
A few studies completed since the Panel’s
report have verified that shifts, and more
probably, simplifications, of flora do oc-
cur.

The Commissioner advises that the na-
ture and quantity of evidence required
to support a judgment of safety and ef-
civeness is dependent on the individu-
al case. The unproven hypothesis that danger may exist in
particular circumstances does not, in
itself, constitute a sufficient basis for
banning the use of a product. The
Commissioner is aware of the theory that
gram-negative bacteria, which may be
undesirable, will replace gram-positive
bacteria that are reduced in number or
eliminated by use of an antimicrobial
soap. The theory is still the subject of
experimentation, documentation, and
debate. The Commissioner encourages
research aimed at testing the validity of
the theory with reference to the use of
OTC antimicrobial products.

The Panel has served a useful pur-
pose in highlighting the need for re-
search on the microbial ecology of the
skin. The Panel was concerned with the
need to understand the factors in-
volved in maintaining the balance
among species of microorganisms that
constitute the normal skin microflora.
This balance is threatened by use of disinfec-
tants, antibiotics, and other anti-
microbial products.

The Panel was particularly concerned
about the effect of overuse of antimicro-
bial products in closed populations, such
as hospitals or nursing homes, where
organisms such as Pseudomonas, which
are effective against gram-positive
organisms, but not against gram-negative
organisms, such as Pseudomonas. Serious
effects can be expected in severely
debilitated patients or in patients at
high risk, such as burn victims, the
elderly, and newborns. If gram-negative
organisms are encouraged to multiply
unchecked by the selective eradication
of gram-positive organisms. The results can be devastating.

The Commissioner concludes that professional labeling (labeling for health professionals but not for the general public) for certain antimicrobial products is appropriate for OTC drug use, but primarily used in health-care facilities, should therefore state: "Caution: Overuse of this and other antimicrobial products may result in the development of drug-resistant microorganisms."

B. COMMENTS ON DEFINITIONS

21. A comment discussed the Panel's definition of active "antimicrobial ingredient": "An agent which kills or inhibits the growth and reproduction of microorganisms" (39 FR 33107). The Panel stated that the definition is not clear and leads to illogical and bizarre results. The comment suggests

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the following definitions for an active antimicrobial ingredient:

"The active ingredients of a product are those ingredients which contribute functionally to the uses of that product claimed in its label. An active antimicrobial ingredient is an agent which, when appropriately formulated and used, kills or inhibits the growth and reproduction of micro-organisms."

The comment poses two basic problems: First, the lack of a clear definition of active versus inactive ingredients; second, some clarity in the basic definition of "antimicrobial." As to the first point, the Commissioner agrees with the comment that for regulatory purposes, the dividing line between an active antimicrobial ingredient considered as a preservative is dependent upon the relationship of the ingredient to the claim that appear in the labeling of the product. The Commissioner, therefore, defines an "active" antimicrobial ingredient as a compound or substance that contributes functionally to the claimed effect of the product. An "inactive" antimicrobial ingredient is defined as an antimicrobial agent that is included in a product strictly as a preservative for the product itself, or for the product formulation. The definition of "antimicrobial" and other definitions in labeling. The definition of "antimicrobial" ingredient is somewhat ambiguous due to inclusion of the phrase "contributes functionally."

Accordingly, the Commissioner is adopting the following definitions in § 333.3 of the tentative final monograph:

§ 333.3 Definitions.

(a) Antimicrobial (active) ingredient. A compound that kills microorganisms or prevents or inhibits their growth and reproduction and contributes to the claimed effects of the product in which it is included.

(b) Antimicrobial preservative (inactive) ingredient. A compound or substance that kills microorganisms or prevents or inhibits their growth and reproduction and is included in a product formulation only at a concentration sufficient to prevent spoilage or prevent growth of inadvertently added microorganisms, but does not contribute to the claimed effects of the product to which it is added.

22. Two comments stated that the definition of "soap" is "metallic salts of organic fatty acids," a definition which has also been used by FDA, and one of which the Panel's definition of "antimicrobial soap" could exclude antimicrobial bars containing synthetic detergents. The comments expressed the hope that "there is no intention to exclude" such soap preparations.

The word "soap" has a strict chemical definition, and is also perceived by consumers as any cleanser or product that includes soap (according to the chemical definition) as an essential part of the formulation. Examples of "antimicrobial soap" for purposes of the monograph relates only to the presence or absence of an antimicrobial ingredient, not to the manner in which "soap" generally is formulated.

The Commissioner concludes that soap formulations containing synthetic detergents are within the scope of the term "antimicrobial soap." Those ingredients which contribute functionally to the claimed effects of the product in which it is included. The Commissioner believes that OTC products should be available for symptomatic relief of normally self-limiting conditions that can be diagnosed by a lay person, he agrees that labeling must be such as to warn any reasonable user if the diagnosis appears to have been incorrect because the condition fails to improve, the lay person should seek appropriate professional treatment.

Accordingly, the Commissioner concludes that the following warning will be required on labeling of skin antiseptics, skin wound cleansers, and skin wound protectants: "Do not use this product for more than 10 days. If the infection worsens or persists, see your physician." The time limit was chosen on the basis of the average length of time for the completion of the normal healing process for a minor wound, which has been reported by Anderson to be 7 to 10 days (Anderson V., "Over-the-Counter Topical Antibiotic Products: Data on Safety and Efficacy," supplement to International Journal of Dermatology, 16:1-18, 1976). In addition, the Commissioner concludes that all product categories (other than antimicrobial bar soaps) should contain the warning, "For external use only.

24. A comment suggested that the definition of antimicrobial soap in § 333.3 (a) of the proposed panel (§ 333.3 (c) in the tentative final monograph) be changed by deleting "in vitro."

The Commissioner agrees with the Panel that there is a need to inculcate results of in vitro testing to delineate or characterize activity of an ingredient as an antimicrobial. Results of in vitro testing will then give some guidance by which safety and effectiveness tests can be confirmed in labs and in testing. The definition of "antimicrobial soap" therefore can be retained because it is more inclusive than the one suggested in the comment. However, the comment has also raised a problem with regard to inclusion of the phrase "in vitro." The Commissioner recommends that any phrase(s) used in definitions of the various product classes be permitted in labeling. Although some of the phrases in the definitions would add clarity to the claims for these product classes, the inclusion of phrases such as "in vitro" or "in vivo" in antimicrobial product classes would not be informative and would likely be misleading. Accordingly, the Commissioner will modify the Panel's recommendation in the monograph to include only selected phrases from the panel's definition. The modified graph will provide for specific labeling indications and other allowable statements.

25. A comment asked that additional terms be allowed for labeling of the product category "antimicrobial soap." The additional terms requested are those presently suggested by the Panel for the category "health-care personnel handwash": "decreases bacteria on the skin, reduces risk and/or chance of cross-infection, recommend for repeated use."

The Commissioner notes that products in the category of "health-care personnel handwash" are intended to serve a different purpose than products in the category "antimicrobial soaps." "Health-care personnel handwashes" are intended to be used as often as 50 to 100 times by the average consumer, though it has specific meaning for health-care personnel who may wash 50 to 100 times a day and who thus require a product that is not irritating. The statement would be inappropriate for an antimicrobial soap; safe antimicrobial ingredient levels in antimicrobial soaps are established by reference to use a few times daily, not 100 times daily.

"Reduces risk and/or chance of cross-infection" does not relate to the circumstances of use by the average consumer and would instill in his mind the expectation of greater health benefits. Health-care personnel ascribe much more specific meaning to this claim.

"Decreases bacteria on skin" applies literally only to both an antimicrobial soap and a health-care personnel handwash (provided it contains an antimicrobial). However, this type of claim could be misleading to the lay person unless accompanied by clarifying language, such as "decreases bacteria on the skin which cause odor." Absent such a qualification, the Commissioner believes, the average consumer could mistakenly conclude...
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that a decrease in bacteria necessarily signifies a decreased likelihood of infection. This could lead an individual who develops a minor infection in a skin wound to use an antimicrobial soap instead of a skin antiseptic. Accordingly, the Commissioner concludes that the additional term should not be included in labeling for antimicrobial soaps.

26. There was comment that extensive trials conducted with antimicrobial soaps (some containing triclosan as an ingredient) were used in prophylaxis of minor skin infections to support the effectiveness of these products, as do testimonials from recognized experts.

The Panel analyzed the clinical trials that were submitted and published in the scientific literature. The Commissioner concurs with the Panel's conclusion that clinical effectiveness has not been shown unequivocally. Under the requirements of the OTC drug review regulations (21 CFR 330.10(a) (4) (ii)) and section 512 (a) (1) (A), U.S.C. 321 (p), opinions of experts, unsupported by adequate and well-controlled clinical investigations substantiating effectiveness, are not evidence of general recognition. The Panel remains firm in its conclusion that adequate, well-controlled trials to demonstrate clinical effectiveness of these products, as set forth in the testing guidelines.

27. A comment suggested that the definition of health-care personnel handwash in proposed §333.3(b) be revised to delete the requirements that the products be "nonirritating" and, if possible, persistent.

The Panel was concerned with the need for frequent, repeated use of these products according to an established regimen intended to reduce the risk of cross-infection in health care facilities. To assure proper use, the products, which may be used as often as 100 times daily, must be nonirritating. Persistence, defined as prolonged activity, is a valuable attribute that assures antimicrobial activity during the interval between washings. The Commissioner agrees with the Panel that these two attributes are important to safe and effective health-care personnel handwash, and is, therefore, retaining the Panel's definition in §333.3(d) of the tentative final monograph. In addition, the Commissioner has provided directions for use as follows: "Wet skin and spread a small amount on hands and forearms. Scrub well and rinse thoroughly after washing."

28. A comment objected to permitting a patient preoperative skin preparation to be an OTC product, especially since it is primarily used in hospitals. The reason given was that the surgeon usually prescribes for his patient the types of antimicrobial to be employed in preparing the site of incision. It was also suggested that surgical hand scrubs be limited to prescription use because their use is directed or supervised by the practicing surgeon.

"Prescribe" can mean to specify use of a drug legally restricted to dispensation, or simply to specify with authority. It is common for physicians, on the basis of their professional knowledge, to direct the use of various products, such as OTC drugs and certain foods, that are not limited to prescription sale. The OTC or prescription status of patient preoperative skin preparations or surgical hand scrubs, therefore, does not affect the surgeon's ability to control what product will be used to prepare his patient for surgery or by those participating in the procedure. Nor does it relate to the safety or effectiveness of these products.

The difference between an OTC or prescription product does not lie in effectiveness, but in whether it can be labeled for safe and effective use by the lay person. Since patient preoperative skin preparations and surgical hand scrubs can be so labeled for use by health care personnel, there is no reason to reclassify these products.

29. A comment suggested that the proposed monograph definition of skin antiseptic in §333.3(d), skin wound cleanser in §333.3(e), and skin wound protectant in §333.3(f) be modified to delete the requirement that the product classes be nonirritating and that the definitions of skin wound cleanser in §333.3(e) and skin wound protectant in §333.3(f) be modified to delete the requirement that such products do not delay wound healing.

The Panel considered these factors that could affect the effectiveness of these products. One of the factors considered was the relationship of irritation to delay in wound healing. The Panel believed, and the Commissioner concurs with the Panel, that irritation should not be nonirritating because irritation may delay wound healing. Therefore, the term "nonirritating" is retained in the cited definitions, as is the requirement that skin wound cleansers and skin wound protectants not delay wound healing.

The Commissioner has further reviewed the proposed warnings for skin antiseptics, skin wound cleansers, and skin wound protectants. Based upon a review of all the data available, he concludes that the labeling should be revised to the statements proposed in the tentative final monograph below.

30. A comment asked for a judicious rather than an absolute interpretation of the requirement that a skin wound cleanser and a skin wound protectant not delay wound healing. It emphasized that a product may compensate for delay in healing with other benefits, such as pain relief. Similar comments were received regarding the nonirritation requirement. The Commissioner agrees, that such products should not be irritating because irritation may delay wound healing. Therefore, the term "nonirritating" is retained in the cited definitions, as is the requirement that skin wound cleansers and skin wound protectants not delay wound healing.

The Commissioner has further reviewed the proposed warnings for skin antiseptics, skin wound cleansers, and skin wound protectants. Based upon a review of all the data available, he concludes that the labeling should be revised to the statements proposed in the tentative final monograph below.

31. A comment stated that the requirement that a skin wound cleanser not delay wound healing is meaningless since no standard is specified by the Panel, the requirement cannot be met.

The comment is incorrect. The Panel agrees to controlled observation that there are experiments in which the product would necessarily be compared to an objective method. For example, a test might include a comparison of wounds on the same subject: one wound treated with the product minus the antimicrobial ingredient, another wound treated with the product itself. Under the Panel's definition, the test product is not formulated in such a way to prevent infection; it must show that healing delay is minimal and is offset by a compensating benefit.

32. A comment suggested that the proposed definition of skin antiseptic in §333.3(d) be modified to delete the requirement that claims for activity against specific microorganisms be supported by controlled human studies demonstrating prevention of infection.

The Commissioner agrees. The Panel was aware that there is testimonial evidence for prevention of overt skin infection by skin antiseptics, but that there is an absence of controlled studies to validate this hypothesis. The Panel's intent was to emphasize the importance of proving effectiveness and to eliminate the need to prove activity against specific microorganisms as sufficient reason to support the claim for activity against specific microorganisms. The Commissioner recognizes and agrees with the Panel's concern for adequate testing; but, in the interest of consistency with the other product category definitions, which do not include such testing requirements, the Commissioner is modifying the definition of skin antiseptic to delete the reference to this testing requirement. Controlled human studies to prove effectiveness of skin antiseptics will, however, be required and will be included in the testing guidelines discussed in this document.

33. A number of comments objected to the Panel's definition of skin antiseptic as inconsistent with section 201(o) of the act, which states:

The representation of a drug, in its labeling, as a skin antiseptic, shall be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, elixir, dusting powder, or such other use as involves prolonged contact with the body.

The comments contend that, under this provision, a skin antiseptic need only have beneficial properties and not demonstrate clinical effectiveness.

The comments erroneously equate the minimum standard of performance established by Congress for products...
The comment is in error in stating that "evaluations must be restricted to judgment based on the literature and long market experience in the case of skin antiseptics." The regulation specifically states that "Isolated case reports, random experience, and reports lacking the details which action, the evaluation will not be considered" (21 CFR 330.10(a)(4)(ii)). The relationship of marketing history to effectiveness was discussed in Section 36. In paragraph 50 of the preamble to the final OTC drug regulations published in the Federal Register May 11, 1972 (37 FR 9469), it was noted that marketing experience which indicated that marketing experience could only be considered to corroborate adequate scientific evidence.

37. A comment objected to defining a skin wound cleanser without a requirement for the presence of an antimicrobial agent. The comment noted that the word "antimicrobial" does not occur in the definition of skin wound cleanser.

The Panel stated that the primary purpose of a skin wound cleaner is to remove foreign material, dirt, and debris (39 FR 33112, paragraph 7). The Commissioner concludes that the Panel's discussion, which reflects that purpose, is reasonable. The definition does not preclude incorporating an effective antimicrobial in such products. Moreover, it preserved for the consumer as to whether treatment of a wound will be a two-step treatment (cleansing a wound of debris and foreign matter and subsequently applying an antimicrobial), or a single-step treatment (applying a cleaner combined with an antimicrobial).

38. Comments asked for a subcategory of skin wound cleanser that would specifically recognize products containing an antimicrobial.

The Commissioner agrees that the public should be fully informed of the contents of the products it uses. In the case of skin wound cleaners, it is important that the consumer know that an antimicrobial ingredient has been included in such a product. So long as the labeling claims remain unchanged, the Commissioner does not believe that the consumer will be misled by identifying the presence of such an ingredient in the active ingredient section of the label. Accordingly, the Commissioner will permit the label to state that the product contains an antimicrobial by listing it as an active ingredient subject to the labeling limitations for skin wound cleaners, no subcategory with additional labeling will be permitted.

39. A comment objected to the phrase "prohibits the growth of microorganisms" in the definition of skin wound protectant in §333.3(c) of the September 1974 proposal as superfluous.

The Panel recognized that a skin wound protectant as a physical barrier can exclude contamination, but also that it might itself be capable of being colonized by microorganisms already present in the wound. Thus, there is justification for requiring that the protectant both prevent admission to a wound of microorganisms from the environment and not provide environmental conditions within the wound that would enable the growth of microorganisms by alteration of the wound environment itself. The requirement that the protectant not favor the growth of microorganisms is important, given the utility of giving the skin wound protectant a chance to establish itself in a wound.

The Commissioner therefore concludes that, except for the changes set forth in paragraph 40 below, the definition of skin wound protectant in §333.3(c) of the tentative final monograph should remain as recommended by the Panel.

40. A comment pointed out that part of the definition in the Panel's report that a skin wound protectant must act as a physical barrier is not consistent with the monograph's definition referring to either physical or chemical barriers to infection.

The Commissioner believes that the comment has misinterpreted the requirements of a skin wound protectant. Such products were intended to serve as a barrier against contamination by external microorganisms entering the wound. The Panel through its definition of skin wound protectant and its discussion of skin wound protectants in the testing guidelines of their report (39 FR 33140) attempted to make clear its view that this class of products must in all cases provide a physical barrier for minor wounds and might also contain an antimicrobial ingredient, a "chemical barrier," to inhibit growth of microorganisms that might remain after a wound is cleansed. These products might include the antimicrobial ingredients reviewed by this Panel, or topical antibacterial ingredients now being reviewed by the OTC Antimicrobial II Panel, or ingredients now being reviewed by the OTC Miscellaneous External Drug Products Review Panel. It is even possible that the latter Panel might suggest nonchemical ingredients to be used solely as physical barriers. However, the Panel made no recommendations on skin wound protectants with only physical barriers. Unless and until such recommendations come to the Commissioner's attention, skin wound protectants must be labeled as antiseptics with the appropriate definition or classification for such products in relation to their function in determining when drugs are generally recognized as safe and effective. Section 201(o) establishes that, at a minimum, a drug classification must be germicidal rather than merely germicidal or bacteriostatic. That is, it must actually kill the organisms, not merely inhibit their growth and/or reproduction. An exception was made for certain types of drugs, such as wet dressings, where inhibition alone might be sufficient due to prolonged contact with the body. That a product has germicidal properties, i.e., the minimum pharmacologic effect required by section 201(o) of the act, however, does not mean that it is "effective" under section 201(p) of the act. Effectiveness refers to the ability of a drug to achieve its intended purpose.

Drugs are generally not considered effective simply because they demonstrate pharmacologic activity, that is, the pharmacologic effect without a corresponding therapeutic benefit is of no use to the patient. Specifically, it is not established that a patient will benefit solely from germicidal action of skin antiseptics, which, therefore, cannot be considered effective within the meaning of the act unless they can be shown to accomplish a useful therapeutic purpose, i.e., prevent skin infection. Accordingly, skin antiseptics must prove effectiveness by means of controlled human studies using the testing guidelines discussed elsewhere in this document.

34. A comment pointed out that "controls infection" is a permissible label term for skin antiseptic, and yet is prohibited in another section of the Panel's report, under "Labeling" (39 FR 33123).

The Commissioner agrees and will delete references that this claim is prohibited in the definition of a drug to achieve its intended purpose. The act, however, does not mean that it is "effective" under section 201(p) of the act. Effectiveness refers to the ability of a drug to achieve its intended purpose. The Commissioner agrees that the inconsistency pointed out in the comment should be corrected. In the Category I discussion below the Commissioner will delete references that this claim is misleading.

35. A comment asked that the phrase "contains antimicrobial ingredients" be permitted in labels for skin antiseptics.

The Commissioner agrees and will permit this term to be used in labeling for skin antiseptics.

36. A comment contended that "evaluations must be restricted to judgment based on the literature and long market experience in the case of skin antiseptics." The Commissioner concludes that the Panel has acted reasonably and in full accord with the regulations governing clinical investigations as defined in §341.111(a)(5)(ii) "**", unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. ** *

** Proof of effectiveness shall consist of controlled clinical investigations as defined in §341.111(a)(5)(ii) "**", unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. ** **
be viewed as products that provide both a physical and a chemical (antimicrobial) barrier to cleansed small wounds. According to the definitions of the tentative final monograph, the word “and” is substituted for the words “and/or” in the definition of skin wound protectant identified in §331.3(h); the paragraph thus refers to a physical and/or a chemical (antimicrobial) barrier.

A comment suggested modifying the directions for use of skin wound protectants to delete the statement “cleanse wound thoroughly before applying.” The Panel’s discussion made it clear why it is necessary to cleanse wounds of debris and extraneous foreign matter before application of a skin wound protectant. The Commissioner believes that the consumer should be informed of the requirements for self-care of wounds. Accordingly, the Commissioner is retaining the Panel’s suggested language, with slight modifications for clarity.

A comment suggested that the definition of surgical hand scrub be revised to delete the requirement that the product be nonirritating. The property of causing irritation it may have an adverse effect on the effectiveness of the product. If the product has the property of causing irritation it would be inadequate for use as a surgical hand scrub. Consequently, the Commissioner is retaining in the tentative order the Panel’s requirement that the product be nonirritating.

As noted in the response to comments in paragraphs 29 through 31 above, irritation may have an adverse effect on wound healing. Although surgical hand scrubs are not intended for treatment of wounds of wounds of healthcare personnel often wash frequently with such a product. If the product has the property of causing irritation it would be inadequate for use as a surgical hand scrub. Consequently, the Commissioner is retaining in the tentative order the Panel’s requirement that the product be nonirritating.

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is safe and is the minimum effective concentration. This is stated in § 333.65 of the tentative final monograph below which provides that "All antimicrobial ingredients used singly or as part of a preservative system * * * shall be tested by the manufacturer to establish the minimal preservative concentration for every product formulation * * * ."

47. A comment objected to the Panel's recommendation to prohibit use, as preservative, methylparaben and propylparaben as Category II ingredients. The Panel's comments as to the preservative dosage level it is toxic and is very effective. The comment argued that other antimicrobials might also be safe for use as preservatives even though they are not considered safe for use as active ingredients.

The Commissioner appreciates the concern that sufficient ingredients be available as preservatives to assure that products are uncontaminated with microorganisms. The comment correctly states the agency's position that even if ingredients are unsafe at active concentrations they may be employed as preservatives if at those concentrations no hazard exists. However, the Commissioner notes that § 250.250 (d) states that methylparaben is only permitted to be included as a preservative where other preservatives are not available and when it is part of a preservative system, not by itself.

Accordingly, the Commissioner will accept use of a Category II ingredient as a preservative, but only if the following conditions are met: It is not a carcinogen, a significant contact sensitizer, or a photosensitizer; it acts as a preservative at concentrations below those causing pathology in mammals; and no adequate substitute is available. Such data must be submitted to the agency in the form of a petition to amend the OTC topical antimicrobial monograph to permit use of such ingredients at preservative levels.

48. A comment stated that contrary to the statement of the Panel (39 FR 33106), methylparaben and propylparaben were not listed as active ingredients by the manufacturer who submitted the data referred to in Reference 1 (OTC volume 020054). The comment further contended that these compounds should not be subject to review by the Panel because FDA on September 23, 1974, affirmed that generally recognized as safe (GRAS) status, under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, at a maximum level of 0.1 percent in food. According to the comment, the use of methylparaben and propylparaben at concentrations of 0.18 and 0.02 percent, respectively, in the formula information submitted to the Panel, the Panel assumed that the manufacturer had considered them active ingredients. As the comment further noted, this was a misunderstanding since both the manufacturer and the Panel considered both these ingredients to have only a preservative function at the concentrations found in the submitted formulation. The Panel clearly acknowledged the preservative function of the parabens in the list of antimicrobial preservatives that it suggested be deferred to the OTC Antimicrobial II Panel (39 FR 33106). However, the Commission has determined that review of inactive ingredients, such as preservatives, is not possible within the present framework of the OTC drug review. With its limited resources, the OTC drug review can presently evaluate only active ingredients, i.e., ingredients for which therapeutic claims are made.

Consequently, though the Commissioner appreciates the suggestion of the OTC Antimicrobial II Panel that preservatives be reviewed, he advises that currently it is not possible to do so. Further, the comment is incorrect that affirmation of a substance as GRAS for food use resolves all safety questions about its drug use. For example, although some antimicrobials are not active when ingested with food, they may sensitize skin when applied topically. Because of these safety considerations, the parabens may be reviewed by appropriate OTC advisory review panels.

49. A comment stated that it was not clear from the original charge that this Panel would review preservatives, or that the same safety and labeling standards would be applied to preservatives as to active antimicrobial levels of ingredients, and requested that oxyquinoline sulfate be submitted to the OTC Antimicrobial II Panel for review. For example, the Panel should properly recognize these limitations of quaternary ammonium compounds in laboratory and hospital environments. The comment said that such examples of pathology could just as easily be attributed to misuse, improper formulation, or a photosensitizer, it acts as a preservative, but only if the comment is correct that outbreaks of infections have been reported related to the quaternary ammonium compounds commonly used often fall short of the minimum necessary to prevent outbreaks of infection. It should be noted that the Panel was obliged to recognize that though the quaternary ammonium compounds have useful properties, such as nonirritancy, these benefits are often offset by poor sanitary practices or by lack of knowledge about the limitations of these ingredients. For example, the Panel noted in the September 1974 preamble to the proposal (39 FR 33131), it is not generally known that some quaternary ammonium compounds in laboratory and hospital environments. The Panel also noted that cationic quats are also inactivated by anionic compounds, soaps, Tween 80, and sodium lauryl sulfate as well as by certain metallic ions. Advocacy of use of quaternary ammonium compounds should properly recognize these limitations through adequate label warnings. With some slight modification of language in the Category III discussion below, the Commissioner accepts the Panel discussion as a judicious warning against uncritical use of the quaternary ammonium compounds.

50. Numerous comments objected, and cited exceptions, to two of the Panel's points that this was a misunderstanding since both the manufacturer and the Panel considered both these ingredients to have only a preservative function at the concentrations found in the submitted formulation. The Panel assumed that the manufacturer had considered them active ingredients. As the comment further noted, this was a misunderstanding since both the manufacturer and the Panel considered both these ingredients to have only a preservative function at the concentrations found in the submitted formulation. The Panel assumed that the manufacturer had considered them active ingredients. As the comment further noted, this was a misunderstanding since both the manufacturer and the Panel considered both these ingredients to have only a preservative function at the concentrations found in the submitted formulation.

E. COMMENTS ON QUATERNARY AMMONIUM COMPOUNDS

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Also, for products distributed only to professionals, the Commissioner is including in § 333.99 of the tentative final monograph the warnings: "Caution: Overuse of this and other antimicrobial products may result in an overgrowth of normal, non-pathogenic bacteria, for example, Pseudomonas. These effects could be serious in severely debilitated patients or patients at high risk such as burn victims, the elderly or newborns." and "This product is for use by healthcare personnel, acidotic water, anionic compounds, soaps, Tween 80, and sodium lauryl sulfate".

53. A comment stated that there is ambiguity in the expression for quaternary ammonium compounds as skin wound cleansers in aerosol form, as suggested in the Panel's report. The comment requested that calculation of the use concentration be permitted on a weight-in-weight basis. The comment referred to a similar weight-in-weight calculation for hexachlorophene (21 CFR 290.350) as a precedent for using this as a standard method of calculation.

Because quaternary ammonium compounds are usually diluted to a use concentration and because that concentration is calculated on a weight-in-weight basis, the Panel, in its discussion of these ingredients (20 FR 33116 and 33151), most likely assumed that readers would be familiar with this calculation. In any event, the comment points out an ambiguity in the calculations of the use concentration of the ingredients that requires clarification.

The Commissioner concludes that the weight-in-weight calculation is an acceptable method for specifying the concentration of quaternary ammonium compounds.

However, the Commissioner notes that there is a question about whether the propellant for an aerosol should be considered in the weight-in-weight calculation. The comment concludes that to consider the propellant in this calculation could lead to potential safety problems since, as the propellant evaporates, the concentration of the residual active ingredient may and could possibly reach high levels. This is particularly a problem for aerosolized quaternary ammonium compounds. Accordingly, propellants may not be considered as part of the weight-in-weight calculation of the concentration of any active ingredient in aerosolized form.

53. One comment noted that the Panel had placed quaternary ammonium compounds in Category I at use concentrations not greater than 1/750 (20 FR 33116). The comment requested that the Panel's reference to 1/750 in the Category III discussion of quaternary ammonium compounds (20 FR 33323) be considered as not having "substantive significance," and that other use concentrations be permitted in Category III. The Commissioner does not interpret the Panel's statement as prohibiting concentrations of quaternary ammonium compounds greater than 1/750 if their use is shown to be safe and effective. The Panel statement was merely intended as a guide, with minimum and maximum use levels to be established at such time as sufficient data are generated to place these compounds in Category I. However, when the Commissioner considers data submitted under the new guidelines for quaternary ammonium compounds, he will require the minimum and maximum concentrations of those compounds to be included in the monograph.

54. A comment stated that the existence of newer quaternary ammonium compounds whose antimicrobial activity is not adversely affected in the presence of acidic or hard water. It was asked that the existence of such quaternary ammonium compounds be recognized.

The Commissioner is aware of the existence of quaternary ammonium compounds that can act as antimicrobials in acidic and hard water environments and has acknowledged their existence in the discussion of quaternary ammonium compounds elsewhere in this document. He also recognizes that not all quaternary ammonium compounds are similar in this regard. To alert the consumer to how individual quaternary ammonium compounds behave in environmental conditions, labeling of these antimicrobials will be required to include the statement of their effectiveness in the presence of acidic or hard water, as set forth in the response in paragraph 51.

55. A comment objected to the statement in the report that quaternary ammonium compounds are inactive against the gram-negative bacteria Pseudomonas. The Commissioner is aware that some quaternary ammonium compounds at very high concentrations can inhibit or kill Pseudomonas. The Panel concluded, however, that the concentrations required are so high that they are very irritating and not desirable for use on the skin. But the Panel does not preclude the Commissioner from approving any new quaternary ammonium preparation at any concentration that is safe and effective against Pseudomonas.

The Panel concluded that the quaternary ammonium compounds have been classified as generally recognized as safe and effective for antiseptic use by the OTC Topical Analgesic, Antihematoma, Otic, Burn, and Sunburn Treatment and Prevention Panel. Recognition of a new class of antimicrobials, "minor antiseptics," to include these compounds was suggested by the comment.

It is premature to anticipate inconsistency on this question between the two Panels. The OTC Topical Analgesic Panel will most likely direct its review of antimicrobial agents toward the effects of products or infections accompanying burns or sunburns, and will be aware of the OTC Antimicrobial I Panel's findings. The OTC topical analgesic final report will thereby be consistent with this report in view, and any conflicts can be eliminated at that time.

The Commissioner rejects as unnecessarily confusing the suggestion for a category of "minor antiseptics." It would increase the number of categories of antimicrobial products without compensating gain. Further, defining a new category of antimicrobial products does not reduce the amount of evidence needed to establish safety and effectiveness.

57. A comment suggested that the section of the proposed monograph dealing with labeling for skin wound cleansers containing quaternary ammonium compounds (proposed § 333.92 (redesignated § 333.92 below) be revised to read as follows:

§ 333.92 Skin wound cleanser.

(5) Warnings. The labeling for quaternary ammonium products marketed at use concentration contains the following warnings:

(i) Caution: May cause eye irritation or damage unless diluted.

(ii) Dilute before each use to avoid spoilage.

(iii) Do not bandage tightly as to exclude air.

The labeling for quaternary ammonium products marketed at use concentrations contains the following warnings:

(i) Do not bandage tightly.

(ii) The labeling for this product shall contain, in the weight-in-weight calculation, the method by which the product shall be used in preventing overt infection due to organisms against which the product is effective.

The Commissioner agrees that the format of this section should be revised, as suggested, to more clearly distinguish between warnings for products intended as concentrates and products marketed at use concentrations. The Commissioner further agrees that the Panel's recommended warning against "occlusive dressing" is more comprehensibly phrased in terms of tight bandaging, and is therefore adopting, with slightly modified wording, the suggestion in the comment. The warning "Do not use solution with occlusive dressing" may be substituted, however, in labeling of products intended for distribution to health care professionals.

The Commissioner does not agree that the Commissioner's recommendation concerning "tightly bandaged" recommended by the Panel is improved by the change suggested in the comments. The tentative final monograph requires that labeling contain the statement "Apply to affected area" and a statement of the recommended dosage for use and method by which the product shall be used to cleanse a small wound without further damage to the injured area. The Commissioner concludes that directions for use that conform to these requirements will be more instructive to the user than directions for use that make the more general recommendations suggested in the comment.

58. A comment contended that a particular mixture of three benzalkonium halide compounds with varying chain lengths meets the definition and requirements of a surgical hand scrub, and that as a result the Panel condemnation of all quaternary compounds as not having broad spectrum antimicrobial activity is not accurate. The comment further pointed out that the combination
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differs significantly from the characteristics of the quaternary ammonium compounds that formed the basis for the Panel's generalization, i.e., benzalkonium chloride, benzethonium chloride, and methylbenzethonium chloride.

The benzalkonium halide compounds in the product referred to in the comment are similar to benzalkonium chloride, which was reviewed by the Panel. None of the compounds was submitted to or reviewed by the Panel. The data in the comment, a part of the record of the Panel's generalization, i.e., benzalkonium halide compounds, do not establish any difference in the quaternary compound viewed and methylbenzethonium chloride.

In addition, the data submitted in the comment do not establish a significant difference in safety or effectiveness from the quaternary compounds discussed in the comment. The data do not establish any difference in the quaternary compounds reviewed and the effectiveness of the Panel's statements relating to the limitations on quaternary ammonium compounds is required. The three ingredients discussed in the comment are placed in Category III. They will have to be tested separately and as a combination under the testing guidelines to fully determine general recognition of safety and effectiveness for OTC antimicrobial use.

F. COMMENTS ON CLOFUCARBAN

69. A comment stated that the further rat-feeding studies requested by the Panel are unnecessary for clofucarban because data on file in the OTC submissions, and in a submission to the master file record, contain adequate data on toxicity. The Commissioner finds that the data although the Panel stated that inadequate data were presented, and referred to testicular effects of clofucarban on male rats, the data were preliminary and not confirmed by the additional data later reported to the agency. The comment went on to note that the Panel was "incorrect in stating that changes (testicular) occurred in the Cox rat at 1,000 mg/kg since such a dose was not used."

The Commissioner has reviewed the data in question. The comment is correct that the 1,000 milligrams per kilogram (mg/kg) dose is not used now. However, the Commissioner finds that there is insufficient question raised by some aspects of these data, especially with respect to possible testicular damage, to justify the filing of a new drug application for treatment of minor, superficial wounds that are not occluded or that are only slightly occluded. The Commissioner cannot conclude at this time that elemental iodine should be classified in Category II or, instead, in Category I with appropriate label warnings against use in situations where the irritancy of the ingredient may inhibit wound healing. For this reason, and because questions remain with regard to the minimal effectiveness dose (use dilution), and the effect of organic load and pH (acidity) on effectiveness, the Commissioner has placed iodine tincture in Category III for use as a skin antiseptic, skin wound cleanser, and skin wound protectant, with testing guidelines for how these questions can be resolved.

G. COMMENT ON HEXACHLOROPHENE

61. One comment discussed in great detail the Panel's findings and conclusion with respect to hexachlorophene, and stated that "there is documented efficacy for hexachlorophene (HCP) for indicated claims and there is no evidence of lack of safety in infants over 1,450 grams as well as adults, including extreme exposure conditions such as ingestion and burns."

The Commissioner has reviewed the arguments and data presented in the comment and finds no convincing basis for changing its classification as a prescription drug, as set forth in the Federal Register of September 27, 1972 (37 FR 19160), and contained in the regulations in §§ 250.250 (21 CFR 250.250).

H. COMMENTS ON IODINE AND IODOPHORS

62. A comment questioned the placement of elemental iodine in Category II for safety on the basis of irritation and effectiveness claims that the Panel stated that such products have been proven effective and contended that they have been marketed for many years without a serious problem of delay in wound healing.

The Commissioner has little doubt about elemental iodine's broad spectrum microbiocidal activity. The Commissioner is also aware of the 136-year marketing history of elemental iodine for use on skin and mucous membranes. The issue before the Commissioner is therefore limited to the Panel's view of the potential of the iodophors complexed without a surfactant, and that toxic effects can be experienced from iodophors complexed with a surfactant which would not be associated with iodophors complexed with a nonsurfactant.

The Commissioner recognizes that different complexing agents are used with different iodophors; some are surfactants while the povidone (polyvinyl pyrrolidone) portion of the povidone-iodine complex was the only nonsurfactant considered by the Panel. The Commissioner recognizes that insufficient data have been accumulated on the toxicity of complexing agents for iodophors. As noted in paragraph 71 below, the Commissioner is concerned about the problems associated with the use of iodophors when it is placed in deep wounds or body cavities because the larger sized molecules of the povidone portions of the complex cannot penetrate the kidney, nor is their toxicity known if the molecules are retained by the body's reticuloendothelial system.

The Commissioner wishes to confirm that this particular effect does not occur with surfactant-complexed iodophors, such as polyoxamer-Iodine. However, the Commissioner notes that the toxicity that may be associated with the use of iodine/surfactant complexed formulations has not been well characterized. The Commissioner is concerned about the possibility of delay in wound healing if the surfactant complexes were to be used in deep wounds.

63. A comment objected to the Panel's statement that all iodophors are dependent on the release of free iodine as the active agent and that the complexing molecule acts only as a carrier.

The Panel's statement reflects a carefully considered and commonly accepted opinion in the scientific community. As will be discussed in the response to paragraph 69 below, the Commissioner has carefully reviewed the available data.
mentation concerning this question and concludes that there is no reason to modify the Panel's statement in the Category M2 classification below. The Commissioner realizes that this is an evolving scientific area and that future data may shed new light on the nature of iodophores. Thus the submission of compelling evidence that will guide the Commissioner's decision on this question.

65. A comment complained that the Panel in its discussion of iodine-containing antimicrobials confused simple soluble iodine with iodophors containing iodine in a complex. The comment stated that the Panel did not recognize a distinction between free iodine and available iodine and that it gave undue emphasis to the kinetics of conversion of available iodine to free iodine in explaining antimicrobial activity.

The Commissioner concludes that practicing surgeons should be made aware of the danger cited in the comment. However, the suggestion that the Panel's categorization of particular iodine-containing antimicrobials is materially affected by the finding of the Commission's decision on this question.

66. A comment pointed out the danger in an iodophor and detergent (surfac- tant) preparation coming in contact with starch granules during a surgical procedure, and submitted a reprint of a paper dealing with the problem (Goodrich, E. A., et al., Starch granule as a cause of serous membrane) and other undesirable effects in the body. The comment concluded that poloxamer-iodine (polyvinyl pyrrolidone-iodine or PVP-I) according to molecular weight, this substance has been initially placed in Category I during the Panel's deliberations.

The Commissioner notes that the pre- liminary Category I categorization was only tentative. The Panel's final category of use is for medical hand wash, patient preoperative skin preparation, and surgical hand scrub. The Commissioner concludes that povidone-iodine is properly considered a complex. Povidone-iodine is listed in the National Formulary, edition XXIII, and the United States Pharmacopeia, edition XXVII, as a composite that gives a positive stab test for the presence of free iodine, which is well known for its antimicrobial property. This iodine can be present in povidone-iodine or povidone-iodine (PVP-I) according to molecular weight, this substance has been initially placed in Category I during the Panel's deliberations.

67. A comment asked if the stability of povidone-iodine could be recognized as lasting for 2 years at ambient temperature. The comment also asked if the source of free iodine is not from the dissociation of povidone-iodine. The comment concludes that the source of free iodine is from the dissociation of povidone-iodine as "povidone-iodine N.F." As noted, both the National Formulary, edition XXIII, and the United States Pharmacopeia, edition XXVII, describe the ingredient as a complex. Other standard reference sources, such as AMA Drug Evaluations and the Physicians' Desk Reference, refer to povidone-iodine as a complex. The description in the latter reference is attributed to the cooperation of the manufacturers whose products are described. The weight of evidence does not support the Commentor's description of povidone-iodine as a complex, and the comment presents no evidence to the contrary.

70. A comment asked for deletion of the statement that povidone-iodine is not capable of being included in a soap formulation. The comment said that the statement is inaccurate. At the time of the Panel's deliberations, the prevailing view was that formulations containing povidone-iodine (polyvinyl pyrrolidone-iodine or PVP-I) could not be successfully combined with other soap ingredients in a soap formulation. However, since publication of the Panel report, the comment suggests that such a formulation has become possible using povidone-iodine. The Commissioner agrees to delete the statement of incompatibility of povidone-iodine in soap formulation.

71. A comment contended that there should also be restrictions on the use of povidone-iodine (PVP-I) according to molecular weight. Published research cited in the comment indicates that povidone-iodine molecules larger than 35,000 daltons cannot be excreted by the kidney, can cause nodules to appear in the lymphatic system, and may induce cosmetic deformities in the area of healing wounds.

The Panel recognized a relationship between molecular size and nodular lymphatic changes accompanying exposure to povidone-iodine, but made no decision on limiting the molecular size of such pathology. The Commissioner, based on expert opinion and the extensively documented comment, has determined that a molecular weight of 35,000 daltons is the safe upper limit for parenteral exposure to povidone-iodine. This calculation assumes that a povidone-iodine molecule with this molecular weight should be too large to pass through the kidney. The Panel recognizes a relationship between molecular size and nodular lymphatic changes accompanying exposure to povidone-iodine, but made no decision on limiting the molecular size causing such pathology. The Commissioner, based on expert opinion and the extensively documented comment, has determined that a molecular weight of 35,000 daltons is the safe upper limit for parenteral exposure to povidone-iodine. This calculation assumes that a povidone-iodine molecule with this molecular weight should be too large to pass through the kidney.

The Commissioner is also aware of inappropriate use of povidone-iodine products in open wounds and in the sub- dominant cavity during surgery. To promote proper use of povidone antimicrobials, therefore, should be included in the monograph, he proposes to recognize two categories of such products. Products with povidone-iodine molecular weights greater than 35,000 daltons will be limited to use on intact skin; those with molecular weights less than 35,000 daltons will be permitted for general use. Appropriate labeling would place each product in its proper category of use. The professional labeling of povidone-iodine products containing molecules greater than 35,000 daltons would also include warnings against parenteral use of, and exposure of open surgical wounds or deep wounds to, the product.

72. Comments asked for transfer of povidone-iodine from Category III to Category I for use as a skin wound cleanser, health-care personnel handwash, surgical hand scrub, as an aqueous solution, and surgical hand scrub. The comments contended that povidone-iodine molecular weights greater than 35,000 daltons will be limited to use on intact skin; those with molecular weights less than 35,000 daltons will be permitted for general use. Appropriate labeling would place each product in its proper category of use. The professional labeling of povidone-iodine products containing molecules greater than 35,000 daltons would also include warnings against parenteral use of, and exposure of open surgical wounds or deep wounds to, the product.

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is less toxic and less irritating than, and just as effective as, tincture of iodine, which received a Category I classification for use as a patient preoperative skin preparation. The comments also argued that many of the concerns stressed by the Panel are not applicable to claims for particular product classes in this report or are irrelevant due to the size of the povidone-iodine molecule.

The Commissioner has carefully considered whether the problems identified in the Panel report are substantial enough to preclude classification of povidone-iodine in Category I. On the basis of submissions made to the Panel, the Commissioner concludes that there still remains a lack of sufficient data to reclassify povidone-iodine in Category I.

I. COMMENTS ON PHENOL

73. A comment asked that para-chloro-meta-xylenol (PCMIX) be reclassified in Category I for use as a skin antiseptic and skin antiseptic/detergent when formulated in an aqueous alcoholic base containing pine oil and vegetable soap diluted before use with water to a concentration of not more than 0.5 percent.

74. Several comments requested transfer of phenol at less than 1.5 percent from Category III into Category I for all product categories. The comments stated that phenol at less than 1.5 percent has been placed in Category I by the Congress of OTC Oral Cavity and OTC Topical Analgesic Drug Panels, and contended that it is contradictory for different Panels to place the same ingredient in different categories.

That one Panel places a substance in a given category does not require another Panel to place it in that category for a different use on a different part of the body. Admittedly, the Commissioner notes that he has not yet received the final report of either of the two Panels referred to in the comment. When the two Panel recommendations are in agreement, he will be able to compare the scientific basis and reasoning for the differences in the Panel recommendations on phenol. If these differences are based on different claims and different uses in different body sites, sufficient to justify different recommendations, he will most likely not modify those recommendations.

The Panel, in its review of phenol at less than 1.5 percent in aqueous or alcoholic solution (39 FR 33133), noted potential safety issues, and the Commissioner agrees that there must be resolved before phenol at less than 1.5 percent concentration can be reclassified in Category I for all the product classes reviewed by this Panel.

X. COMMENTS ON POLYXAMER 188

75. A comment was received requesting that pluronic P-88 be placed in Category I as a safe and effective skin wound cleanser. Poloxamer 188 is a member of a family of block copolymers called pluronic polymers of polyethylene oxide and polypropylene oxide of weight and has a molecular weight of 8,350. There is a long history of its use as a nonionic surfactant detergent in a variety of preparations, including certain intravenous products. It is generally regarded as nontoxic and is rapidly excreted intact by the body. Although it has no antimicrobial activity, it has been employed widely as a detergent and fat emulsifier and is recognized as nonirritating and efficient for minor wound cleansing when employed in aqueous solutions.

After reviewing the comment and the submitted supporting data, the Commissioner places poloxamer 188 in aqueous solutions in Category I as a skin wound cleanser. The use concentration of poloxamer 188 as a skin wound cleanser is limited to 20 to 40 percent aqueous solution. Since this compound has no antimicrobial activity, it cannot make those claims permitted for an active antimicrobial ingredient in a skin wound cleanser, e.g., "contains antimicrobial ingredient", "contains antimicrobial ingredient", nor can it be generally recognized as safe and effective for the other product classes. This classification does not, of course, prohibit its use as an inactive ingredient or pharmaceutical aid for its detergent and surfactant properties.

L. COMMENTS ON TRICLOCARBAN

76. A comment indicated a belief that data would be forthcoming that would resolve the issue of the degree of absorption of triclocarban through the skin such that triclocarban could be placed in Category I as an ingredient in an antimicrobial soap. The Commissioner has received recent data from a study on the percutaneous penetration (absorption) and metabolic decomposition of triclocarban in man. These data were determined after total body showering with a liquid soap containing 2 percent radioactively labeled triclocarban (approximately 7 mg). The absorption of triclocarban absorbed from topical application in one shower closely corresponds with the amount yielded by the calculations of the Panel. The study thus confirmed a number of key points about the potential uses of this ingredient that the Panel had in the absence of data. The Commissioner concludes that the Panel accurately risk assessed the safety factor suggested by the Panel.

Although the safety questions the Panel raised about the degree of absorption in humans have been resolved to his satisfaction, the Commissioner is unable to modify the tentative final monograph to include triclocarban in Category I for use as an OTC antimicrobial soap. This is due to a question that has arisen regarding the validity of one of the basic long-term toxicity studies performed on this drug, a 2-year oral chronic toxicity animal study. The Commissioner has reached the conclusion, in another forum, that though the study design is adequate this study cannot be accepted for approval.

The Commissioner will therefore retain triclocarban in Category III as an antimicrobial bar soap at a concentration of 1.5 percent until such time as this study is duplicated. Upon reviewing all evidence surrounding the study in question, the Commissioner has also reached the conclusion that omission of this data is not sufficient justification for classifying triclocarban in Category II as an antimicrobial bar soap at this time. Since the bulk of the data are based upon absorption characteristics of bar soap formulations, Category III status for antimicrobial soaps will be restricted to bar soaps. Because no data were presented to the Panel during its deliberations or to the Commissioner during the comment period concerning the safety and effectiveness of triclocarban for use in other types of products, triclocarban remains in Category II for use in nonantimicrobial bar soaps, health-care personnel handwashes (bar soaps only), and skin wound cleansers (bar soaps only).

77. A comment stated that determination of substantive of triclocarban (the degree to which it binds to the cells of the outer layer of the skin) is irrelevant to normal use of bar soaps and is only of academic interest, and that the only important concern is the determination of blood levels of the active ingredient. The comment is apparently arguing that, with knowledge of blood levels of triclocarban, one can infer its amount and persistence on the skin is not needed. The Commissioner agrees with this contention insofar as it relates to antimicrobial soaps. However, adequate knowledge for a determination of the safety and effectiveness of triclocarban for the other product classes within the purview of this document includes data on substantivity.
Greater substantivity may increase effectiveness by permitting the ingredient to remain at the site of action for a longer period of time. In addition, substantivity affects the duration and maximum concentration of the ingredient in the bloodstream; the Panel concludes that knowledge of substantivity is a necessary part of the toxicologic profile of all topical antimicrobial product classes except antimicrobial soaps. Whether an ingredient is adsorbed onto the skin, held for a long time, and, when accumulated to the maximum extent possible, causes skin pathology, are important factors in evaluating the safety of the ingredient.

78. A comment stated, on the basis of personal experience, that, after stopping use of triclocarban soap and using another kind of soap, skin blotches cleared up.

The report is testimonial and is not supported by independent verification from a study through the interested party. It cannot be considered a definitive demonstration of the phenomenon because the possibility of the phenomenon is increased by the ingredients in the soap was not eliminated.

79. A comment stated that the Panel relied solely upon unpublished and non-public comments and conclusion that triclocarban and clofucarban should be limited to a 1.5 percent concentration in soaps. The comment objected to sole reliance on unpublished data, contending that this made it impossible for interested parties and the public to make meaningful comments on the Panel's conclusions.

The comment disregards the fact that virtually all data relied upon by the Panel were placed in the public record in the office of the Hearing Clerk, Food and Drug Administration, 30 days after publication of the report and proposed monograph. In fact, the Commissioner extended the period for public review and comment specifically to permit greater time to analyze any data that had not been available before the report was published.

80. Comments contended that the scientific literature does not show clofucarban and triclocarban to be photosensitizers. The comments objected to the language of the Panel discussion that implied these antimicrobials could be photosensitizers. The comment noted that the paper of Masuda, et al., listed in the references under clofucarban, did not record any evidence for photopatch-test positive reaction with triclocarban or clofucarban among 140 patients tested.

The Commissioner agrees that the literature cited by the Panel and the comment contains no data that triclocarban and clofucarban cause photosensitivity; therefore, the Commissioner will not require testing of either ingredient for photosensitivity.

II. COMMENTS ON TRICLOSAN

81. A comment contended that a double standard was applied to place triclosan in Category II but benzalkonium chloride in Category III for use as a health-care personnel handwash, patient preoperative skin preparation and surgical hand scrub. The comment argued that application of the same standard to both compounds would place them in the same category, and requested reclassification of triclosan into Category III.

The Panel clearly indicated in its report that triclosan was placed in Category II for the use mentioned on the basis of its known lack of activity against Pseudomonas aeruginosa. In fact, triclosan is used in isolation medium to bring about the selective growth of Pseudomonas species. The Panel action was based on its opinion that triclosan presents a greater selective ecological pressure for growth of Pseudomonas in the closed hospital environment than do the quaternary ammonium compounds. Today the Pseudomonas aeruginosa infections constitute the greatest bacteriological threat of infection in the hospital environment. The questions and risk assessment increased use of triclosan in multiple daily-use products have continued to increase since the publication of the Panel's report and resolution of this issue becomes even more critical. The Commissioner concludes that the Panel's classification of triclosan in relation to benzalkonium chloride was based on a relevant difference between the two ingredients and was entirely proper.

82. A comment asked that the use of triclosan be allowed up to a 2 percent concentration to ensure effectiveness and claimed that such a concentration is well within appropriate safety limits for toxicity. The comment included calculations on safety factors that indicated a range of from 5,000- to 5,000-fold over the concentrations requested.

The Commissioner has reviewed the data and the Panel discussion pertinent to the comments. Because of the possibility that increasing use of triclosan in consumer products may raise blood levels, the Commissioner will restrict the concentration of triclosan to 1 percent for the Category III conditions. The Commissioner wishes to emphasize that he is in accord with the Panel's view that no more than the minimal effective concentration should be used in these products, as determined by the results of the tests in the testing guidelines.

83. A comment asked for reclassification of triclosan from Category III to Category I for use in skin antiseptic, skin wound cleanser, and skin wound protectant products. The comment requested that triclosan be placed in Category I as an antimicrobial bar soap in view of additional data submitted with the comment and expressed no dissatisfaction with the Category III classification for the "first aid" product classes and indicated a willingness to perform the testing required to justify Category I classification for such indications.

The Commissioner notes that until the summer of 1976 no data were available that would justify reclassifying triclosan from Category III to Category I for use in skin antiseptic, skin wound cleanser, and skin wound protectant products. Even though additional animal data have been reported since the Panel's report, questions have recently arisen regarding the validity of key animal studies with triclosan and in view of the apparent ever-widening distribution of triclosan in consumer products, the final resolution of risk to human health requires further testing. Therefore, at this time. Accordingly, triclosan is retained in Category III for these indications.

84. Comments pointed out that a report, skin wound protectant products. The comment asked that the use of a triclosan-containing soap should not be interpreted to mean that triclosan caused the hyperpigmentation. The case referred to by the Panel showed development of hyperpigmentation on both the nonexposed control hand and on the hand washed with triclosan soap. No other products were studied.

The comment is accurate. Therefore, the Commissioner is deleting from the Category III discussion of triclosan any reference to its known to cause skin hyperpigmentation.

II. INGREDIENTS REFERRED TO OTHER PANELS

85. A number of comments requested that 3 percent hydrogen peroxide, and methyl, ethyl and isopropyl alcohol, be included in the antimicrobial monograph because of their long and widespread use as antimicrobials. The comments stated that other antimicrobial products would not be available for use as antimicrobials. Another comment requested that gentian violet 1 percent and 2 percent solutions, thimerosal tincture, and mercurochrome be included in the OTC antimicrobial monograph as Category I skin antiseptics.

The Commissioner recognizes that these ingredients have a long history of use and that data on their toxicity and antimicrobial activity are readily available. These preparations have, however, been assigned for review by the OTC Miscellaneous External Panel and public comment has been solicited. Relevant data may be submitted to that Panel in the form required by 21 CFR 350.10(a)(2) and addressed to: Food and Drug Administration, Division of OTC Drug Evaluation, Rm. 12-55, HFD-510, 5600 Fishers Lane, Rockville, Md. 20857. In accordance with the policy announced by the Commissioner in the preamble to the Procedures for Classification of OTC Drugs published in the Federal Register of May 11, 1972 (37 FR 5649), no action will be taken to remove them from the marketplace pending completion of their review by the OTC Miscellaneous Panel and publication of a final monograph for them.

O. COMMENTS ON TESTING REQUIREMENTS AND GUIDELINES

86. Several comments objected to the requirement for testing both the individual antimicrobial ingredient and the finished formulation, contending that
such testing is duplicative and only of academic interest.

While (as noted in paragraph 7 above) the amount of such testing will be limited to certain products, the Commissioner disagrees that testing both the ingredient and the product is duplicative. For certain product classes specified for product formulations may render the ingredient ineffective or unsafe. If the ingredient and the formulation have not both been tested, it is not possible to determine if there is a divergence in safety and effectiveness of the active ingredient as compared with the finished product. Once an ingredient has been classified as generally recognized as safe and effective, no further finished formulations need be submitted to the agency. However, such data should be on file for inspection.

87. Several comments objected to use of the phenol coefficient determination as a requirement in the testing guidelines because phenol coefficients have the most value in comparing the relative bactericidal activity of modified phenolic compounds with phenol. They further argued that the phenol coefficient is not a valid criterion for testing effectiveness of bacteriostatic preparations and is not even complete for basicidal preparations because many effective nonphenolic antimicrobials may, because of their chemical structure, not have a high phenol coefficient.

The Commissioner concludes that the phenol coefficient is not always the best way of judging the value of an antimicrobial. The textbook Basic Bacteriology by C. Lamanna, M. F. Mallette, and L. Zimmerman (1976) states that "it is probable that the search for a single test, numerical value, or coefficient (i.e., phenol coefficient) to express the relative worth of disinfectants will remain a 'whip as a scientific venture'" (p. 1044).

The phenol coefficient has the merit of expressing the degree of disinfection by a number, thus permitting ready comparison. This exercise, however, is only as meaningful as the numbers that are used. Bacteriologists agree on the weakness of the phenol coefficient, although some are willing to rely on it for want of a better method.

The Commissioner concludes that, in light of the diversity of opinion and the strong feelings throughout the scientific community on the value of the phenol coefficient, the testing guidelines should be modified to make clear that this method is optional. Therefore, the testing requirement for effectiveness, which call for a phenol coefficient determination, will be deleted, and paragraph f., will be modified by adding the term "and phenol coefficient" after "Sykes-Kelsey" in paragraph (4) of the testing requirements later in this document.

These changes meet the criticisms in the comments and are fully consistent with the intent of the Panel that the activity of an antimicrobial ingredient be fully characterized. The phenol coefficient determination will be one of several standard tests permitted, depending on the circumstances.

88. A comment requested clarification of the meaning of subchronic and chronic exposure tests of a product on interest and abraded skin, as discussed in the Panel's safety testing requirements (39 FR 33135).

Although the Panel did not specifically define chronic and subchronic testing, these terms have a generally accepted meaning in the scientific community. Subchronic testing means repeated application or dosing of the test material for up to 90 days. Chronic testing means repeated exposure for more than 90 days.

89. A comment argued that investigation of the degree of absorption of an ingredient from intact and abraded skin and mucous membranes in subchronic animal testing (less than 90 days) is superfluous once results of chronic human studies are obtained.

Absorption tests are necessary for the determination of effectiveness of antimicrobials in chronic use. The Commissioner is primarily concerned with the time it takes for blood levels to plateau. It is possible to extrapolate chronic absorption data to absorption for basalidal preparations because many effective nonphenolic antimicrobials may, because of their chemical structure, not have a high phenol coefficient.

90. A comment stated that it is improper to require carcinogenicity, mutagenicity, teratogenicity or other reproduction studies with finished antimicrobial products. The comment did not object to such testing of the active ingredient.

The Commissioner agrees that it is not necessary to conduct such studies with the marketed product where adequate data are available on the active ingredients alone.

91. A comment objected to the Panel's calculation of the safety factor for triclocarban. The calculation assumed 100 percent retention and absorption, whereas data for triclocarban show less than 100 percent retention and absorption, the comment said. The comment pressed concern that the Panel's assumption would be interpreted as a requirement for making calculations in disregard of real life situations for particular compounds, such as triclocarban, for which it can be demonstrated that retention and absorption are less than 100 percent.

The Panel clearly stated that due to the lack of objective data its calculations were based on assumptions intended to illustrate the kind of calculation required in evaluating retention and absorption. The Panel statement did not preclude use of objective data to replace the assumption of 100 percent retention and absorption for a specific ingredient or product. Subsequent to publication of the Panel report, a study was carried out by the National Research Council on percutaneous penetration (absorption) and metabolic decomposition of radioactively labeled triclocarban in humans (see paragraph 78). The Panel's assumptions relating to absorption and retention of 100 percent of the available antimicrobial on the skin were not confirmed. However, the quantity of triclocarban absorbed was remarkably close to the calculations based on the Panel's assumption, for the other ingredients reviewed, but not yet tested for the degree of absorption in the same manner as triclocarban, the Commissioner agrees that when reliable data are available for retention and absorption of that particular ingredient or product, the safety factor calculation ought not be made on the basis of an assumption of 100 percent retention and absorption.

92. A number of comments objected to the requirement in the guidelines for obtaining the LD₅₀ and the LD₆₀ in addition to the LDₐ₀.

The Panel's guidelines for testing call for "The LDₐ₀, highest dose killing no animals and lowest dose killing all the test animals by oral and topical routes, if possible" (39 FR 33135). The LDₐ₀ and LD₆₀ can be estimated from the dose-response curve necessary to determine the LDₐ₀. Since the Panel impose no requirement beyond obtaining the LDₐ₀, other than performing additional calculations, the Commissioner concludes that no change is appropriate.

93. Several comments objected to the requirement that the fungicidal and viricidal activity of antimicrobial soaps be tested even when the products make no such claims. The comments stated that testing of products for effectiveness against microorganisms for which they are not labeled should not be required.

In characterizing the activity of an active ingredient for antimicrobial soaps, the Panel limited labeling claims to "reduction of odor." The Commissioner believes that a deodorancy claim must be substantiated by testing to characterize the antimicrobial activity of the active ingredient because odor is generally caused by gram-positive or gram-negative bacteria. Since odor is not usually caused by fungus or virus conditions, testing of the active ingredient for fungicidal and viricidal activity will not be required. Of course, there must be no claims, either direct or by implication, that a product has activity against organisms for which it has not been tested.

The Commissioner notes that this testing requirement is limited to effectiveness. If there is a reasonable scientific indication that the activity of an ingredient will affect the microbial flora, resulting in a possibly harmful rise in the fungus or virus population for fungicidal and viricidal activity would be required.

94. A comment objected to the Panel's recommendation of the Sykes-Kelsey procedure for antimicrobial effectiveness testing because it measures only the effectiveness of hard surface disinfectants.

The Sykes-Kelsey test is designed to determine the effect of organic material, i.e., killed yeast cells on the antimicrobial activity of an ingredient or formul-
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The test is not limited to testing products for use on hard surfaces, and is equally applicable to testing products for topical use on humans. Moreover, the Panel did not recommend that only the Sykes-Kelsay procedure be used, but suggested other procedures “where applicable.”

85. A comment referred to the safety testing guidelines and stated that “skin pigmentation is a routine observation made as part of all Repeated Insult Patch Tests, and separate tests seem superfluous.” The Panel’s test requires observation for that phenomenon concomitant with patch tests for other purposes, and the testing guidelines below are modified to make this clear.

86. A comment requested clarification of those areas of the body tested for photoxicity and photosallergy. The appropriate age group is males over 40 years of age. The reported incidence of photosallergy is highest in this group.

97. A comment noted that the Panel’s testing requirements called for determining the primary irritation potential of the active ingredient both alone and in its final formulation on the skin, with special attention devoted to eyes, mucous membranes, and genitalia. The comment did not object to testing the active ingredient alone on skin and eyes because microorganisms and the manufacture of antimicrobial ingredients would have their skin and eyes exposed to the active ingredient in its raw form. However, the comment contended that since mucous membranes and genitalia would be exposed to the active ingredient only in the final product formulation, and not in its raw form, testing of the active ingredient alone is not necessary.

The importance of accurately determining the safety of these products and their ingredients makes it necessary that both the active ingredient and the finished product be tested for the potential of irritation. The Panel recognized the merit of carrying out this primary irritation potential test in animal models first, while the elimination of obviously irritating materials without the need for further testing in humans. Because the use of antimicrobial bar soaps exposes the entire human body to the active ingredients they contain, it is important to test each active ingredient, as well as the finished product, on the most sensitive tissues of the body, such as the skin, mucous membranes, and genitalia. The purpose of testing the active ingredient alone is not to duplicate anticipated conditions of actual use, but to reveal any drastic irritation potential of the ingredient that might be masked in the finished product.

98. One comment stated that it is not necessary to test the effect of the active ingredient alone on wound healing, and that substantivity studies on the active ingredient are not appropriate. Only the final product should be tested, the comment contended.

The Commissioner disagrees. The purpose of the testing required by the Panel is to identify the toxicologic profile of the test product formulation and to determine the possible effects on its activity of the formulation of which it is a part. This information is necessary to the Commissioner’s determinations in establishing criteria governing drug safety and effectiveness. As explained in the preceding comment, testing of the active ingredient alone, in relation to delay in wound healing or any other adverse potential, is necessary to eliminate the possibility that its effects are concealed by other ingredients in the formulation of the finished product. Substantivity testing (testing to determine retention of the ingredient in the horny layer of the skin) is also a necessary part of the toxicologic profile. It should be carried out with the formulated product, and, for the reasons indicated, with the active ingredient in an innocuous vehicle.

99. A comment stated that it is not necessary to require controlled human studies with a skin antiseptic such as povidone-iodine in cases where the product claims are limited to degerming, microbicidal, bacteriostatic, and bacteriolytic effects. These claims, the comment contended, can be adequately demonstrated by in vitro testing, especially when the product is not for use as a skin antiseptic, but only in conjunction with medical devices, such as catheterization products, to reduce the potential that skin organisms will be transferred by the device to the body parts in contact, with it.

The comment refers to preparations associated with procedures intended for lay use either by patients at home or by paramedical personnel on the advice of physicians. The uses are for special or limited circumstances, including needs of colostomy hygiene and urinary catheterization by individuals at home who have suffered loss of control of their bodily functions. When such products are used, they are applied to the site of insertion into the body and frequently to the device at the time of insertion of the body. Because of the serious nature of infections resulting from such sites, the Commissioner believes that antimicrobial ingredients to be used for such purposes must be both safe and effective and must, therefore, meet the requirements of product preoperative skin preparations set forth in the definition of this product class and in the testing guidelines. Although such testing would necessarily include clinical studies, the Commissioner is prepared to accept suggested modifications to the testing guidelines because of the ethical considerations relating to the control aspect of the studies.

In addition, the Commissioner notes that no submissions were received during the comment period that would indicate the indications described above. Consequently, specialized labeling for such products will only be permitted through an amendment to the OTC topically antimicrobial monograph of a new drug application.

100. A comment, referring to the Panel’s recommended testing for solution of gram-negative and other organisms from the skin,” suggested deletion of triclosan containing agar as a selective medium for isolation of Pseudomonas species because work has shown that triclosan has limited effectiveness for this purpose.

Triclosan-containing agar medium is not the only bacteriologically active medium of limited effectiveness. It is currently accepted, available, and marketed as a selective medium for use in diagnostic and other laboratories. Until the consensus of expert opinion on the usefulness of triclosan agar changes, it would be inappropriate for the Commissioner not to permit the use of triclosan agar medium for isolation of Pseudomonas species.

101. A comment suggested that there is no need to demonstrate effectiveness of antimicrobials on superficial skin wounds against viruses or the Neisseria species of bacteria, both of which are virulent microorganisms that cause serious diseases, e.g., meningitis and gonorrhea, and neither of which is found in the normal environment of the skin or in a superficial wound.

The testing required for proof of effectiveness against microorganisms, which appears in the testing guidelines below, is in vitro and is intended to characterize the activity of the antimicrobial ingredient and product in the normal environment and not under every possible circumstance. Therefore, although the Commissioner expects representatives of the various microbial groups to be tested in vitro, use of the claim “skin antiseptic” will be permitted without demonstration of antimicrobial action against viruses and Neisseria species. However, the Commissioner cautions that such in vitro testing will not be the sole determinant of effectiveness and that clinical testing in accordance with the testing guidelines described above, is required to place an ingredient in Category I. The Commissioner also notes that because of the limited spectrum of action of antimicrobials and the fact that testing a substance against a microorganism must be done, the labeling must include the monographs for skin antiseptics (21 CFR 333.SO), skin wound cleansers (21 CFR 333.92), and skin wound protectants (21 CFR 333.84) is modified to include a warning that the product is not to be employed in wounds as a prophylactic against rashes, infection in the case of animal bites unless proof for this use is provided to the agency. The warning states: “This product is not for use on wild or domestic animal bites. If you have an animal bite, consult your physician immediately.”

102. Comments referring to both the product class definitions and the Panel’s testing guidelines discussed the difficulties of in vivo testing in humans for the effectiveness of skin antiseptics and skin wound protectants against experimentally induced wounds (39 FR 33108, 33133). The comments raised questions about the ethics of such experimentation and noted constraints imposed on the scientific value of such tests by the current state of the art. The comment noted...
that the Panel did not specify what pathogens should be used to induce the experimental infections, and additional data on effectiveness against one pathogen are of limited predictive value with respect to effectiveness against other pathogens. For this reason, the comment suggested that there should be a requirement for testing only for in vitro tests. This would make it practical to test a wide spectrum of pathogens and would avoid ethical questions about experimentally infecting wounds in human volunteers.

The Commissioner agrees that the comment raises serious questions. However, the Panel's statements do not imply a rigid limitation to testing in experimentally infected human wounds. Rather, they recommend that antimicrobial ingredients be tested for their effectiveness in the normal wound healing process in the presence of those organisms (including pathogens) encountered in the normal environment. The kinds of tests to be performed, which are determined by the characteristics of the disease for the products, are set forth in the testing guidelines below. Since the subjects of studies will be volunteers who have given informed consent and since there is no evidence that known virulent microorganisms, the Commissioner concludes that the testing procedure described in the testing guidelines is ethical and should be followed. There are three kinds of tests that can be considered:

1. Controlled study of experimental wounds in humans conducted in accordance with established ethical standards; (2) controlled study of wounds in experimental animals; (3) in vitro tests employing human tissue culture models. Which test is employed will depend on the nature of the claims made for the product. However, under the present testing guidelines, delay of wound healing by antimicrobial ingredients will be considered a separate issue from the termination of effectiveness against specific pathogens that affect healing.

The Commissioner has received recent information on the use of hygrometers to assess cleanliness and has included it in the testing guidelines. The Commissioner encourages further research and development of wound models employing human tissue cultures. Potentially, such research should lead to scientifically validated substitutes for the experimental wounding of humans and thus eliminate the need for testing in human volunteers.

105. Several comments suggested substituting the micro-organism, Escherichia coli for Serratia marcescens in tests for the effectiveness of health-care personnel handwash products. The comment raises serious questions. How-
113. A comment asked for a reduction in the total number of time intervals for bacterial counts in the glove juice test. Instead of taking samples at the 1-minute, and the 1-, 2-, 3-, 4-, 5-, and 6-hour intervals, samples would be taken at the 1-minute, and the 1-, 2-, and 3-hour intervals. The comment stated that this would be more economical and would not reduce the reliability of the result. The time intervals were chosen on the basis of advice from expert consultants in biostatistics, who advised that the sampling times are required to establish the rate of re-growth of the bacterial flora after the gloves are donned. The comment does not substantiate its conclusion that fewer sampling intervals will not decrease the reliability of the result. The protocol accordingly will not be changed.

114. A comment asked that the requirement for a 1-minute massage of the gloved hand be eliminated from the glove juice test because the bacterial count can vary with the vigor of the massage, independent of its duration. Although the bacterial count may vary with the vigor of massage, without massage there will be an inherent variation among samples due to differences in the strength of adhesion of various bacteria to the skin surface. The Commissioner concludes that careful execution of the procedure will minimize differences in the vigor with which hands are massaged, and that completely abandoning the procedure would merely introduce another variable that could not be dealt with by any technique, other than massage, known to the Commissioner.

115. A comment stated that a 1-day prohibition on hand washing is an excessive demand to place on persons volunteering as subjects for glove juice tests. The Commissioner is not restating the prohibition on hand washing is an excessive demand to place on persons volunteering as subjects for glove juice tests. The prohibition recommended by the Panel would extend from awakening to the time activating the counting takes place. Since counting can be scheduled at any time, it is open to the investigators to schedule it early in the day, thus minimizing inconvenience to the participants. This is clarified in the testing procedures included in this document.

116. A comment characterized the proposed glove juice test as so expensive that only the largest manufacturers can afford it. The testing requirements were said to be unnecessary and a waste of time, resources, and money and that insistence upon the testing make it desirable, if not necessary, for the government to take over the costs involved. The criticism ignores the general acceptance by industry, the scientific community, and the medical profession of the need for the glove juice test. The given ingredient, the glove juice test is a one-time requirement for entrance into the marketplace as a surgical hand scrub, not a recurring cost. The Commissioner realizes that the cost factors involved are of importance to industry, however, public health considerations are an overriding concern. Moreover, the Commissioner realizes that Category III testing be carried out by each manufacturer has been changed by a regulation published in the Federal Register of April 12, 1977 (42 FR 19137).

P. MISCELLANEOUS COMMENTS

117. A comment suggested that the section of the monograph dealing with the labeling of patient preoperative skin preparations (§ 333.80, redesignated § 333.87 below) is somewhat confusing and should be rewritten to indicate which labeling requirements apply generally to patient preoperative skin preparations and which apply specifically to tincture of iodine.

The Commissioner has reviewed the request and finds it reasonable. This section is rewritten and reorganized into both general and specific labeling requirements.

II. THE COMMISSIONER'S CONCLUSIONS ON THE CATEGORY II RECOMMENDATIONS

The Commissioner's conclusions and restatement of the Panel's recommendations and conclusions for Category II are set forth below. The Commissioner adopts these findings by restating the appropriate sections of the Panel's findings in this document, with modifications for clarity and regulatory accuracy, as well as for new data and information that have come to his attention. Changes based on new data and information are discussed in the preamble. Gratuitous or unsupported statements have been excluded. The Commissioner's agreement with comments suggesting modification of the Panel's findings are incorporated in the Commissioner's restatement of them.

The Commissioner is not restating those parts of the Panel's findings that are not directly relevant to his decision on the content of Category II. Specifically, he has omitted sections of the Panel report relating to preservatives, inactive ingredients, balance of normal flora, effectiveness for erythrasma, and all comments). The Commissioner has already taken final action on Category II when he included salicylamides, particularly triclofen (21 CFR 310.508), and that completely abandoning the procedure will minimize differences in the total number of time intervals.

Therefore, based upon the record before him (all data submitted, the minutes of the Panel meetings, the Panel report, and all comments), the Commissioner determines that the use of topical antimicrobial products under the following conditions is unsupported by scientific data, and in many instances by sound theoretical reasoning. The Commissioner concludes that the ingredients, labeling, and combination drugs involved should not be permitted in interstate commerce effective as of 6 months after publication of the final monograph in the Federal Register, until scientific testing supports their use.

A. PHENOL GREATER THAN 1.5 PERCENT AQUEOUS/ALCOHOLIC SOLUTION

The Commissioner has reviewed the Panel's report on a number of products containing phenol in a variety of vehicles.

The Commissioner concludes that phenol in concentrations greater than 1.5 percent in aqueous or alcoholic vehicles is not safe for general use as an OTC antimicrobial agent in man.

1. Place in Category II due to a physical and/or chemical incompatibility in formulation.
2. Category II when formulated in any manner other than as a bar soap.
3. Category II for use outside the neonatal nursery.
Several references document the toxicity of phenol when applied topically. For example, authors have noted that a 2 percent ointment resulted in blood levels of 0.8 milligram (mg) of free phenol or 2.3 mg of conjugated phenol per 100 ml of blood. It should be noted that 30 mg of free and 1 mg of conjugate are fatal concentrations. One to 5 percent phenol applied as a dressing or compress has caused gangrene.

It has also been recorded that 2 percent and higher concentrations of phenol an aqueous vehicles have caused serious hazards, including gangrene, anesthesia, mummification, and even coma. Phenol is more soluble in alcohol than in water and would penetrate to deeper layers of the skin, producing severe burns, and might be systematically absorbed in higher concentrations.

The acute systemic toxic effects of phenol in man and animals is observed primarily as an effect on the central nervous system. Sudden physical collapse may result from ingestion or inhalation. There may be marked blood pressure fall. There may be headache, fainting, vertigo, and mental difficulty in swallowing, diarrhea, and digestive disturbances, such as vomiting, diarrhea, and anorexia. Nervous disorders, such as headache, fainting, vertigo, and mental disturbances also occur. There is a report that phenol is a carcinogen in animal tissue. In severe cases, sometimes fatal, there may be extensive damage to the kidneys and liver. Most of the reported cases of chronic poisoning have resulted from ingestion or inhalation. However, it is possible that repeated topical application over large surfaces of the body could lead to the systemic effects described above.

After absorption, phenol is excreted in the free form in the urine or is conjugated in the liver to the glucuronide or sulfate, prior to excretion in the urine. It has also been recorded that 2 percent to 2 percent of the phenol in aqueous solutions have been used with dressing or compresses. This has resulted in gangrene, primarily when applied to fingers and toes. Preparations containing 1 to 2 percent phenol have been formulated frequently in salves to obtain the antiseptic or the all or calamine lotion for antipruritic effects. The use of 2 percent phenol ointment has resulted, as reported above, in blood levels of 0.5 mg of free phenol and 2.3 mg of conjugated phenol per ml of blood. Blood levels of phenol attained after application of phenol in liquid preparation have not been presented.

It is evident of low concentrations of phenol (1 to 2 percent) in ointments, lotions, salves, or solutions can cause toxicity leading to severe incidence of gangrene with prolonged contact and/or occlusion of the treated area. Rat studies have shown that a 1.78 percent phenol to liquid petrolatum solution will cause gangrene in the same period of time. The dosage in 2 to 3 days. A 4.15-percent aqueous phenol solution caused gangrene in the same period of time.

The use of oil in the formulation may enhance the toxicity.

Camphor also has been used in formulations containing phenol. Camphor may in fact retard the absorption and availability of phenol from the solution. However, the local toxicity of phenol in a camphor-containing preparation depends upon the amount of free phenol and the aqueous phase resulting from the presence of tissue fluids or perspiration. Camphor, if present with phenol, will "hold" the phenol, as is evidenced by the study that demonstrated that, while 60 percent of the phenol in a saturated solution of liquid petrolatum is in the aqueous phase, only 22 percent of the phenol in a 4 percent camphor phenol/10 percent camphor combination is in liquid petrolatum in the aqueous phase. When the camphor concentration was raised to 21 percent, only 10 percent of the phenol was in an aqueous phase. The presence of camphor also retards the absorption of phenol after topical application.

A 1-hour exposure of the rat tail to a 4.5 percent aqueous phenol solution resulted in the absorption of 71 mg of phenol; whereas, the presence of 10.9 percent camphor combined with 4.5 percent phenol resulted in the absorption of only 16.6 mg phenol.

C. CLOFACUCARBAN

After reviewing the data and the Panel's recommendation, the Commissioner concludes that clofencucarbon is not generally recognized as safe and effective for the following product use: Patient preoperative skin preparation, skin antisectic, skin wound protectant, surgical hand scrub, health-care personnel handwash, and skin wound cleanser (except when formulated in a bar soap). This ingredient has never been marketed or formulated in any of these product classes. Safety data for these product classes were submitted to the OTC drug review; no data were received or reviewed by the Panel; and no comments were received by the Commissioner in response to the proposed monograph. The ingredient is therefore outside this monograph and may not be marketed in products in any product classification except skin wound cleanser, health-care personnel handwash (only when used in a bar soap) and, antimicrobial soap (for which it is classified in Category I11) unless there exists an approved new drug application.

D. TRICLOSAN

The Commissioner recognizes that a health-care personnel handwash, patient preoperative skin preparation, or a surgical scrub hand is designed primarily for extensive use in the hospital or other closed environment.

The Commissioner concludes that formulations containing this ingredient should not be within these environments because of possible increased one-way environmental pressures toward gram-negative (especially Pseudomonas) infections. (See part III. Part B, above—Triclosan.) He therefore concludes that triclosan in the above-mentioned topical antimicrobial product classes is not generally recognized as safe and effective and is misbranded.

CATEGORY II LABELING

The Commissioner has reviewed the claims which the health-care personnel are expected to communicate to the consumer and which they recommended be placed in Category I1. While no discussion of these claims was included in the report, the Commissioner has reviewed the administrative record and concludes that, with the exception of the claim, "controls infection," as noted in paragraph 34, these claims are not supported by the data on file and that their use with topical antimicrobial products described in this document will result in the product being misbranded. His spo-
The above claims imply to the consumer that antimicrobial products play a prime role in the healing process and thereby shorten healing time. In fact, their only action is to remove pathogenic microorganisms that might slow the healing process from the wound. This allows the body's healing process to follow its usual course at a normal rate. Since the ingredients reviewed do not directly affect healing, as the claims imply, the Commissioner concludes that these or similar phrases are false and misleading to the average consumer.

b. "STERILIZES" THE SKIN OR WOUND

"Sterilizes" is defined and commonly understood to mean a process by which all microorganisms are removed from an object. Such removal would include removal from the skin of both pathogenic and nonpathogenic microorganisms. The Commissioner concludes that the commonly understood or lay meaning of these terms and their scientific meaning. The Commissioner is concerned that, as he attempts to set general standards in this area, terms and claims not be ambiguous or have dual meanings. Such is the case with the terms "disinfect" and "sanitize," which when used, scientifically, refer to antimicrobial action or inanimate objects, but when used in the labeling of antimicrobial products, refer to antimicrobial activity on the body (39 FR 33114).

The Commissioner concludes that to assure clarity and conciseness of the meaning of these claims, as well as to eliminate the confusion caused by the dual meaning, their use should be limited to denoting antimicrobial action only on inanimate objects. Therefore, the above claims (or similar claims) will be considered misleading when applied to the use of topical antimicrobial products on humans.

c. "SPEEDS," "PROMOTES," OR "HEALS" WOUNDS

While the purpose of this claim may be to suggest removal only of pathogenic organisms from the skin, the Commissioner concludes that it is reasonably likely to convey to many consumers the idea that removal of all microorganisms from the skin will result from the use of products for which such claims are made, and that such a result is beneficial. As explained above, the removal of all bacteria on the skin cannot be accomplished with the concentrations of the ingredients found in OTC topical antimicrobial products. Further, the removal of all microorganisms including normal flora is not necessarily desirable. The Commissioner concludes that this or similar phrases are vague and misleading when applied to use of topical antimicrobial products on humans.

The Commissioner realizes that these terms are intended to imply cleansing of human tissue. However, there is some discrepancy between the commonly understood or lay meaning of these terms and their scientific meaning. The Commissioner concludes that, as he attempts to set general standards in this area, terms and claims not be ambiguous or have dual meanings. Such is the case with the terms "disinfect" and "sanitize," which when used, scientifically, refer to antimicrobial action or inanimate objects, but when used in the labeling of antimicrobial products, refer to antimicrobial activity on the body (39 FR 33114).

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1.5 percent Phenol or less aqueous/alcohol. Poloxamer-lodine complex.

Povidone-lodine complex.

Surgical hand scrub

Benzalkonium chloride.

Benzethonium chloride.

Hexylresorcinol.

Iodine complexed with phosphate ester of alkyarylpolyoxyethylene glycol.

Methylbenzethonium chloride.

Nonyl phenoxynonyl (ethylenoxy) ethanol.

Para-chloro-meta-xylenol.

1.5 percent phenol or less aqueous/alcohol. Poloxamer-lodine complex.

Povidone-lodine complex.

UNDECOYLIUM-CHLORIDE IODINE COMPLEX.

The oral LDo for cloflucarban is in rats as compared with hexachlorophene. The interim period specified below. The basis for the Category III claims and not were suggested in the comments to the report, the Commissioner concludes there are none. He is therefore deleting any discussion of Category III claims in this document.

GENERAL COMMENT APPLICABLE TO ALL INGREDIENTS IN CATEGORY III.

The Commissioner concludes that adequate and well-controlled studies are not available at this time to permit the final classification of the active ingredients listed above.

The hexachlorophene experience has made apparent to the scientific community that toxic levels of antimicrobial chemicals applied to the skin are absorbed into the body. The greatest lack of substantial data is in the following areas: skin type (young, mature, aged, diseased), concentration of skin (young, mature, aged, diseased), contact sensitization. More to the point, perhaps, is the lack of adequate research addressing this potential. Some studies show that interlaboratory differences in the safety testing guidelines under the discussion of triclocarban and cloflucarban. The Commissioner therefore does not consider these to be problem areas.

The Commissioner is concerned about the potential for contact sensitization. More to the point, perhaps, is the lack of adequate research addressing this potential. There are reports showing that contact sensitization concerning cloflucarban. These authors indicated that the potential for contact sensitization from cloflucarban is greater than that from triclocarban, but for less that from certain other antimicrobial agents. On the other hand, the existence of photo-sensitization cases was not found and therefore does not have to be studied.

In summary, the Commissioner concludes that cloflucarban or a combination of cloflucarban with triclocarban can be used in antimicrobial soap at a total concentration not to exceed 1.5 percent and only for a period of 2 years following publication of the final monograph in the Federal Register. The toxicity studies outlined in the guidelines will be required and should include determination of the oral toxicity, including target organ determination, with blood levels and “effect” and “no-effect” dose in the same study.

THE COMMISSIONER OF TRICLOCARBAN AND CLOFLUCARBN IN BAR SOAP.

The Commissioner is placing the combination of triclocarban and cloflucarban in Category III. These two chemicals are quite similar in their use, mode, and spectrum of antimicrobial action, and, in all likelihood, toxicity. However, it is the view of the Commissioner that additional data are needed on the cloflucarban component. Also, no data were submitted showing a dose/effect relationship. Conflicting data were submitted that are at such variance that interlaboratory differences could not possibly account for the discrepancies. For example, data showed that cloflucarban caused testicular effects in rats after 4, 8, 11, and 13 weeks of study at the lowest oral feeding level, 25 mg/kg, and liver changes at 1,000 mg/kg. This study showed that a “no-effect” oral feeding level was somewhere below 25 mg/kg. In contrast to this study, another study indicated that the “effect” and “no-effect” level in the same study. Just as important is a determination of the “effect” and “no-effect” blood level of cloflucarban.

As a word of caution, it should be pointed out that the Commissioner was presented suggestions in the combination procedure for cloflucarban in biologic fluids was not available.

In view of these conflicting data and the absence of definitive data on absorption, the Commissioner concludes that a limit of 1.5 percent cloflucarban (or a combination of cloflucarban and triclocarban) be set until such time as adequate data relating blood levels and toxic effects are made available.

The Commissioner has reviewed additional data submitting during the
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ment period in response to questions raised by the Panel. The Panel stated that further studies are necessary to determine whether the triclosan molecule, the metabolite(s) or both produce liver toxicity in rats and dogs. In addition, the Panel concluded that more data on human blood levels following topical application were needed. A variety of skin areas, types, and conditions should be studied. The Panel expressed concern over the possibility of increased blood levels resulting from widespread use of triclosan in soaps and deodorant products and recommended that this should also be investigated.

After reviewing these additional data, the Commission concludes that triclosan should remain in Category III for use in antimicrobial bar soap because adequate data are not yet available to permit final classification of this ingredient. Even though industry has submitted additional data (discussed below) subsequent to the Panel’s report, questions arise regarding the validity of these studies as well as some data originally reviewed by the Panel.

Triclosan is one of the most highly absorbed antimicrobial ingredients reviewed by the Antimicrobial Panel. Even though additional data were submitted during the comment period, human absorption data from exaggerated human use (similar to the data from use of radiolabeled triclosan discussed above) are not available for triclosan. The results of such a study are critical to assessing whether the increasing number of products now being formulated with triclosan, such as cosmetics, infant clothing, and diaper rinses will increase the blood levels of triclosan to an appreciable degree. Because data contained in a recently received comment have shown that triclosan has a higher rate of absorption than other currently marketed antimicrobial products (i.e., approximately 3 percent topical absorption compared to approximately 12 percent topical absorption for triclosan), concentrations of triclosan in antimicrobial bar soaps must be limited to 1 percent resulting.

The Commissioner finds that the safety factor in submitted data is based on the assumption that the population will be exposed to triclosan only in antimicrobial soaps and related antimicrobial products. This is no longer the situation, and in view of the increasing use of triclosan in consumer products, the final resolution of risk to benefit, particularly with respect to increasing body burden of triclosan, cannot be made at this time.

In addition, adequate safety and effectiveness data are not yet available to permit final classification for this ingredient. Although the triclosan molecule, skin antiseptic, and skin wound protectants. From the data submitted, the Commissioner concludes that there is no known hazard to human blood levels following topical use of triclosan in concentrations not greater than 1 percent. He therefore concludes that triclosan should be permitted for use in antimicrobial bar soap, as a skin antiseptic, skin wound cleanser and skin wound protectant and allowed to be sold to the general public for a period of 2 years. Upon completion of the final monograph in the Federal Register in order to allow interested parties time to conduct the necessary research to supply necessary data, the following safety factors are indicated as deficient in the following summary:

- It has been shown in animal experiments that triclosan can be absorbed through intact skin. This has been verified by the data in the table, which details human blood levels following the use of a triclosan-containing soap on intact skin.

- The primary target organ for toxicity from triclosan is the liver. There is still a question as to whether the damage to the liver is due to the intact molecule, a metabolite, or a combination of both (triclosan and/or triclosan metabolite).

- A subchronic (90-day) oral study in dogs revealed liver damage at blood levels of 6.4 parts per million (ppm) total triclosan (free and/or metabolizable) resulting from an oral dose of 25 mg/kg/day. A no-effect oral dose of 12.5 mg/kg/day, in the same study, resulted in a total blood level of 6.1 ppm. Similar studies, using the absolute dose given, showed liver toxicity in dogs, but actual blood levels were not measured. The dose-related histopathological damage in the dogs was described as perportal (zone 1) centrilobular hepatocytic degeneration, which led to focal necrotic hepatitis. This change appears to be reversible when exposure to triclosan is terminated. In other studies, when triclosan was administered in the diet to dogs or rats for 90 days at doses equivalent to those used in previously discussed studies, no liver damage resulted. Triclosan absorption varies in animal species; therefore, the amount of intestinal and topical absorption needs to be established.

Taking into consideration animal toxicity and human absorption and blood levels, safety factors were calculated. It was found in subchronic 90-day dog studies that the highest no-effects dose was 12.5 mg/kg. The absolute dose given was 75 mg (12.5 mg/kg x 6 kg/dog). Extrapolating to man, by surface area, using the technique of Paget and Barnes, (Panel report 39 FR 33113), the no-effect level might be expected to be 225.5 mg in the human. The value was calculated by multiplying the absolute dose in dogs showing no-effect by the conversion factor for surface area (75 mg X 3.1). Similar calculations were also possible with a 90-day monkey study.

If, as assumed by the Panel, an antimicrobial bar soap contains 1 percent triclosan as the active ingredient and an average bath consumer 7.0 gm of soap, then the total available triclosan per bath would be 70 mg. Since 1 percent of the 70 mg of the available triclosan remained, about 0.7 mg of triclosan is available for absorption after each bath. Also, since the data show that approximately 9.9 percent of the 0.7 mg of triclosan is absorbed, then 0.062 mg would be in the blood. Thus, the following hypothetical safety factor, using surface area, can be calculated:

- 225.5 mg (expected no-effect dose) divided by 58.1 m2 = 3.86 safety factor

Another way to calculate a safety factor is to assume that an average size human has 5,000 ml of blood. Since the data show that 0.062 mg of triclosan is instantaneously absorbed from the skin, the concentration of free triclosan in the blood would be approximately 12 parts per billion (ppb). Assuming that some persons take two baths per day, and that the total triclosan per bath is absorbed and accumulates, the blood level would be 24 ppb. Data from the submission suggest that rapid conversion of free triclosan to the glucuronide occurs and that within a few minutes, most of the absorbed triclosan exists only as the metabolite.

If the lowest “no-effect” blood level data (66.110 ppb triclosan/triclosan metabolite) is taken in dogs, and recognizing that the data were reported from a 90-day study, the following safety factor could be calculated:

- 21.1 ppb (blood level of triclosan) divided by 66.1 ppb (from a single bath)

Data from humans revealing a blood level of 44 ppb of triclosan/triclosan metabolite exist and the Panel made the following calculations:

- 0.064 ppb (blood level at effect) divided by 1,280 ppb (from two baths)

These calculations would indicate a substantial safety factor, but it should be pointed out that studies relating blood levels to toxic effects, are short-term studies. Humans may be exposed to bar soap daily over their entire life span. The Panel made several assumptions based on unresolved data, particularly on the degree of subcutaneous and rate and amount of absorption. But these are only assumptions and must be tested. Research should be on humans in various age groups and with varying skin conditions.

No evidence of potential mutagenesis or teratogenesis was found in studies on various rodent species. The study on the carcinogenic potential of triclosan has been declared invalid by the agency and must be repeated or validated.
Data indicate that triclosan cannot be considered a primary sensitizing or photosensitizing agent in animals or in humans. But studies have not eliminated possible cross-reactivity following previous sensitization with hexachlorophene, salicylanilides, or carbamides and further cross-sensitization studies should be performed. (The halogenated salicylanilides have been removed from OTC use (49 FR 5930, October 30, 1975; see 21 CFR 109.500).

The Commissioner now feels that adequate data concerning elimination and toxicity in young animals have been submitted. Research in young animals with unavailable glucuronide systems has been conducted in order to define the toxicity potential for human infants and individuals with inadequate liver function. Recently received data, including a 30-day monkey study, establish the rate of absorption of triclosan and indicate that rhesus monkey neonates can eliminate triclosan by conjugation with glucuronic acid. One type of gram-negative bacteria, Pseudomonas aeruginosa, is a potential hazard. In attempts to define the spectrum of triclosan, some of the gram-negative bacterial strains listed in the reports were revealed to be susceptible to triclosan. These gram-negative bacteria, showing in vitro susceptibility to triclosan included strains of the various coliforms, Proteus and Salmonella. One type of gram-negative organism of increasing importance in the hospital environment that was found to be quite resistant was Pseudomonas aeruginosa. Other microorganisms showing low levels of susceptibility included various fungal agents such as the polio virus. Influenza, adeno-, and vaccinia viruses are inhibited at lower concentrations. The reports suggest that reduction of the number of microorganisms in the skin microflora with the use of triclosan in soaps is similar to that of other biocidal agents. In addition, triclosan can be selectively established at high levels on the skin with the topical use of biophenyl. In addition, triclosan can be selectively established at high levels on the skin with the topical use of biophenyl.

The reports suggest that Pseudomonas aeruginosa can be selectively established at high levels on the skin with the topical use of biophenyl. In addition, triclosan can be selectively established at high levels on the skin with the topical use of biophenyl. These materials include food and microflora samples from the skin. This isolation study described the use of a patented Pseudomonas isolation triclosan-containing agar.

Triclosan differs from other bacteriaactive primarily against gram-positive bacteria. In that it does have limited in vitro and probable in vivo activity against some gram-negative bacteria, but unfortunately not against Pseudomonas. With the widespread use of antibiotics and disinfectants selectively active, primarily against gram-positive bacteria in the hospital environment, gram-negative, nosocomial, opportunistic pathogens, are increasingly life-threatening. With the environmental pressures being pushed in one direction (one-way selective pressure) toward the selection of gram-negative bacteria, i.e., Pseudomonas, in the hospital environment, unexpected reservoirs and mechanisms of transmission are being reported. It is essential to eliminate sources of gram-negative bacteria in particular areas of the hospital such as burn units, neonatal nurseries and intensive care units in which immunosuppressive drugs are administered. One study describes the use of a triclosan-containing soap in hospitalized and immunosuppressed patients. This study reports the results of the bathing of leukemia patients in a protected environment (life Island) with a bar soap containing 1 percent tribromsalan and 1 percent triclosan. The authors report eradication of multiphycological species, including some potential pathogens and gram-negative bacteria on various body sites. It is the Commissioner's view that the results of this in vivo study cannot be projected to a normal environment.

The patients in this uncontrolled study were all immunosuppressed and receiving concomitant antibiotic therapy, both oral and topical. In addition, the skin sampling and culture techniques were not optimal for the isolation of Pseudomonas from the skin. The serious possibility of carryover of inhibitory antimicrobial residue from topical therapy would invalidate the cultural results. And there is a risk involved in using a soap that has activity against Pseudomonas on immunosuppressed and colonized patients. A subsequent study of a similar type concluded that, although 76 percent of aerobic bacteria, including gram-negative bacteria, were eliminated by cleansing with a soap containing a combination of triclosan and tribromsalan, strains of potential pathogens such as Enterobacter species, Klebsiella species, Proteus species, and Pseudomonas aeruginosa persisted. Thirty-three percent of the patients had persistent pathogenic bacteria and 40 percent had persistent E. coli. Extensive systemic and topical antibiotic therapy and washing with an antimicrobial soap as a protective measure, the organisms persisting are those most likely responsible for nosocomial infections in these seriously ill patients.

The Commissioner concludes that clinical effectiveness in the prophylaxis and treatment of superficial pyogenic infections of the skin has not been documented. The skin has not been inhibited with the use of a patented Pseudomonas isolation triclosan-containing agar.

The Commissioner concludes that triclosan can be used in an isolation medium which will permit the selective isolation of Pseudomonas from the skin. Additionally, it is known that triclosan is effective in vitro primarily against gram-positive organisms and against some gram-negative organisms, but is not effective against Pseudomonas. Human skin is a culture medium superior in many instances to those devised by microbiologists. This raises the possibility that use in the hospital environment, in closed environments such as hospitals and nursing homes would act to selectively promote the growth of Pseudomonas, especially on their hands, in an environment where Pseudomonas is ubiquitous and may be life-threatening to many patients.

Because of this potential for influencing the gram-negative and/or the addition of another potential selective agent for Pseudomonas, the Commissioner concludes that triclosan-containing products should not be used in the hospital or other closed environments, such as nursing homes, where individuals are present who may be highly susceptible to infection with microorganisms not normally pathogenic (opportunistic pathogens). Accordingly, the Commissioner has determined that triclosan as a single ingredient is not safe for use in health care personnel hand-washes, surgical gowns, and patient preoperative preparations.

This restriction on the use of triclosan also applies to any combination products containing triclosan unless the deficiency in the microbial spectrum is compensated for by another antimicrobial ingredient. Triclosan should be used only in products where there is no exposure to persons who have debilitating diseases, or who are physically debilitated, or immunologically compromised, or where the closed environment in the hospital or other institution would possibly allow the shift of environmental pressures toward Pseudomonas.

Many animal toxicity studies for this ingredient have been submitted, and they are discussed above. Before triclosan can be considered safe as a skin wound cleanser, skin wound protectant or skin antiseptic, further work is necessary to determine what produces the toxic effect. More data on human blood levels following topical application on abraded skin are needed, and a variety of skin areas, types, and conditions should be studied. The Commissioner concludes that in vitro data indicate that triclosan has
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D. TRILOCARBAD

The Commissioner had determined that the only permitted use of triclocarban (TCC, 3, 4, 4-tiol analogs) at the present time should be as an antimicrobial ingredient in bar soap and only when used as a health-care personnel handwash, skin wound cleanser, or antimicrobial soap.

The Commissioner reviewed the available effectiveness and safety data on triclocarban and concludes that adequate data are not yet available to permit final classification of triclocarban for use in bar soap. The available evidence does not indicate that the use of triclocarban in bar soaps presents any known hazard to the general public. Based on blood level data, triclocarban does not appear to be as toxic as hexachlorophene.

A primary area of concern is the data defining the target organ for toxicity. At high blood levels of triclocarban (in excess of 200 ppm TCC/TCC metabolite), the apparent target organ in rats is the testicles. In the opinion of the Commissioner, the available blood level data of triclocarban to testicular damage are still not definitive. For example, one set of data in OTC Volume 020169 estimated that under conditions that resulted in blood concentrations of 50 to 10 ppm TCC/TCC metabolite caused pathological changes in the testicles of test animals. More recent data from a 2-year chronic animal toxicity feeding study at 400 mg/kg/day, in OTC Volume 020165, suggest that 200 ppm TCC/TCC metabolite in the blood was an "effect level" and that a dose of 200 mg/kg/day giving a blood concentration of 50 to 10 ppm TCC/TCC metabolite was a "no-effect" level. Still other data in the OTC Volume 020139 suggested testicular lesions at oral doses lower than those which resulted in the "no-effect" blood levels mentioned above (100 ppm). In view of these conflicting data regarding blood levels and ensuing testicular damage and in view of the fact that the 2-year chronic animal feeding study mentioned in OTC Volume 020165 has recently been found to be invalid, the Commissioner regards this as an area of significant deficiency in the data. Adequate data relating blood level to target organ toxicity and "no-effect" levels will be required in the form of a 2-year chronic animal toxicity study to replace the above-described study, which the Commissioner now considers invalid.

As was shown by Maibach (Maibach, H. L., "Skin Penetration of Hexachlorophene in Living Man," Draft of unpublished paper is included in OTC Volume 020169) and confirmed by more recent data for humans, submitted as a comment in the Panel Report, triclocarban may be absorbed through human skin, after topical application at a rate of approximately 14 percent of the dose applied. Elimination of triclocarban after topical application is slower than after ingestion, suggesting possible accumulation in the body. However, the adequacy of analytical methods for the detection of triclocarban and all its metabolites is still questionable, and is made more difficult by the fact that it cannot be detected in blood or tissue. Based on some theoretical and some actual data, calculations of potential blood levels in man were made. It is the conclusion of the Commissioner that, until definitive data are accumulated to show blood levels in man from actual use, the concentration of triclocarban in bar soaps should be limited to 1.5 percent. The calculation that led to this conclusion follows, but it should be emphasized that the cause of testicular lesions has not yet been determined to be triclocarban (parent compound), TCC-metabolite or the combination, (TCC/TCC metabolite).

Recently received data confirm that TCC is absorbed at approximately 5 percent under human use conditions. These data correspond closely to the calculation originally made by the Panel without this information and using certain assumptions.

If a bar soap contains 1.5 triclocarban and an average bath uses 7.0 gm of soap, the total available triclocarban, if instantaneous absorption occurred, would be 105 mg.

1.5 percent of this 105-mg triclocarban remains on the skin as a substantive agent. This retention presents to the body a total of 2.1 mg of triclocarban for absorption.

Since 14 percent of the available 2.1 mg is absorbed, as shown by Maibach, this would allow 0.281 mg of triclocarban to be absorbed from a single bath.

Since an average size human has 5,000 ml of blood, and 0.284 mg of triclocarban is absorbed, the concentration of triclocarban in the blood would be 0.075 ppm. Considering that some portion of the population takes two baths per day, and assuming that the total triclocarban to which the individual was exposed accumulated during that day, the blood level would be 0.150 ppm. Data from the submissions to the Panel indicate that triclocarban as the parent compound disappears from the blood within minutes. The exact mechanism(s) of absorption and elimination is not yet clear.

If the most recent data indicating that 100 ppm total TCC (TCC/TCC metabolite) in the blood is the "no-effect" level are confirmed by the additional chronic toxicity study being required, then a safety factor could be calculated as follows:

\[ \frac{105 \text{ ppm}}{14 \text{ percent}} = \frac{1316.4 \text{ ppm}}{100 \text{ percent}} \text{ safety factor} \]

0.8 ppm

0.35 ppm

A major route of elimination of triclocarban from the body is reported to be via conjugation to the glucuronide in the liver. This mechanism is deficient in young animals and human infants. There are no data available. It is the conclusion of the Commissioner that, until definitive data are accumulated to show blood levels in man from actual use, the concentration of triclocarban in bar soaps should be limited to 1.5 percent.
from use in infants. The label for the preparation containing the ingredient should therefore state: "Not to be used on infants under 6 months of age."

The Commissioner recognizes that the triclocarban will decompose at elevated tempera -tures resulting in the formation of chloroanilines. There are reported incidences of methemoglobinemia resulting from high-temperature decomposition of triclocarban by Johnson et al (Johnson, R., K. Haynes and E. L. Larson, "An Unusual Epidemic of Methemoglobinemia," Pediatrics, 31:222-225, 1963). Therefore, soaps or soap products containing triclocarban should not be heated and subsequently used on humans. Additionally, since chloroanilines do have a potential for inducing methemoglobinemia at higher blood levels, the chloroaniline content in bar soaps containing triclocarban should be monitored to limit it to less than 100 ppm. The Commissioner feels that adequate levels, such as found in the Panel to indicate that 100 ppm chloroaniline, or less, in bar soaps would present no hazard to humans even after multiple baths with such soaps.

The Commissioner further concludes from the references and data submis- sions reviewed that photosensitization and contact dermatitis from triclocarban are of such rarity that they present no major problem to the general user of a soap containing triclocarban.

Therefore the Commissioner concludes that the only permitted use of triclocarban should be as an antimicrobial ingredient in bar soap formulations at a concentration not to exceed 1.5 percent for use as an antimicrobial soap, health-care personnel handwash, and skin wound cleanser and only for a period of 2 years following publication of the final mono -graph in the Federal Register. During this period a 2-year chronic toxicity study in animals via oral feeding must be performed to replace the 2-year chronic feeding study involving over 400 rats, which the Commissioner has recently declared invalid. This chronic toxicity study will be required to resolve any questions of potential testicular, brain, or splenic changes with concomitant biochemical changes in the liver. Other possible deposits of drug after absorption, such as the lymphatic system, should be determined in the 2-year study.

E. IODOPHORS

The Commissioner recognizes the existence of at least three categories of iodophors: (1) solubilized inorganic elemental iodine complexed with a surfactant for broad spectrum antimicrobial activity; (2) iodine complexed with surfactant products such as poloxamer-iodine complex; and (3) iodine complexed with various non surfactant compounds such as PVP-Iodine complex (polyvinyl pyrrolidone-iodine). The antimicrobial activity of all of these complexes is dependent on the release of elemental iodine. Iodine is recognized to be a broad spectrum antimicrobial with activity against fungi, viruses, and both gram-positive and gram-negative bacteria.

1. Solubilized inorganic elemental iodine complexed with a surfactant for broad spectrum antimicrobial activity. There is extensive literature documenting the effectiveness of aqueous and alcohol solutions of elemental iodine as an antiseptic. Pharmses Sipes (Pharmaceuticals Sipes, "Antiseptics and Disinfectants," Pharmacology of Antimicrobial Agents, 1958, pp. 510-527) have listed iodine preparations since 1840. The Commissioner concludes that elemental iodine hydroalcoholic solution is safe and effective when properly diluted with a patient preoperative skin preparation and is effective for first-aid use on minor wounds as a skin antiseptic, skin wound protectant, or skin wound cleanser. How- ever, he has insufficient information on the effects of its irritating properties and delay in wound healing to classify it in Category 1 at this time.

A variety of values has been proposed for the minimum concentration at which iodine is lethal to cells. It has been reported that all microorganisms are killed at 2 percent hydroalcoholic strength, but the organic load (in a wound, with serum, or on the skin) and pH (acidity) may dramatically change the concentration required to achieving ef- fect on the skin. It is difficult to set a level of free iodine that is effective against all types of microbial flora, viruses, fungi, spores, and vegetative bacteria. However, 138 years of clinical ex- perience with this ingredient at a 2-percent hydroalcoholic strength seems to indicate effectiveness at that strength for small burns and minor wounds (the Commissioner, though disagreeing with the recent conclusions of the Panel's ultimate conclusion declaring iodine tincture unsafe (Category II) for "first-aid" uses, nevertheless is concerned about delay in wound healing, and therefore requiring that either of the wound-healing procedures outlined in the testing guidelines be carried out at the 2-percent hydroalcoholic strength before determining whether iodine can be considered generally recognized as safe and effective for such uses. In addi- tion, because elemental iodine causes burns, severe or fatal, the warnings for such products should contain the follow- ing warning:

Do not apply this product with a tight bandage or dressing.

2. Iodine complexed with various surfactant compounds. The Commissioner recognizes that elemental iodine complexed with a surfactant type "carrier" molecule reduces the amount of immedi- ate "free" iodine, since most of the formulated iodine is bound in the com- plex. The Commissioner believes that the iodine is dependent on the release of free iodine as the active agent and the complexing molecule acts only as a carrier. The Commissioner was not presented adequate data to determine if the complex is really a micellar solubilization of iodine at the molecular level or whether loose chemical bonding exists producing what could be termed a "sociable moiety." Indeed, the complexa- tion of iodine with the carrier molecule is responsible for the changes in characteris- tics observed in staining, burning, or irritation of the skin. The amount of "free" elemental iodine in solution is a function of the equilibrium constant of each complexing formulation. All of the "free" elemental iodine is removed from solution (as in the case of application to a wound where potentially all iodine present is bound to total organic load). Therefore, a finite time period would be required before a new equilibrium would be established. Once the iodine is released from the complex, it acts as ele- mental iodine, a broad spectrum anti- microbial. However, only a fraction of the carrier molecule remains at the site as any other similar surfactant molecule.

The Commissioner concludes from the data submissions that iodine complexed with a surfactant is an acceptable way of presenting iodine as an antimicrobial agent to a wound site or the skin. The purpose of presenting iodine in such a form is to reduce the staining and toxic (locally) properties inherent in the io- dine molecule. Since most of the formu- lated iodine is tied up in the complex, the "free" iodine iodine is present in a given instant is relatively small. There- fore, theoretically, the degree of irrita- tion should be lessened. Indeed, the data submitted substantiate a reduced degree of iodine burn from these products in many cases, because the amount of "free" elemental iodine released from the complex is not enough to cause tissue burns, the area covered by it may safely be covered with an adhesive tape or bandaged.

This is a significant advantage for these iodine preparations over older iodine formulations, such as tincture of iodine.

The concern of the Commissioner has been that advantage of complexed iodine may also be its most serious dis- advantage. The advantage of the iodo- phor is that the area can be treated and bandaged without irritation, while the serious disadvantage may be that actually there is less free iodine as an active antimicrobial. The Commissioner was presented no significant data about the "release" or dissociation of iodine from the complex. Additionally, the Com- missioner is concerned about the lack of stability data of iodophor formulations. The Commissioner proposed mechanism, which has been de- scribed in U.S. Pat. 3,028,299 (Winicov, M. W. and W. Schmidt, "Germicidal Compositions and Methods for P-""orrating the Same," United States Patent No. 3,028,299, issued April 3, 1962), and the theory of the establishment of an equi-librium between free iodine and complexed iodine. The labeling for a given product states the amount of available or titratable iodine in the formulation. However, only a fraction is in the "free" elemental iodine form at the time of use. The concern of the Commissioner is the lack of data in the cases of actual use of the product which identifies the fraction that is "free." For example, once the "free" elemental iodine is bound to an organic load (in a wound, with serum, or on the skin), how rapidly is new ele- mental "free" iodine available from the complex? Does pH influence rate of re- lease? Only preliminary data were pre- sented to the Panel in the form of rap- idity of titration with thiocyanate or ra-
pacity of partitioning between two immiscible solvents. The Commissioner considers that data taken in vitro do not reflect actual conditions of use. For example, will the dissociation of iodine from the complex take place at the same rate under conditions in vivo as in vitro data were taken? Such data were presented and before final classification of these iodophors for most applications can be made, such data are necessary.

Another area of concern for the Commissioner was the lack of stability data submitted for the several iodophor preparations. It is recognized that elemental iodine is a rather powerful oxidizing agent, as are all the halogens. It was suggested that some iodophors are not stable over a 2-year shelf life period. The Commissioner concludes that until such data are submitted, stability of iodophor products is sufficiently in question to require an expiration date not to exceed 2 years after manufacture and that stability data be submitted to the agency.

The Commissioner concludes that inadequate data on stability and availability of information were presented to all applications to permit final classification of these surfactant iodophors at this time. Some data submitted suggest that with certain of the surfactant iodophors the volatile characteristics of iodine are not changed. In an occluded environment such formulations may corrode the tissue resulting in tissue burns. It was also suggested that all surfactant ac- tions can cause hemolysis and tissue irritation and for this reason all surfactant-containing iodophors should be removed from soft tissue or surgical wounds prior to their closure. The Commissioner notes only a very small number of clinical studies with the surfactant iodophors which could shed light on these problems. The Commissioner therefore concludes that surfactant iodophors must be studied to define retardation of wound healing before they are labeled as skin wound cleaners and skin wound protection. The Commissioner will therefore require that appropriate controlled clinical studies for effectiveness and safety be conducted for each surfactant iodophor in accordance with the testing guidelines below.

The Commissioner recognizes a danger in the use of iodophor and detergent (surfactant) preparations when there is contact with starch granules during a surgical procedure. Surgical gloves lubricated with powdered starch can cause idiosyncratic pathogeny after surgery. Such starch can absorb iodophors or detergents and the resultant complex can cause general aedhesion and other undesirable effects in the body. The Commissioner will therefore require an appropriate label warning for products containing both povidone-iodine complex and surfactant-iodine complexes should they be classified as Category I in the monograph.

In specifying some shortcomings in the data submitted, the Commissioner does not mean to imply that a known hazard exists from these products. On the contrary, the Commissioner received enough toxicity data to convince him that there is no known hazard from the use of these iodophors.

3. Iodine complexed with nonsurfactant compounds. The primary recommendation for additional work in this area is to show the extent of scavenging of residual povidone-iodine molecules by the reticuloendothelial system and possible lymph node involvement following use in abdominal cavi ties or in large wounds. As noted in paragraphs 71 and 72 above, in the event that povidone-iodine is classified as Category I and included in the monograph, it would need to carry a warning against use in deep or puncture wounds and in a warning in professional labeling against use of this ingredient parenterally, use in the body cavities, and exposure of open surgical wounds. The Commissioner is convinced by the Panel report that there is little, if any, danger of

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data submitted in the comments and conclusions that the data proving the identity and effectiveness of povidone-iodine are still inadequate and the product must remain in Category III.

Data were presented that indicate that povidone-iodine preparations are not in volume on large burn areas, on vaginal mucosa, in large open wounds, and in abdominal surgery. Following such indiscriminate use, it was shown that some povidone-iodine preparations exhibited free iodine and free iodide levels and thyroid function. Therefore, the Commissioner cautions against such use in large volume or areas until more controlled research is conducted to show conditions of use under which thyroid function would or would not be altered, and the amount of povidone-iodine required placed in Category I.

While reviewing the data submissions and comments to the Panel report, the Commissioner was concerned about label claims made without adequate supporting clinical effectiveness data implying "long-acting germicidal" activity or prolonged viricidal or sporidid activity with iodine suggested clinical effectiveness over relatively long periods of time. Two questions concerning the effectiveness of skin antisepsis arose from such implication: (1) What is the rate of release of "free" iodine from the complex in a clinical application and (2) what is the evidence supporting activity over a period of time in a clinical application? The Commissioner concludes that definitive research must contain a series of questions as well as to define the limiting conditions for the antimicrobial activity of iodine, whether free or bound in an iodophor before povidone-iodine complex can be placed in Category I.

Reports have appeared in the literature which have indicated possible lymph node changes by circulating povidone-iodine. The Commissioner recognizes that certain molecules of povidone-iodine have been used as plasma expanders, which have caused the node changes. Povidone-iodine preparations have been used in large open wounds and in the abdominal cavity, but the Commissioner feels that adequate data were made available to prove positively that such lymph node changes do not take place following such uses of povidone-iodine. This primary recommendation for additional work on this area is to show the extent of scavenging of residual povidone-iodine molecules by the reticuloendothelial system and possible lymph node involvement following use in abdominal cavities or in large wounds. As noted in paragraphs 71 and 72 above, in the event that povidone-iodine is classified as Category I and included in the monograph, it would need to carry a warning against use in deep or puncture wounds and in a warning in professional labeling against use of this ingredient parenterally, use in the body cavities, and exposure of open surgical wounds. The Commissioner is convinced by the Panel report that there is little, if any, danger of
carnogenesis from residual povidone-
iodine molecules.

4. Comments on iodophors. The general deficiencies noted with the iodophors involve both safety and effec-
tiveness, while the issues related to ele-
mentary safety would be beyond the ques-
tions of wound-healing delay. For iodophors, the question of iodine release from the complexed molecule, including rate of release and binding to other mater-
ials, as well as the influence of the release rate on effectiveness, must be resolved.

The stability of complexed iodine over time and with varying environmental conditions must be known and controlled, so a stable product is marketed and ef-
fectiveness can be assured. Because of this instability problem, all topical anti-
microbial products containing complexed iodine must bear an expiration date. The systemic absorption of topicaly applied iodine must be measured using the cur-
rently accepted assay procedures. In some cases, the toxicology of complexed iodine molecule has been only superficially characterized.

Neither the Commissioner nor the Panel was presented any data to show that iodine (elemental) or iodophors can be formulated into antimicrobial soaps. Accordingly, these ingredients are not generally recognized as safe or effective for such use (Category 1D).

F. QUATERNARY AMMONIUM COMPOUNDS

Since the first introduction in 1935 of quaternary ammonium salts ("quats") with surface active characteristics used as antimicrobial agents, there has been wide use and acceptance of these com-
ounds as antiseptics and disinfectants. There has also been much controversy concerning their microbial spectrum, inac-
activation with incompatible materials, and potential hazard as a result of gram-
negative contamination, particularly with Pseudomonas.

Quaternary ammonium compounds are cationic surface active agents. They can be divided into nonionic and anionic under the general role that they are essentially organically substi-
tuted ammonium compounds which can be characterized by the following gen-
eral representation: 

\[ RN+X^- \]

where \( R \) represents a lipophilic group such as long chain hydroxy alkyl or aryl-alkyl radicals or other groups; \( X^- \) represents a negative ion, such as a halide, sulfate or other radical; and \( N^- \) represents nitrogen.

The inherent nature of this type of molecular structure allows the synthesis of a large variety of compounds. The challenge has been met by the produc-
tion of extremely large numbers of these compounds. The Commissioner has re-
viewed only three of these, and restricts his comments to those for which data were submitted: Benzalkonium chloride, benzenthionium chloride, and methyl ben-
zenthiocyanum chloride. It should be under-
stood, however, that some components have characteristics that are common to the whole class of quaternary am-
nonium compounds. While the microbial

spectrum does not vary significantly among these compounds, an expanding list of new products could lead to a wider variation in the spectrum of microbes attacked. However, because only these three quaternary ammonium active ingredients were submitted to and reviewed by the Commissioner, it is not all other qua-
ternary ammonium compounds are not generally recognized as safe or effective unless and until appropriate petitions were received and approved modifying the monograph. Only holders of new drug applications may continue to market quaternary ammonium compounds other than benzalkonium chloride, benzeth-
ionium chloride, and methyl benzenthionium chloride.

There is an interference action between cationic and anionic surface ac-
tive agents with the result that these two types of compounds cannot be formulated together without inactiva-
tion of the germicidal activity of both com-
ponents. In contrast, the nonionic surfactants can be combined with cationic "quats" in products known as germicidal detergents.

"Quats" and all surface antibacterials have been shown to effect membrane permeability. Indeed, the group of compounds has been called membrane-
active. Many authors have recorded the loss or leakage of cell contents after exposure to "quats." Specific transport mechanisms may also be affected. "Quats" probably produce a generalized breakdown in the semipermeable char-
acteristics of the membrane.

Gram-positive microorganisms are generally more susceptible to the effect of the "quats" than gram-negatives.

The "quats" are nonspecifically ad-
cated to the cell wall. In any case, the unprotected cell membrane is sensitive to the action of the "quats." Difference in sensitivity is conferred by access to the cell membrane.

This difference is probably due to the differences in the wall thickness gram-
pasive and gram-negative microorganisms. The adsorptive character of the cell wall probably determine the susceptibility of the quaternary to reach and affect the cell membrane beneath the cell wall. Early reports of the bactericidal ac-
tivity of "quats" in low concentrations could not be supported when adequate neutralizing chemicals were added to the culture medium for testing antibacterial activity. In early tests, enough "quats" molecules adsorbed to the cells were carried over into the subculture medium to prevent the cells from growing when transferred to culture media. The mean-
ing of the results of such tests was mis-
interpreted and data were carried over into the early effectiveness testing of the "quats."

The gram-negative Pseudomonas spe-
cies are frequently resistant to destruc-
tion by "quats." The cationic activity of "quats" against Mycobacterium tuberculosis has been well established. The fungicidal activity of "quats" is generally less than against bacteria and yeasts. What is so far of little use in showing any significant antiviral activity. Tables listing the spectrum of "quats" against a variety of microorganisms are numer-
ous.

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The presence of organic materials substantially reduces the antimicrobial effectiveness of "quats." Their surface active nature permits easy adsorption on surfaces of even glass and plastic, and consequently, residues of "quats" may remain. In fact, the "quats" may bond onto the bacterial cell surface and sub-
sequent carryover to the subculture medium in testing accounts for early exaggerated claims of effectiveness for "quats."

The cationic "quats" are inactivated by anionic compounds, soaps, Tween 80, and sodium laurel sulphate as well as by certain metallic ions. Hard water and acidity also alter the activity of the "quats." On the other hand, among newer "quats" synthesized there are some which are not adversely affected by hard water and acidity.

Because of their reported low toxicity and ease of use, especially with deter-
gents, these compounds have been widely
deployed in hospital sterilization procedures. Organic material is commonly added to the solutions; and as a result of failure to clean materials or replace old sol-
utions, added microorganisms are not in-
activated and can grow and reproduce.

Several serious outbreaks of gram-nega-
tive infection, as well as infections caused by other organisms, have been reported as a result of contaminated quaternary ammonium solutions.

Preservative ingredients can be added to quaternary ammonium salts to prevent the growth of gram-negative microorgan-
isms, particularly Pseudomonas. Such a preservative system must be adequately challenged by effectiveness testing. The minimum acceptable standard for chal-
lenge testing of the preservative system and the chemical content would be the USP XIX Antimicrobial Preservative-
Effectiveness Test (pp. 887-888) and the Antimicrobial Agents-Content Test (p. 886).

The Commissioner is not seriously concerned with the safety of "quats" for "first-aid" uses, i.e., in skin wound cleansers, skin wound protectants, and skin antiseptics. However, before "quats" in general can be finally classified for such uses, the following minor issues must be resolved: delay of skin wound repair, contact dermatitis, and sensitivity to "quats." Data on the effectiveness of "quats" for these uses must also be devel-
oped. The three "quats" for which data were submitted have, however, had these questions sufficiently resolved to be class-
ified in Category 1 for use in skin wound cleansers.

While human systemic absorption and toxicity after topical application cannot, be precisely established based on a review of the scientific literature or sub-
mitted data, the systemic toxicity of "quats" in animals is low. The LD₅₀ and chronic oral study values in several ani-
mals species are high. The toxicity reported is indicative of and reflects the surfactant nature of the molecule. The
"use dilution" for the "quats" is usually about 1/750 for topical application.

Further, even though specific absorption and systemic levels in humans have not been reported for the "quats" reviewed, consideration of the concentrations applied, and extrapolating from animal studies, toxic effects at use levels would be unlikely.

The irritating nature of quaternary compounds on the skin, mucous membranes, and in the eye have been reported extensively. The degree of irritation is dependent on concentration and/or occlusion. However, there is little irritation potential with the use concentrations.

Various reports of toxicity related to the detergent nature of these compounds have been published. Two authors reported that repeated application of 1 percent benzethonium chloride to the skin caused damage with cellular degeneration. "Quats" have been shown to alter the permeability of the human skin to sodium and potassium ions and to cause enhanced percutaneous absorption. Allergic and contact dermatitis caused by "quats" have been reported in several reports.

Neurotic ulceration has occurred where detergent creams containing "quats" have been applied to moist areas of the skin of the genitals and buttocks under occlusion.

A number of published articles that deal with the toxicity of the specific "quats" have been reviewed. References to sensitivity and contact dermatitis produced with "quats" have been reported.

One aspect of the result of the use of "quats" deals with both effectiveness and safety. Over the years since their introduction, the variety and frequency of their use have increased. Several reports indicate systemic side effects when "quats" are used, but, the "quats" are not generally recognized as safe or effective in vivo studies must be conducted to show the antimicrobial effectiveness of "quats" in vivo. There are few reports on the in vivo or in vivo susceptibility of pathogenic fungi or prototax to "quats."

Various reports show that the application of "quats" to the skin reduces both the bacterial count on hands and in the axilla with a reduction of Staphylococcus aureus by 50 to 75 percent. The mechanism of action on the microbial cell is very likely the disruption of the cell wall and precipitation of bacterial proteins.

Because phenols have a high oil/water partition coefficient (tendency for phenol to remain in the oil phase), the antimicrobial activity may be lost in the presence of excess oil or fats. Since many phenol products are formulated as ointments or creams, in vivo studies must be conducted to show the antimicrobial effectiveness of phenol in these formulations. In addition, many of the reported effectiveness tests for phenol published in the literature and/or submitted to the OTC Panel were carried out before the development of use of neutralizers in antiseptic testing.

Phenol is a classic example of a chemical which is metabolized and eliminated from the body by glucuronide conjugation. However, the liver may be deficient in young animals and human infants. The Commissioner finds that adequate data concerning elimination and toxicity should also be determined.

Therefore, the Commissioner recommends that unless such studies as described above are conducted within 1 year following publication of the final monograph in the Federal Register this ingredient should not be used on infants. The label for the preparation containing the ingredient would need to state: "Not to be used on infants under 6 months of age."

The Commissioner notes that the Panel reviewed a published report that does of
The label for a preparation containing the ingredient would need to state: "Not to be used on infants under 6 months of age.

PCMX is a halogen substituted phenol compound. Many of the comments made for the effectiveness testing of phenol apply here. Halogenation increases the antimicrobial activity of phenol derivatives. The halogen in the para-position to the hydroxy group is considered the most effective substituent. This indicates that this compound would show good in vitro activity. Very little information about its in vivo activity on the skin is published or was submitted to FDA for review. At least one report, using a serial washing technique, indicated only a slight effect on resident bacterial flora of the skin. Another study reported approximately a 70 percent reduction in microbial count of the flora of the hands after 10 days of use.

PCMX is primarily active against gram-positive organisms with activity against gram-negative microorganisms in vitro. Fungicidal activity in vitro is also reported. The phenol coefficient is reported to be around 40, but the results are contradictory.

Claims for broad spectrum activity have been made for this compound; however, the Commissioner finds that inadequate effectiveness data were submitted. Many studies were old and not performed with modern antiseptic testing procedures. The Commissioner concludes that effectiveness testing both in vitro and in vivo should be done in accordance with the Guidelines elsewhere in this document.

Only the most superficial toxicity data in animals were submitted and reviewed by the Panel. The Commissioner concurs with the Panel that toxicity in rodent and nonrodent species, substantivity, blood levels, distribution and metabolism as well as any significant systemic absorption studies must be characterized before this ingredient can be considered for placement in Category I. Although additional data were submitted after publication of the Panel's report, the Commissioner has reviewed these data and finds that they are not sufficient to permit classification of PCMX in Category I. The additional material consists of routine toxicity tests and some in vivo testing. The techniques used and the level of sophistication displayed do not meet the Guidelines discussed elsewhere in this document.

The degree of absorption of PCMX following topical administration has not been established. The target organ for PCMX toxicity in animals also remains unidentified and should be shown in a long-term animal toxicity study. Therefore, the Commissioner concludes that additional data concerning absorption should be conducted within 2 years following publication of the final monograph in the Federal Register. PCMX should not be used on infants until these studies have been completed and evaluated.

The toxicity of phenol has been extensively described. The major lack of data is in vivo efficacy studies with concentration at 1.5 percent or less. In vivo studies performed with testing skin and sampling procedures, including the use of neutralizers, are required.

Because of the reports of local and systemic toxicity after the use of phenol-containing products covered with bandages or dressings, the use of phenol is restricted to small areas over large areas of the body, or coverings. The Commissioner will carefully review the results of the NCI study and will determine at that time whether any regulatory action is appropriate. The Commissioner concludes that, since no evidence of tumor or malignant toxicity was presented to and reviewed by the Panel, and since there are no reports in the many years of experience with phenol suggesting a teratogenic potential, mutagenicity and teratogenicity studies are not required.

The Commissioner concludes that the total concentration of phenol in powders and in aqueous, alcoholic, or oil formulations be restricted to less than 1.5 percent. When camphor is used with phenol in an oil formulation, the concentration of phenol should be no more than 5 percent. Chemicals with phenol activity, such as sodium phenolate and secondary-amylcresols, should be considered as phenol in the calculation of the total phenol in any formulation. The amount of phenol available as an antimicrobial will, of course, depend upon the particular formulation and the amount of phenol in a free state. The Commissioner further concludes that phenol may be used as an inactive ingredient for its aromatic characteristics in formulations, but at a concentration of less than 0.5 percent of phenol in a free state.

It seems apparent that even with phenol's long history of use, the Commissioner must now recognize that the levels at which phenol in aqueous and alcoholic formulations is effective topically are also the levels at which topical and systemic toxicity may occur, even though severity of toxicity is dependent on concentration. The fact that these two elements converge has made it necessary for the Commissioner to limit the concentration which may be marketed testing safety and effectiveness to less than 1.5 percent. Because the Commissioner is aware of rather severe toxicity with the use of phenol in animals at concentrations greater than 1.5 percent are not generally recognized as safe. (See discussion of phenol greater than 1.5 percent.) Even though the toxicity severity at these concentrations is similar, the severity is dependent on the concentration. It is the Commissioner's view that the demonstration of effectiveness at 1.5 percent or less may be exceedingly difficult but that the use of this concentration does not present a known hazard to the consumer. The toxicity of phenol has been extensively described. The major lack of data is in vivo efficacy studies with concentration at 1.5 percent or less. In vivo studies performed with testing skin and sampling procedures, including the use of neutralizers, are required.
Commissioner disagrees with the Panel that carcinogenicity, mutagenicity, or teratogenicity studies must be completed. He, as well as her, concludes that in the absence of any data suggesting PCMX has any carcinogenic, mutagenic, or teratogenic potential, testing for these properties should not be required.

2. HEXYLSORCINOL

The Commissioner has reviewed the Panel's report on other data regarding the safety and effectiveness of hexylresorcinol and has determined that though this ingredient is safe, it has insufficient information regarding its effectiveness to place it in Category I. Hexylresorcinol has a history of use as an oral antihelminthic in humans. In these cases the dose used in children has been 600 to 800 mg and in adults 1,000 mg, without systemic toxicity. However, irritation and ulceration of the oral and gastrointestinal mucosa have been reported from these high doses. The effectiveness data submitted as summaries indicate a low order of toxicity.

During its long history of use, there have been few reports of dermatitis following topical applications of hexylresorcinol and has determined that the skin and of irritation of the oral mucosa from the use of cough drops and toothpaste containing hexylresorcinol. The Commissioner concludes that hexylresorcinol does not present a known hazard to the general public from use as a topical preparation.

Data have been submitted demonstrating in vitro effectiveness using techniques available some years ago. Neutralizers for antiseptic testing were not in general use at the time these studies were performed and their use was often ignored. Nevertheless, that effectiveness data looked very promising.

The Commissioner has reviewed reports of the oral administration of hexylresorcinol by animals without accompanying data and has concluded that topical application of hexylresorcinol does not cause any adverse effects. The absorption that might occur at high levels is safe. The area in which data are lacking concerns the in vivo and in vitro effectiveness of the ingredient and of formulations containing it. Appropriate effectiveness data for the different product classes must be generated using testing procedures and skin-sampling techniques, including the use of neutralizers as set forth in the testing guidelines.

3. TRIPLE DYE

The Commissioner has reviewed the safety and effectiveness of the combination of antibacterial dyes (crystal violet, 2.29 gm, brilliant green, 2.23 gm, and proflavine hemisulfate, 1.14 gm and sufficient water to make 1,000 ml) known as triple dye for the treatment of the umbilicus prior to the availability of hexachlorophene. He concludes that the evidence indicates that a single application of triple dye to the umbilicus is effective in the prevention of staphylococcal colonization in infants in the hospital nursery. However, additional safety data, including the degree of parenteral absorption in man, must be considered in the evaluation of hexachlorophene and must be considered in further tests of effectiveness.

It is the opinion of the Commissioner that the data reviewed were not sufficient to permit final classification of triple dye.

The application of triple dye to the umbilicus is a potential replacement for hexachlorophene and other products in the market to reduce staphylococcal colonization. Further data on the absorption and possible carcinogenicity of the dyes should be generated before the triple dye is placed in Category I for this limited indication.

E. COMBINATION ANTIMICROBIAL PRODUCTS

The Commissioner has reviewed data on antimicrobial bar soaps containing a combination of active ingredients. One of these, containing triclocarban and clobacarban, is classified in Category III. The other, containing triobramosalan and triclocarban, is placed in Category II. No information on the safety and effectiveness of other combinations of ingredients was received. Therefore, for lack of data, they are not generally recognized as safe or effective. Conditions possibly exist where the benefit-to-risk ratio is such that their use may be valuable. If not necessary, combination antimicrobial agents should not be available for over-the-counter use until sufficient safety and effectiveness data are submitted. In addition, information data on this combination containing quaternary ammonium compounds, was submitted during the comment period. Data contained in the submission were sufficient to show that the combination does not pose a health risk of any kind, but insufficient to show whether the individual ingredients or the combination is generally recognized as safe and effective. Accordingly, that combination is placed in Category III.

For all combinations the level of each antimicrobial ingredient in the combination must make a contribution to the claimed effect for the product. The total amount of individual antimicrobial ingredients in the combination should result in an effect that is at least equal to that achieved when any one of the individual ingredients is used alone at the same total concentration without significantly reducing safety. In some instances the Commissioner has established maximum dose levels of an antimicrobial when used alone. If such antimicrobials are placed in combinations, no individual antimicrobial in the combination may exceed the dose level approved by the Commissioner.

The Commissioner believes that antimicrobial agents are somewhat different from combinations of other OTC ingredients. They act, not on the microorganism, rather than the host. In combinations of nonantimicrobial ingredients, the advantage of the combination may be that therapeutic effects of the individual ingredients may be enhanced or synergistic effects. There can be no contribution to effectiveness of an antimicrobial ingredient by combining it with antimicrobial ingredients having identical bactericidal, virucidal, and fungicidal properties. Consequently, the Commissioner concludes that a rational combination of antimicrobials should have one of the following purposes: expansion of the microbial spectrum relevant to the product class for which the combination is intended, reduction of the toxicity of one of the ingredients, or detoxification or synergistic effect of the combinaison.

Furthermore, when two or more ingredients are combined as antimicrobial ingredients, toxicity data must be available to show that the metabolism, excretion, or target organ toxicity are not enhanced or synergistically affected by the combination. For example, through the metabolism or excretion of one of the ingredients, when two or more antimicrobial ingredients are combined for the other product class, data must be available to show no decrease in safety.

IV. FINAL TESTING GUIDELINES FOR SAFETY AND EFFECTIVENESS OF OTC TOPEICAL ANTIMICROBIALS

A. INTRODUCTION

As noted above, the Commissioner adopts the findings of the Panel for Category III testing guidelines by restating them in this document. However, these guidelines have been extensively modified to incorporate new data, new testing approaches, and to reflect the needs of the agency in determining general recognition. The findings have also been modified for clarity, regulatory accuracy, and to delete gratuitous or unimportant statements. In some instances, the Commissioner's agreement with comments that suggested modification of the Panel's findings are reflected in the Commissioner's version of this section.

Important substantive modifications made by the Commissioner are: 1. Addition of the safety factor calculations discussion contained in the Panel report (39 FR 33112); 2. Modification of the topical safety discussion in section A.1 (39 FR 33153), relating to the effect of an antimicrobial ingredient on shifts in the body's normal microbiological flora, to result in evident pathological changes; 3. Modification of the systemic safety discussion in section A.2 (39 FR 33153) to: a. delete the requirement of development of chemical analysis and/or bioassay techniques for detection of the chemical or its metabolites in biological tissues and secretions;
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b. Require determination of blood levels reaching plateau and other long-term pharmacologic effects; and

c. Delete the requirement of determining metabolic fate of an ingredient as it is metabolized in the body. Such a requirement is not needed to ensure adequate and well recognized scope of testing guidelines for general recognition of safety and effectiveness.

4. Modification of the in vitro effectiveness testing requirements in section B.1 (23 FR 33116) to: Accept the concept that reduction of normal microbial flora, both resident and transient, is beneficial,

b. Set limits of microbial flora reduction needed before certain claims can be made, e.g., 1 log. reduction for antimicrobial soap effectiveness; and

c. Set forth those organisms upon which these antimicrobials must be tested.

5. Modification of the in vivo effectiveness testing requirements in section B.2 (23 FR 33116) a. Require a determination of the minimum concentrations of active ingredients required to produce the claimed effect for particular product classes; and

b. Delete the Quinn Handwashing Test for antimicrobial soap effectiveness.

6. Set forth several additional testing protocols including: a. Animal and human tests for determining delay in wound healing for “first-aid” product classes;

b. A test for demonstration of the ability of a skin wound protectant to act as a barrier against further contamination with microorganisms; and

c. A test for determining that a skin wound protectant does not favor growth of microorganisms.

7. Inclusion of U.S.P. and CTPA tests, with modifications, for determination of the effectiveness of antimicrobial ingredients as preservatives.

The Commissioner considers these testing guidelines to be final, subject to modification upon a properly supported request. These guidelines, and future modifications, will be published in the Federal Register. However, notification of amendments to the guidelines will appear as a notice in the Federal Register pursuant to § 10.50 (b) (5) of the agency’s regulations on Administrative practice and Procedures (21 CFR 10.50(b) (5), formerly § 2.20(b) (5) prior to recodification published in the Federal Register of March 22, 1977 (42 FR 15691).

After review of the data submitted for antimicrobial ingredients in soaps, surgical scrubs, skin washes, skin cleansers, and first-aid products submitted to and considered by the Panel, the Commissioner has developed the following guidelines for safety and effectiveness studies. These guidelines, which must satisfy the requirements for adequate and well-controlled studies as specified in 21 CFR 314.111(a) (5) (11), may be followed to develop data for specific ingredients where the information does not currently exist.

The Commissioner recognizes that antimicrobial use ranges from total body exposure to application on small areas of the body. Such use may extend from a single application, intermittent and occasional application. The Commissioner also recognizes that the list of products may include solids, liquids, creams, powders, and aerosols formulated with chemical excipients. Those manufacturers or distributors who desire to move Category III ingredients or combinations into Category I should select from the guidelines those tests appropriate for their type of product and its intended use. They should be prepared to explain and justify their test selections. Test data submissions will not be required beyond those which the Commissioner has stated are required in the Category III discussion above. For example, the Commissioner will not require long-term toxicity studies. The product classes may be divided into the short-term or single-use variety, such as the “first-aid” product classes.

The Commissioner recognizes that there may be honest disagreement among scientists about the most appropriate design of a protocol for a test to provide data on which a final determination of general recognition of safety and effectiveness can reasonably be made. The Commissioner also recognizes that some of the studies are in areas or require procedures for which precedents are not common and for which agency guidance is necessary. In these areas, conferences with expert consultants and representatives of the Food and Drug Administration are recommended and requests for modification of these guidelines will be considered. Such requests should be submitted to the agency. All such submissions shall be mailed or delivered in person to the office of the Hearing Clerk (HFC-20), formerly § 20857. The Hearing Clerk recognizes that the list of ingredients contained in the table is not all-inclusive, and that the table may be changed at any time to reflect new information or changes in the circumstances under which the ingredients are used. However, he will not restate the methods for calculating such factors, only the methods for calculating such factors.

Calculations were made from data presented for various ingredients. Toxological studies, where applicable, show the assumptions made, and intended to explain the method. They are as follows:

1. Safety—Tests below should be performed on suitable animals and then on humans when applicable. They should be done in a suitable manner when applicable, appropriate, and ethically feasible.

The following tests should be performed for all product classes, except skin wound cleansers without antimicrobials, unless otherwise specified. Use the active ingredient alone and in the final complete formulation to judge the effect of vehicle in the release of active ingredients.

a. Safety factor calculations. The Commissioner concludes that a minimum of a 100-fold safety factor should apply to the exposure dose for ingredients labeled for repeated daily use. At present this is applied to antimicrobial soaps, health-care personnel handwashes, and surgical hand scrubs. The Commissioner has reviewed the Panel’s discussion of safety factors for topically applied antimicrobial agents (29 FR 33112–33114). He fully concurs with the conclusions reached by the Panel and adopts them as part of the testing guidelines. However, he will not restate the entire discussion on safety factors, only the methods for calculating such factors.

Calculations were made from data presented for various ingredients. Toxological studies, where applicable, are shown in the table. The following test results show the assumptions made, and show the method for calculating such factors.

(1) Expected no-effect dose level in man: Determine the lowest toxic effect and the highest no-effect dose in mg/kg topically applied in an animal species. If an effect cannot be determined in a topically applied application, the oral route of administration should be used. Take the highest no-effect dose in that animal species and calculate the absolute dose. From the absolute dose the multiplication factor is made for the specific animal used in the test and this, then, is the dose level at which no-effect might also be expected in man.

(2) Expected blood level from product use in man: Assume a bar soap with 3 percent active antimicrobial is used for one bath per day. Assume that 7 gm of soap are used in one bath. This would give an exposure of 0.21 mg, or 210 mg per bath of active ingredient. Assume retention of all 210 mg active ingredient on the skin (there is very little skin data presently available on the amount of antimicrobial retained after exposure). If 3 percent of the applied active ingredient is absorbed into the blood stream, the dose per bath would be:

\[ 0.03 \times 210.0 \text{ mg} = 6.30 \text{ mg/mg} \]

If the assumption is made that the total dose is immediately absorbed, the dose distributed in the blood of a 70 kg human would be:

\[ 6.30 \text{ mg} \times \frac{5,000 \text{ ml blood}}{70 \text{ kg human}} = 0.12 \text{ mg active ingredient per ml of blood.} \]
The assumption is made here that the amount of chemical presented to the individual in a single bath is all retained on the skin and absorbed and distributed in the blood, giving a blood level of 1.25 mcg/ml.

As a further example, assuming retention of 0.5 mcg of active ingredient per sq cm of skin and that the product is to be used over the entire skin area, (as a bar of soap, the total dose retained would be 9.25 mg over the entire body. The calculation would be 0.5 mcg per sq cm X 19,500 sq cm of skin (based on a 70 kg, 5'10" human). Assuming, for this case, a 10 percent absorption:

9.25 mg X 0.10 = 0.93 mg dose per bath

If the assumption is also made that the total dose is immediately absorbed, the dose distributed in the blood of a 70 kg human would be:

0.93 mg
5000 ml blood/70 kg human
= 0.0186 mg/ml

Safety factors were calculated using the available evidence. For the calculations, the individual ingredient statements.

These two hypothetical calculations using known facts with stated assumptions are examples of the type of safety factor calculations considered by the Commissioner. In this calculation, the information required is the retention of the chemical by the skin after exposure. The missing information here is the absorption-excretion kinetics for that chemical.

A direct comparison can be made, and thus a safety factor can be estimated, by a comparison of the calculated human blood level with the blood level in animals, if known. A comparison of the dose where there is no effect in animals translated to the dose in which no effect may be expected in humans against the hypothetical dose to which a person is exposed from the use of a product containing the ingredient can be made if blood level data are not available.

It must be stressed again that the best calculations and judgments are made when all of the pertinent data are available and frequent assumptions do not have to be made. The variety of calculations presented to the Panel and then to the Commissioner are based on assumptions because the data are not available. Subsequent to the publication of the Panel report data were received on the absorption of a radioactively labeled triclocarban soap formulation applied in a shower (see paragraph 74 above). These data were remarkably close to the hypothetical calculations of the Panel.

If the safety factor is extrapolated from an animal species to man, considering surface area, the highest no-effect dose should be used for the multiplier. In the absence of complete data, a 100-fold safety factor should be applied when translating the animal highest no-effect dose to man.

The ideal situation would occur where enough animal data have been collected to construct a dose response curve with concurrent blood levels so that analysis for threshold effect and safe level estimation for the animal can be made. Threshold effect and safe level (1) Primary irritation potential following acute and subacute exposure. Special attention is devoted to eyes, mucous membranes, and general systemic effects. (2) Allergic contact dermatitis potential following acute and subacute exposure, (3) Photosensitivity potential. This involves photosensitization and phototoxic reactions. (4) The age group would be males over 40 since the reported incidence of photosensitivity is highest in this group, (5) Effect on wound healing (only for skin antiseptic, skin wound protectant, and patient preoperative skin preparation), (6) Effect on skin pigmentation. (This observation may take days to weeks to be evident with photopatch testing to determine photosensitivity potential.), (7) Effect on total skin flora to ensure no detrimental overgrowth of a particular bacterial or fungal species that results in evident pathology. (8) Substantivity, accumulation, or persistence in or on the skin, although storage classes are single usage, very short-term use type products, e.g., patient preoperative skin preparation, this requirement for all product classes will help to assure safety for more long-term absorptive use, e.g., daily use of a patient preoperative skin preparation for a long period.

c. Systemic. Determine: (1) Degree of absorption (and subsequent blood level) through intact and abraded (damaged, diseased) skin and mucous membrane after single and multiple exposures. Testing to determine plateauing of blood levels and other pharmacologic effects of the ingredient may be appropriate. (2) Route of absorption (and subsequent blood level). Testing to determine potential absorption (and subsequent blood level) of the chemical(s) alone and in its final formulation using both standard procedures that exist previously have been defined, there has been a need to develop adequate testing procedures in some of these new areas, particularly in vivo procedures. These guidelines that follow are designed as an outline of procedures that the Commissioner believes will characterize the effectiveness of an antimicrobial ingredient for each of these product categories.

a. In vitro testing. The following tests should be performed for all product classes (except skin wound cleansers without antimicrobial ingredients) unless otherwise specified.

(1) Determine the antimicrobial spectrum of the chemical(s) alone and in its final formulation using both standard cultures and recently isolated strains of each species. Cultures representing normal skin flora and skin pathogens should be selected as set forth above.

Develop techniques for adequate neutralization of the active ingredient, before testing its antimicrobial spectrum. Ensure that the neutralizer is not toxic to the test organisms.

The following outline has been prepared to serve as a basic guide for the in vitro characterization of the activity of an antimicrobial ingredient:

(2) Determine the minimal inhibitory concentration (MIC) under standard conditions against standard organisms with known phenol resistance and susceptibilities to other antimicrobial chemicals.

A series of recently isolated mesophlic strains, including members of the normal flora and cutaneous pathogens (100 isolates), should be selected. The list of organisms to be tested are those considered to exist in the "normal environment" (organisms likely to be found in a minor wound). The Commissioner requires that they be used in testing unless data can be provided to the contrary. Other organisms are equally representative of those found in the "normal environment." There must be no claims, either direct or by implication, that a product...
has any activity against an organism, or that it reduces the number of organisms, for which it has not been tested.

The Commissioner notes that, if there is some reasonable scientific indication that the activity of an ingredient will affect flora, and thereby causes a rise in the fungus or virus level that might result in greater harm, then further testing will be required.

Representatives of the following groups should be included (note: special media and/or environmental conditions may be required):

(i) Staphylococci-5 groups.
(ii) Micrococci.
(iii) Pyrogenic Streptococci (Groups A, C, and D should be included).
(iv) Diphtheroids-Lipophilic, Anaerobes (Propionibacterium).
(v) Gram-negative enteric bacilli.
   (a) Escherichia, Enterobacter, Klebsiella, Proteus, and Serratia.
(vi) Pseudomonas aeruginosa and Pseudomonas aeruginosa species.
(vii) Yeast—Candida albicans, Candida parapsilosis.

(3) Determine possible development of resistance to the chemical. Sublethal concentrations of the active ingredient(s) can be incorporated into the culture medium for an extended series of exposures. Use standard methods to determine the emergence of resistance.

(4) Data substantiating antimicrobial action by standard procedures, such as the Sykes-Kelsey procedure, phenol coefficient, or others where applicable, should be provided. It would be advisable to include in the in vitro test a chemical(s) with recognized antimicrobial activity, for purposes of comparison.

b. In vivo. (1) The following tests, approximating use conditions for the clinical evaluation of each label claim, should be carried out for the product classes specified:

(i) For all product classes, a determination should be made of the quantitative and qualitative estimation of reduction of the skin flora, both transient and resident through the skin-stripping or cup-scrubbing techniques (discussed below in the specific protocols). All product classes should include not only alteration in total numbers of microorganisms, but qualitative changes (such as dominance of a different type or change in antimicrobial resistance) in the residual cutaneous populations. For antimicrobial soaps only, sampling should be carried out on microbial communities in several different areas of the body, such as axilla, groin, feet and hands, showing of a 0.5 log reduction of skin flora or a significant inhibition of microbial species shown to be responsible for odor production.

(ii) Glove juice procedure (surgical hand scrubs only).

(iii) Antimicrobial soap effectiveness (odor reduction)—Cup handwashing test (antimicrobial soap only).

(iv) Handwashing effectiveness preliminary contamination (health-care personnel handwash only).

(v) Preoperative skin preparation effectiveness (patient preoperative skin preparation only).

(vi) Procedure for determining delay in wound healing (skin wound cleaner, skin wound protectant, skin antisepsic, patient preoperative skin preparation only).

(vii) Absence of contamination in wound (skin wound protectants only) would require testing to show no microorganisms except "normal flora" and no significant increase in microorganisms.

(2) Data substantiating antimicrobial action in vivo. (a) Escherichia; Enterobacter, Klebsiella, Proteus, and Serratia. (b) Pseudomonas aeruginosa and Pseudomonas aeruginosa species. (c) Yeast—Candida albicans, Candida parapsilosis.

(3) Filamentous Dermatophytes species. (Required only for health-care personnel handwash, surgical hand scrub, skin wound cleaner, skin wound protectant, and skin antisepsic.)

A. QUALITATIVE AND QUANTITATIVE ESTIMATION OF SKIN FLORA.

1. Skin stripping technique. Of the techniques which have been developed, a reliable procedure for the determination of qualitative changes in the microbial skin flora consists of skin stripping of skin microorganisms using cellophane tape. The skin can be stripped in consecutive layers, followed by culturing and identification of organisms removed by consecutive stripplings. This method can be used to remove layers of epidermal cells to expose the glistening dermal cells to exposure. The skin can be stripped in consecutive layers, followed by culturing and identification of organisms removed by consecutive stripplings. This method can be used to remove layers of epidermal cells to expose the glistening dermal cells for creation of a "standard" wound for testing effectiveness of "first-aid" product classes. (4)

2. Cup scrubbing technique. Cup-scrubbing techniques utilize a scrubbing solution placed in a cup that is used to remove layers of epidermal cells to expose the glistening dermal cells for creation of a "standard" wound for testing effectiveness of "first-aid" product classes.

3. Glove juice procedure (surgical hand scrubs only).

The Commissioner concludes that the following test must be performed to support the effectiveness of a product labeled as a surgical hand scrub:


b. Adults.

Subject will vary greatly in the number of microorganisms carried on the hands.

Subjects with a high hand count as measured by sampling with the glove juice procedure should be used for the test. Counts should be in the range from 1.5 X 10^7 to 5 X 10^7 per hand.

d. Medication. Subjects receiving antibiotics or taking oral contraceptives should be excluded from the test.

e. Thirty subjects per test.

2. Pretest period (2 weeks). The subjects for this test should not use any products containing antimicrobials for at least 2 weeks prior to the test. This restriction includes antimicrobial anti-perspirants and deodorants, antiperspirants, soaps, or powders. Subjects receiving antibiotic therapy or taking oral contraceptives should be dis-qualified.

Subjects should be issued rubber gloves to be worn during their daily routine when they come in contact with detergents, acids, bases, or solvents.

3. Gloves for test. Gloves should be washed with sterile distilled water before use, and they should be used as wet. Gloves that are prepowdered should be carefully washed free of powder, as many of these powders contain antimicrobials.

4. Baseline period and sampling. The baseline period should be 1 week following the 2 weeks of the pretest period. The baseline count should begin on day one of the baseline period. The initial count is a screen to determine eligibility. The day-one count is also one count to be included for the mean baseline count. The counting procedure should be performed on day seven and also on either day three or five for a total of three estimations of the baseline count.

The baseline counts should be performed using exactly the same sampling and recovery techniques used for the test products under the testing procedure. This information will be needed to provide evidence to assess the assumption that the right and left hand gave comparable results.
Both hands should be sampled for the baseline count. Subjects should not wash their hands for a minimum of 24 hours prior to the start of the test and for the duration of the test day. This should not be construed as a 24-hour pretest ban on washing. If the test is to be run in the morning, subjects should not wash after rising and must not wash the hands again following the control handwashing test.

Baseline procedure is as follows:

- Hands and % of the forearm are washed for 30 seconds with Camay soap and sterile distilled water if the hands are dry. This was conducted for 3 to 6 hours. The excess water is shaken from the hands and the gloves are donned with the hands wet. Sampling solution (Sampling Solution: Triton X-100—0.1 percent in 0.075 molar phosphate buffer at a pH of 7.9) is added to the gloves (volume of sampling solution should remain constant for all tests). The glove is held closed at the wrist by the subject while an attendant massages the hand for 1 minute. A measured volume is withdrawn for the count.

5. **Scrubbing procedure.** The scrubbing procedure is performed as directed on the label of the product being tested, including the use of nail cleaner and/or a brush, if indicated. The hand and % of the forearm are washed, and the glove is donned immediately. Immediately, the designated control hand is sampled for the 1-minute count as follows: Sampling solution containing 1% camazine is added to the glove, the hand is massaged for 1 minute, and a measured sample removed for plating. The volume of the sampling solution added to the glove should be kept constant for all tests. The fluid should be shaken vigorously prior to dilution or culturing. If diluent is used, neutralizer should be added to dilution blanks.

6. **Sampling technique and times.** After the scrub is performed, loose-fitting surgeon's or examining gloves are donned. Leave the hands wet by shaking off excess water when the gloves are donned. Immediately, the designated control hand is sampled for the 1-minute count as follows: Sampling solution containing 1% camazine is added to the glove, the hand is massaged for 1 minute, and a measured sample removed for plating. The volume of the sampling solution added to the glove should be kept constant for all tests. The fluid should be shaken vigorously prior to dilution or culturing. If diluent is used, neutralizer should be added to dilution blanks.

The glove is to remain on the other hand for the duration of the time of the test. It is suggested that at least 1, 2, 3, 4, and 6 hours post scrub should be tested.

The times for which a glove remains on one of the hands after scrub should be allocated by random selection among the subjects in groups of five. This procedure is performed on day one and day two of the test period. The procedure should be repeated on day five after scrubbing with the product according to directions two additional times on day two and three times per day on day three and day four at 1-hour intervals. One scrub should be performed on day five and the gloves allowed to remain on the left hand for 1, 2, 3, 4, 5, or 6 hours.

The number of subjects used for the test should be 30, with randomization into six groups (n=5 per group) corresponding to 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, and 6 hours. The allocation of subjects to groups remains constant after initial randomization.

7. **Recovery media.** A medium containing a neutralizer specific for the antimicrobial agents being tested could be used. Media that have been used in the past include: Lethen and Trypticase Soy Agar with Tween 80 and serum or lactulum added.

The neutralizing system used for antimicrobial agents should be tested, and the data from the tests submitted, to show that the system is adequate. The neutralizer should not be toxic to cells or affect the ability to neutralize the specific chemical.

The cultures should be incubated at 30°–32° C for 48 to 72 hours. If culturing is continued for longer than 14 hours, the culture of anaerobes, is undertaken, appropriate culturing procedures should be instituted. Duplicate plates have been routinely used for plating in the past. Because of the inherent variability in counts and the presence of clumps of cells from skin sampling, at least triplicate plating should be used. A larger number may be required, depending on the variability. The counts should be reported as count per hand.

There are variations of this procedure in use. For instance, instead of sampling the count, the glove is removed, turned inside out into strippling fluid, and the hand rinsed with sampling solution as well. The sampling solution should be used for the glove (monobasic) 0.4 g, sodium phosphate (dibasic) 10.1 g, triton X-100 1.8 g, and enough distilled water to make 1 liter. (Final pH=7.8). If variations of this test are to be used, the protocol should be checked with Food and Drug Administration personnel first.

8. **Data handling, design, and statistical aspects.** It is assumed that there are no right versus left hand differences in microbial counts. It is known that microbial handedness (a difference in count of the right hand compared to left hand baseline) is a covariant. Tests of trends using the orthogonal procedures should be employed.

The analyses should be performed first on each replication. There is replication of the entire test on day two and on day five after three consecutive washes at hourly intervals on day three, day four, and day five. Use the original group assignments of subjects observed for the test periods as determined by random allocation.

Tests of trends may be done using either an orthogonal procedure or some suitable regression method. A combined analysis using the results of the three replications is possible using an appropriate analysis of variance technique. For example, an analysis of variance on the total set of experimental results using the model described on page 519 of Statistical Principles in Experimental Design (J. J. Winer, McGraw-Hill Book Co., 1961) where hours correspond to factor A and replications are tests and factor B. Baseline could be introduced as a covariant. Tests of trends using the orthogonal procedures should be employed.

The comments on the use of multiple plates in the culturing procedures and on the evaluation of specific neutralizers for use in the testing of antimicrobial agents apply to all in vivo testing.

C. **TEST FOR ANTIMICROBIAL SOAP EFFECTIVENESS.**

The following test will be used to determine the antibacterial effectiveness of ingredients with claims for antimicrobial soaps:

1. **Modified Cade procedure.** The Cade handwashing test was developed to standardize exposure to a given test product, usually an antimicrobial soap. The hands were washed standardized in Cade's original publication. The techniques for sampling and recovery of microbial flora have been refined over the time since the original publication. Some of these refinements are incorporated in the following discussion of the Cade test.

2. **The data that can be derived from a Cade handwashing test are greatly expanded if a baseline is established prior to the controlled washing with the test antimicrobial soap.** The analyses can be expanded to give reductions from a baseline with samples from the first basin, with subsequent basins combined using from subsequent basins.

3. **Some adaptations of the test employ a technique for this study, which in-"
volves utilizing the numbers of microorganisms determined in the first basin test as a representation of the level of the transient flora. They also utilize the fourth and fifth basin to average what is considered the reduction of the resident flora achieved by the repeated handwashings. Any protocol with significantly altered procedures should be checked with FDA personnel.

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**Data Analysis.** Much data derived from this study have been analysed with appropriate procedures to determine if a significant reduction has occurred after known exposure to the test soap. A more desirable procedure is to employ a null hypothesis that a given reduction, i.e., a 1-log, or 2-log reduction, has taken place and to then test that hypothesis. Determination of a statistically significant reduction is also done with the microbial count as a naive approach since significance can be achieved with a small reduction. Therefore the approach described above should be used.

**D. TEST FOR HEALTH CARE PERSONNEL HANDWASHING EFFICACY.**

Since the result expected from the use of this type of product is the reduction of the transient flora acquired as a result of patient care or as a part of hospital routine, the testing should involve the artificial contamination of the hands and forearms. This procedure can be executed by dipping the hands into a liquid culture with at least 10⁶ organisms per ml and/or known aliquot of the inoculum on the hands allowing 1 minute before proceeding. The artificial contamination of the hands may also be produced by handling heavily contaminated materials to simulate actual practice.

The product under test should be used according to the directions on the label. Since these products are designed to be used with multiple replication, the effectiveness testing procedure of hand contamination and washing followed by evaluation of the count of the contaminating organisms should be done at least 25 times in succession. A minimum of 5 minutes should be allowed between repetitions. Evaluation of the count on the hands can be done approximately every 5 washes. The millipore filter sampling of fluid as an alternative to plating.

**E. EFFECTIVENESS OF A SKIN WOUND CLEANSER.**

Inherent in the definition is a demonstration of the product's ability to assist in the cleansing and removal of foreign material while causing no delay in wound healing or infection.

The Commissioner recognizes that the testing of delay in wound healing, particularly in human subjects, is difficult. There is a need for the development of procedures to determine whether topical products applied to minor skin wounds would delay healing in human subjects. Until adequate human testing methods are available, data from animal models will be required to support safety of a product to be labeled as a skin wound cleanser.

1. **Animal test for delay in wound healing.** The Commissioner concludes that the following animal test will evaluate and compare the skin wound healing delay effects of skin wound cleansers or bar soap with and without antimicrobial activity, as well as for skin wound protectants and skin antiseptics.

   a. The subjects should consist of 12 young adult male New Zealand White rabbits. Both antimicrobial-treated and antimicrobial-untreated control animals should be used.

b. The back of the rabbit should be shaved or clipped so that approximately 20 percent of the total body surface area is shaved.
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wound) should be subject to one of the treatments. One ml of soap solution (45 percent) should be gently applied for 1 to 2 minutes daily for 14 consecutive days. These daily applications should be 6 hours apart. The applied material should be allowed to dry. After the initial application, each incision should be rinsed with tap water immediately prior to surgery. Wound dressings and gauze pads should be removed. The animals should wear collars throughout the study to prevent oral ingestion of test material.

d. To evaluate the test, the following parameters should be utilized: Body weight should be determined for each rabbit on days 0, 7, and 14; wound healing progress and general conditions should be observed and described daily. This is to be supplemented by color photographs; two animals each should be sacrificed on days 1, 3, 5, 7, 10, and 14 by air injection. Wound sections should be includated and compared microscopically.

2. Human test for assessment of wound repair by use of hygrometry. The Commissioner concludes that the following procedure yields valid and reliable data in the skin wound-healing delay effects of skin wound cleansers or bar soaps with and without antimicrobials, as well as those of skin wound protectants and skin antiseptics.

a. Insensible water loss. The reduction of insensible water loss that occurs during the healing of adhesive tape-stripped wounds has been widely reported in the literature. The insensible water loss that is measured is often referred to as transepidermal water loss (TWL). Because of the great difference in TWL values between damaged and intact skin (50- to 100-fold), the return to normal water loss can be easily measured. This nondestructive technique allows one to follow the repair process by measuring an important physiological skin function, the ability of the body to limit loss of water to its environment. The adhesive tape-stripped wound is fairly representative of mild abrasion-type wounds for which OTC "first-aid" products are recommended. It represents a high surface area wound involving only epidermal repair. The test is not a measure of physical or chemical trauma in an unaffected intact skin (50- to 100-fold).

b. Method. Strips of an industrial adhesive tape are placed on silicone release paper and cut to 1" x 1' segments for sequential stripping of the horny layer. A stripping tape is placed on the surface to be stripped and outlined at the corners with a ballpoint pen to define the area of the subject. The stripped area is then removed and repeatedly until a smooth, even, glistening surface is achieved. This usually requires 20 to 30 strips, but varies widely with the subjects used.

Adhesive tape-stripped wounds (1' x 1") are made on the upper backs of six volunteer subjects. Initial TWL values for the stripped areas are determined using an air flow hygrometry system as follows.

c. Airflow hygrometry system. The system essentially involves the passing of dehumidified air over a 4 sq cm area of skin surface. Inflowing commercially dried air is first promoted to maintain a constant flow, and then passed through a freeze trap at ~ 80° C. This process reduces the probability of the "dried" air containing traces of water. The air is then dried further with a cooler, a radiator, and a fan to bring it to room temperature. Before the air reaches the skin, its humidity is recorded. This value is calibrated to "zero." After the air leaves the skin surface area its humidity and temperature are again monitored. The change in water content of the air after passing over the skin is determined and is equal to the TWL value.

Further information on technology and evaluation of this test (Baker, H. and A. Kligman, "Measurement of Transepidermal Water Loss by Electrical Hygrometry," Archives of Dermatology, 98:441-452, 1967) is on file and available through the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-55, 5600 Fishers Lane, Rockville, Md.

d. Treatment of wounds. After initial TWL readings are taken, the wounds are treated with the various test materials. An untreated control wound is always included on each subject. The wounds are treated twice daily for 4 days. Transepidermal water loss readings are taken on all wounds on days 2 and 4 following wounding.

e. Evaluating the data. The transepidermal water loss values are converted to "percent damage" values according to the formula:

\[
\text{Percent damage} = \frac{y - x}{x} \times 100
\]

The "percent damage" figures are analyzed statistically to compare the healing rates of treated wounds with the untreated control wounds.

g. Effectiveness Testing Of A Skin Wound Protectant. The determination of the ability of a skin wound protectant to act as a barrier against further contamination with microorganisms. a. A skin wound protectant must act as a physical barrier. The testing of barrier materials can be done with a model system and fluorescent particle challenge to the system with subsequent detection of the challenge microparticles on the other side. The barrier is then challenged to a tube containing 9 mL of fluid. Aliquots from this tube and from serial dilutions made from it are plated in an appropriate agar culture medium.

Further information on evaluation of this test (Williamson, B. and A. M. Kligman, "A New Method for the Quantitative Investigation of Cutaneous Bacteria," Journal of Investigative Dermatology, 45:498-503, 1965) is on file and available through the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-55, 5600 Fishers Lane, Rockville, Md.

VI. Preservative Levels of Active Ingredients

The active antimicrobial ingredients reviewed by the Panel can be formulated in topical products at various concentrations. The minimal concentration required for effectiveness as an active ingredient will be established by in vitro and in vivo efficacy testing as will the range of concentrations that can be safely used. The Commissioner recog-
ROr procedure and stressing with an "organic, effectiveness test of the preservative concentration. The dilution recommended for use as distinguished from marketed concentrates.

Subpart B—Active Ingredients
§ 330.20 Antimicrobial soap. [Reserved]
§ 333.30 Patient preoperative skin preparation.

The active ingredient of the product consists of any of the following, within the maximum dosage limit established:
(a) Iodine tincture. This product is for use as a solution or tincture containing not less than 1.6 gm and not more than 2.2 gm of iodine (I) in each 100 ml of purified water U.S.P. or 44 to 50 percent ethyl alcohol (or an appropriate denatured alcohol).
(b) [Reserved]

§ 333.40 Skin wound cleanser.

The active ingredient of the product consists of any of the following, within the potency (or concentration) established:
(a) Quaternary ammonium-containing active ingredients. Topical dosage for use of quaternary ammonium compounds (as benzalkonium chloride, benzethonium chloride, and methylbenzethonium chloride) is limited to a use concentration not greater than 1/150 in water. All preservative systems, in any such product formulation shall be tested according to the procedure identified in § 333.65.
(b) Hexylresorcinol. Topical dosage is limited to a use concentration not greater than 1/1000.
(c) Poloxamer 188. Topical dosage for poloxamer 188 is limited to an aqueous solution of 20 to 40 percent use concentration. The solution shall contain not less than 85 percent nor more than 100 percent of the labeled amount of poloxamer 188. All preservative systems included in any such product formulation shall be tested according to the procedure identified in § 333.65.

§ 333.45 Skin wound protectant. [Reserved]
§ 333.50 Surgical hand scrub. [Reserved]

Subpart C—Testing Procedures
§ 333.65 Preservative testing.

(a) Determination of effective preservative concentration. All antimicrobial ingredients used singly or as part of a preservative system for use in a topical

three that many of these antimicrobial ingredients might also be added to products at much lower concentrations to prevent spoilage or growth of microorganisms, inadvertently added, introduced as a result of customer use. Many of the antimicrobials reviewed are primarily active against gram-positive microorganisms and would not generally be considered good candidates for use as preservatives. However, some of these may be considered for use of a preservative system.

Effectiveness levels for antimicrobials as preservatives can be determined by use of the antimicrobial preservatives effectiveness test of the USP (p. 587) with the addition of a rechallenge procedure and stressing with an "organic, load" or use of the Cosmetic Toiletry and Fragrance Association tests published in 1970, with the addition of specific organisms to be tested and interpretive criteria. The specifics of these additions to the USP and CTFA tests are set forth in § 333.65 below.

Such data do not have to be submitted to the agency, but must be available upon request for inspection.

The Commissioner has reviewed the potential environmental impact of the proposed regulation and has concluded that the proposal will not significantly affect the quality of the human environment and that an environmental impact statement is not required. The Commissioner has also considered the economic impact of the proposed regulation and no major economic impact has been found, as defined in Executive Order 11821 (as amended by Executive Order 11949) and OMB Circular A-107, and guidelines issued by the Department of Health, Education, and Welfare. Copies of the environmental impact analysis report (or statement of exemption) and environmental and economic impact assessments are on file with the Hearing Clerk, Food and Drug Administration.


Subpart A—General Provisions
§ 333.1 Scope.
An over-the-counter antimicrobial product in a form suitable for topical use is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in § 330.1 of this chapter.
§ 333.3 Definitions.
For topical preparations when applied at acceptable use concentrations as used in this part:
(a) Antimicrobial (active) ingredient. A compound or substance that kills microorganisms or prevents or inhibits their growth and reproduction and contributes to the claimed effects of the product in which it is included.
(b) Antimicrobial (inactive) ingredient. A compound or substance that kills microorganisms or prevents or inhibits their growth and reproduction and is included in a product formulation only at a concentration sufficient to prevent spoilage or prevent growth of inadvertently added microorganisms, but does not contribute to the claimed effects of the product in which it is included.
(c) Antimicrobial soap. A soap containing an active ingredient with both an irritant and in vitro activity against skin microorganisms.
(d) Health-care personnel handwash. A nonirritating antimicrobial-containing preparation designed for frequent use; it reduces the number of transient microorganisms on intact skin to an initial barrier level adequate for washing, rinsing, and drying; and it is broad-spectrum, fast-acting, and, if possible, persistent.
(e) Patient preoperative skin preparation. A fast-acting broad-spectrum antimicrobial-containing preparation that significantly reduces the number of microorganisms on intact skin.
(f) Skin antiseptic. A nonirritating, antimicrobial-containing preparation that prevents overt skin infection.
(g) Skin wound cleanser. A nonirritating, liquid preparation (or product to be used with water) that assists in the removal of foreign material from small superficial wounds, does not delay wound healing, and that may contain an antimicrobial ingredient.
product identified in § 333.3(c) through (i) shall be tested by the manufacturer to establish the minimal effective preservative concentration for every product formulation by one of the following two methods:

(1) Determine the minimal effective preservative concentration according to the procedures described in the United States Pharmacopeia (USP) XIX (page 687) (Preservatives effectiveness test) with the addition of a re-challenge procedure and stressing with "organic load." The preserved formulation should be tested by adding a challenge of cells (final concentration 1×10^10/milliliter) in the presence of the organic load described below. The microbrial challenge should be in contact with the preserved formulation containing the organic load for a period of 15 minutes before inoculation into the preserved formulation. Then the first sample can be taken immediately or 12 hours after inoculation. For the initial challenge, the rechallenge level should be 1×10^6 cells/milliliter. The test culture is incubated for the time specified in the USP test (3 weeks), and then the same tube is used with the rechallenge cells and again incubated for 2 weeks. The organic load consists of heat-killed yeast cells and inactivated horse or bovine serum. The yeast culture must be quantitated, then heated and the cells. Then 10^6 yeast cells (Saccharomyces cerevisiae) per milliliter of preserved formulation should be added as the final concentration load. The yeast cells should be added to horse or bovine serum (inactivated at 55° C for 30 minutes). Whole bovine serum should be used as the protein organic load. The results of the rechallenge test should be the same as those described in the USP test for the original challenge.

(2) The minimal effective preservative concentration of these ingredients may also be determined according to the procedures of the Cosmetic, Toiletry and Fragrance Association Preservative Test, with the addition of specific organisms to kill the particulate organic load. The yeast culture should be added to horse or bovine serum. The yeast culture must be quantitated and used in the rechallenge formulation should be added as a challenge to the test as well as the inoculated with the rechallenge cells. This test was published in the Toilet Goods Association, Cosmetic Journal, 2(1): 20-23, 1970, and is also available in the office of the Hearing Clerk (HFPC-20), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Use cultures of the following microorganisms: Candida albicans (ATCC No. 10231), Aspergillus niger (ATCC No. 18404), Escherichia coli (ATCC No. 8739), Pseudomonas aeruginosa (ATCC No. 9027), and Staphylococcus aureus (ATCC No. 6538). Mixed culture inoculation should not be used. Other microorganisms not listed, those listed, may be included in the test, particularly if it appears likely that such microorganisms may represent resistant contaminants likely to be ingested during manufacture or use of the article or that such organisms may constitute a risk to the user of the final product formulation.

(b) Preservative effectiveness. The preservative should not allow growth of the challenge organisms in the preserved formulation. The preservative is therefore effective in the product if:

(1) The concentrations of viable bacteria are reduced to not more than 0.1 percent of the initial concentration by the 14th day;

(2) The concentrations of viable yeasts and molds remain at or below the initial concentrations during the first 14 days; and

(3) The concentration of each test microorganism remains at or below these designated levels during the remainder of the 28-day test period. The preservative is not effective if, after several days, repeated isolation of the microorganisms contained in the initial inoculum occurs.

(c) Test data retention. The resulting data from testing for every product formulation shall be available for inspection by the Food and Drug Administration.

Subpart D—Labeling

§ 333.80 Antimicrobial soap.

(a) Statement of identity. The labeling of the product shall contain the following statements in the following order:

(1) For products containing iodine tincture: "Do not apply this product with a bandage or bandage may result".

(2) Directions. The labeling of the product shall contain the following statements under the heading "Directions" for products containing iodine tincture: "Apply to (paint) the operative site prior to surgery and remove immediately upon drying after application with 70 percent alcohol, or use as directed by a physician".

§ 333.87 Patient preoperative skin preparation.

(a) Statement of identity. The labeling of the product shall contain the following statements under the heading "Warnings":

(1) "For external use only".

(2) For products containing iodine tincture: "Do not apply this product with a bandage or bandage may result".

(b) Indications. The labeling of the product shall contain a statement of the indications that shall be limited to one or more of the following phrases: "Kills microorganisms", "reduces the number of microorganisms in the treated area", "antibacterial", "antimicrobial".

(2) Other allowable statements. The labeling may also contain the phrases "broad-spectrum", "fast-acting" (if applicable); provided such phrases are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(c) Warnings. The labeling of the product shall contain the following warnings:...

§ 333.85 Health-care personnel handwash.

(a) Statement of identity. The labeling of the product shall contain the following statements in the following order:

1. "Contains antimicrobial..."

2. "Fast-acting" (if applicable), and "broad-spectrum"; provided such phrases are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(b) Indications. The labeling of the product shall contain the following statements under the heading "Indications":...

(c) Warnings. The labeling of the product shall contain the following statements under the heading "Warnings":...

§ 333.90 Skin antiseptic.

(a) Statement of identity. The labeling of the product shall contain the following statements under the heading "Indications":...

(b) Indications. The labeling of the product shall contain the following statements under the heading "Indications":...

(c) Warnings. The labeling of the product shall contain the following statements under the heading "Warnings":...
(2) **Other allowable statements.** The labeling may also contain the phrase “nonirritating”; provided such phrase is neither placed in direct conjunction with information required to appear in the labeling nor occupies labeling space with greater prominence or conspicuousness than the required information.

(c) **Warnings.** The labeling of the product shall contain the following warnings under the heading “Warnings”:

(1) “For external use only.”

(2) “This product is not for use on wild or domestic animal bites. If you have an animal bite, consult your physician immediately.”

(3) “Do not use this product for more than 10 days. If the condition worsens or persists, see your physician.”

(4) “Do not bandage tightly.”

(5) “For products marketed as concentrates: “Caution: Use only after dilution to use concentration. May cause eye irritation or eye damage unless diluted.”

(6) “For concentrated products containing one or more of the following compounds: “Dilute with distilled water before use because acidic or hard water may render the product inactive.”

(d) **Directions.** The labeling of the product shall contain the following statement under the heading “Directions”:

“Impress the area.” The labeling shall also contain the recommended dosage for use, time interval (if any), and method by which the product shall be used to prevent overt skin infection for those particular organisms for which the product is generally recognized as safe and effective.

§ 333.92 Skin wound cleanser.

(a) **Statement of identity.** The labeling of the product shall contain the established name of the drug, if any, and shall identify the product as a “skin wound cleanser.”

(b) **Indications.** The labeling of the product shall contain a statement of the Indications under the heading “Indications” that shall be limited to one or more of the following phrases: “Skin wound cleanser.”

(c) **Other allowable statements.** The labeling may also contain any of the following phrases: “Nonirritating,” “protects wounds,” “first aid for small cuts, abrasions and burns,” “protects against wound contamination.”

§ 333.93 Skin wound protectant.

(a) **Statement of identity.** The labeling of the product shall contain the established name of the drug, if any, and shall identify the product as a “skin wound protectant.”

(b) **Indications.** The labeling of the product shall contain a statement of the indications under the heading “Indications” that shall be limited to one or more of the following phrases: “Protectant,” “provides a protective physical (and chemical) barrier,” “does not delay wound healing,” “contains antibacterial ingredient(s)” and “contains antimicrobial ingredient(s);” provided such phrases are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence or conspicuousness than the required information.

(c) **Warnings.** The labeling of the product shall contain the following warnings under the heading “Warnings”:

(1) “For external use only.”

(2) “This product is not for use on wild or domestic animal bites. If you have an animal bite, consult your physician immediately.”

(3) “Do not use this product for more than 10 days. If the conditions worsens or persists, see your physician.”

(4) “Do not bandage tightly.”

(5) “For products marketed as concentrates: “Caution: Use only after dilution to use concentration. May cause eye irritation or eye damage unless diluted.”

(6) “For concentrated products containing one or more of the following compounds: “Dilute with distilled water before use because acidic or hard water may render the product inactive.”

(d) **Directions.** The labeling of the product shall contain the following statement under the heading “Directions”:

“Impress the area.” The labeling shall also contain the recommended dosage for use and method by which the product shall be used to clean a small wound without further damage to the injured area.

§ 333.97 Surgical hand scrub.

(a) **Statement of identity.** The labeling of the product shall contain the established name of the drug, if any, and shall identify the product as a “surgical hand scrub.”

(b) **Indications.** The labeling of the product shall contain a statement of the Indications under the heading “Indications” that shall be limited to one or more of the following phrases: “Kills microorganisms,” “significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care,” “bacteriostatic,” “bactericidal.”

(c) **Other allowable statements.** The labeling may also contain any of the following phrases: “Nonirritating,” “first aid for small cuts, abrasions and burns,” “protects against wound contamination.”

(d) **Directions.** The labeling of the product shall contain the following warnings under the heading “Warnings”:

(1) “For external use only.”

(2) “This product is not for use on chronic skin conditions, such as eczema.”

(3) “Do not use on newborns.”

(4) “Do not use on debilitated patients or patients at high risk of infection.”

(5) “This product may render the product inactive.”

(6) “Apply to affected area”. The labeling shall identify the product as a “surgical hand scrub.”

§ 333.99 Professional labeling.

The labeling for each type of product defined in § 333.3 (a) through (l) that is provided only to health professionals and the labeling for those products primarily used in health-care facilities shall contain, in addition to the warnings required by each monograph, the following:

(a) “Caution: Use of this and other antimicrobial products may result in an overgrowth of gram-negative or other resistant organisms, particularly *Pseudomonas*. These effects could be serious in severely debilitated patients or patients at high risk of infection, such as burn victims, the elderly, or newborns.”

(b) **For products containing quaternary ammonium compounds:** “This product is rendered inactive by hard water, acidic water, anionic compounds, soaps Tween 80 and sodium lauryl sulfate.”
(c) The warning "Do not use solution with occlusive dressing" may be used instead of the warning "Do not bandage tightly" in the "Warnings" section of the labeling for a skin wound cleanser product.

Interested persons may file written objections and request an oral hearing before the Commissioner regarding this tentative order on or before February 6, 1978. Requests for an oral hearing must specify points to be covered and time requested. All objections and requests shall be submitted (in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) to the Hearing Clerk (HFC-20), Food and Drug Administration (HFC-20), room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be accompanied by a memorandum or brief in support thereof. Objections and requests may be seen in the above office, between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

The Food and Drug Administration has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11821 (as amended by Executive Order 11949) and OMB Circular A-101. A copy of the economic impact assessment is on file with the Hearing Clerk, Food and Drug Administration.


DONALD KENNZY,
Commissioner of Food and Drugs.
FRIDAY, JANUARY 6, 1978
PART III

DEPARTMENT OF
HEALTH,
EDUCATION, AND
WELFARE

Public Health Service

HEALTH SYSTEMS
AGENCIES

Designation and Funding
Title 42—Public Health
CHAPTER 1—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PART 122—HEALTH SYSTEMS AGENCIES

AGENCY: Public Health Service, HEW.
ACTION: Final regulations.

SUMMARY: These amendments revise several sections of the regulations governing the designation and funding of health systems agencies (42 CFR Part 122), in order to make those regulations consistent with recent statutory changes in Title XV of the Public Health Service Act (hereinafter the Act) and to conform to a recent court decision concerning the regulations.


FOR FURTHER INFORMATION:
Harry P. Cain II, Ph. D., Director, Bureau of Health Planning and Resources Development, Health Resources Administration, Room 6-22, Center Building, 3700 East-West Highway, Hyattsville, Md. 20782.

SUPPLEMENTARY INFORMATION: The Assistant Secretary for Health, Department of Health, Education, and Welfare, with the approval of the Secretary of Health, Education, and Welfare amends Part 122 of Title 42, Code of Federal Regulations, to make those regulations consistent with statutory changes in the Public Health Service Act made by Pub. L. 94-484, October 1976, also amended the same two sections of Title XV of the Act. It amended section 1512(b) (3) (C) (i) (I), which contains a list of health professionals who must be represented on the governing body of a health systems agency, to include optometrists, and it amended section 1531(a) (A) of the Act, which contains a list of health professionals who may be determined to be direct providers of health care, also to include optometrists. Sections 122.109 (b) (2) (I) and 122.110 (a) (1) are revised to accommodate these statutory changes.

On April 28, 1977, the U.S. District Court for the District of Columbia in the case of State of Missouri v. F. David Mathews, USDC DC, Civil Action 76-1065, held that the portion of 42 CFR 122.109 (b) (2) (I) which limited the number of public elected officials, representatives of governmental authorities, and representatives of public agencies concerned with health that could serve on a health systems agency governing board to not more than one-third of the total membership on the governing board, was unreasonable in light of the legislative history of the Act. The Department has decided not to appeal this decision. Accordingly, § 122.109 (b) (2) (I) is revised to delete the one-third limitation.

Because the amendments described above are technical in nature, the Secretary has determined, pursuant to 5 USC 553 and applicable Department policy, that it would be impracticable, unnecessary, and contrary to the public interest to follow proposed rulemaking procedures or to delay the effective date of these amendments. These amendments will therefore be effective January 6, 1978.

Accordingly, 42 CFR Part 122 is amended as set forth below.

NOTE: The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11621 and OMB Circular 821 and OMB Circular 8-107.

Dated: November 9, 1977.

Julius B. Richmond, Assistant Secretary for Health.


Joseph A. Califano, Jr., Secretary.

§ 122.1 [Amended]
1. Section 122.1(a) (1) is amended by inserting “optometrist,” after “podiatrist,” and by inserting “substance abuse treatment facilities,” after “long-term care facilities.”

§ 122.109 [Amended]
2. Section 122.109(b) (2) (I) is amended by inserting “optometrists,” after “nurses.”

3. Section 122.109(b) (2) (II) is amended by inserting “substance abuse treatment facilities,” after “long-term care facilities.”

4. Section 122.109 is amended by revising paragraph (b) (3) (I) to read as follows:

§ 122.109 Governing body; executive and other committees.

• (b) * * *

• (I) Include (either through consumer or provider members) public elected officials and representatives of governmental authorities in the agency’s health service area and representatives of public agencies in the area concerned with health.

[FR Doc.78-2 Filed 1-5-78;8:45 am]
ENVIRONMENTAL PROTECTION AGENCY

STATE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

Proposed Rulemaking
ENVIRONMENTAL PROTECTION AGENCY

PROPOSED RULEMAKING

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: These proposed amendments will revise EPA's regulations governing State National Pollutant Discharge Elimination System (NPDES) Programs for two purposes: to conform the regulations to the requirements of the Settlement Agreement approved by the United States District Court for the District of Columbia on June 6, 1976, in "Natural Resources Defense Council, Inc., et al. v. Russell E. Train," and to clarify the procedures under which EPA will exercise its power to object to ("veto") the issuance of State NPDES permits. Both of these proposed changes are necessary to assure national uniformity in water pollution control efforts, particularly with respect to toxic and hazardous pollutants.

DATES: All comments received on or before February 6, 1978, will be considered.

ADDRESSES: Interested persons may participate in this proposed rulemaking by submitting comment or suggestions to Mr. Edward A. Kramer, Permits Division (EN-336), Office of Water Enforcement, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. Each person submitting a comment should include his or her name and address and give reasons for any recommendations. A copy of all public comments will be available for inspection and copying at EPA's Public Information Reference Unit, Room 2922 (EPA Library), 401 M Street SW., Washington, D.C. 20460. The EPA information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

CONSENT DEGREE REQUIREMENTS

The Settlement Agreement approved by the United States District Court for the District of Columbia on June 6, 1976, in "Natural Resources Defense Council, Inc. et. al. v. Train," (1949), "Cf. (1949)," 8 ERC 2120 (D.D.C. 1976) (hereinafter the "Consent Decree") establishes a new program for, among other actions, the establishment by EPA of effluent limitations guidelines, new source performance standards, and pretreatment standards in 21 major categories of industries, focusing on 65 classes of pollutants of particular concern. When these guidelines and standards are promulgated, Paragraph 10(a) of the Consent Decree requires EPA to provide for their prompt application to all point sources and discharges into publicly owned treatment works.

To assure national uniformity in water pollution control, the proposed regulations will implement the requirements of the Consent Decree as they apply to States with approved NPDES programs. Under the proposed regulations, these states must modify, or alternatively, revoke and reissue permits when new guidelines for best available technology economically achievable (BAT) are issued. Permits issued by EPA are subject under the Consent Decree to similar requirements.

It is EPA's position that permits subject to the Consent Decree are the only permits which are reissued prior to the time that new guidelines are promulgated in accordance with the Consent Decree should be reissued to require continued compliance with best practicable control technology currently available (BPT) as specified in the expiring permits (making any necessary adjustments), as well as compliance with the existing regulations for those effluent standards and other applicable requirements under sections 208, 301, 302, 307, and 403 of the Federal Water Pollution Control Act (hereinafter the "Act"). Nevertheless, when the Regional Administrator finds a discharge of a substance posing a threat to the public health, or where other unusual circumstances exist, prompt action to revoke the permit must be taken. These new procedures and requirements have been established in order to assure expeditious compliance with requirements for the control of pollutants of particular national concern, as well as to meet the July 1, 1983, deadline established in the Act for the achievement of BAT effluent limitations.

VETO PROCEDURES

Under section 402(d)(2) of the Act, States with approved NPDES programs must submit draft permits to the Administrator for formal review. If the Administrator objects to the issuance of the permit "as being outside the guidelines and requirements of the Act," a State may not issue the permit. While this veto authority is a basic device ensuring a nationally uniform water pollution control effort, the existing regulations do not spell out detailed procedures for its exercise, nor do they identify circumstances under which the Administrator will exercise this power. These proposed regulations clarify both the procedures which are to be followed in reviewing State NPDES permits and the scope of the Administrator's review. Where these regulations conflict with existing agreements between the Regional Administrator and the States, the regulations would be controlling.

A. PROCEDURES

The present regulations (40 CFR 124.46) leave the procedures for EPA review of State NPDES permits to be worked out in the agreement between the Regional Administrator and the State at the time a State NPDES program is approved.

Under these proposed regulations, the Regional Administrator and the State would work together in both formulating the permits and ensuring that the supporting record is complete. Thus, before the State formally transmits a draft permit to the Regional Administrator for review, the Regional Administrator will have reviewed the tentative determinations of the State under § 124.31(a) and the draft NPDES permit prepared under § 124.31(b). Under this procedure, any concerns the Regional Administrator has with respect to the State's draft permit will be identified and made known to the State before the Regional Administrator's opportunity for formal review. This early review system also will allow the Regional Administrator to provide to the State any information or data (such as research reports, draft effluent limitation guidelines and development documents, and information about attainable levels of control) the State must consider in formulating its final proposed permit.

EPA expects that this proposed system will in most cases allow EPA to resolve any differences with the State prior to public notice of the NPDES permit issuance by the State. If not, the public notice should identify the State's tentative position and the concerns registered by EPA on issues underlying the permit issuance, and seek public comment on those issues. EPA believes that this proposed approach will facilitate informed public participation in the permit issuance process.

The provisions relating to transmittal of the final draft permit from the State to EPA are based upon the present requirements, except that comments on the permit presented at any State public hearing must be submitted to the Regional Administrator. Moreover, the Regional Administrator does not inform the Director in writing of his lack of objection to the tentative determinations; where the draft permit differs from or is less stringent than the tentative determinations; or where significant objections to the tentative determinations were raised.

The proposed regulations do not provide for a hearing or other mandatory public procedure in connection with the exercise of the Regional Administrator's review responsibility. An opportunity for hearing must be provided by the States in connection with permits under the tentative determinations; or where significant objections to the tentative determinations were raised.

The purpose of section 101(e) of the Act, which requires public participation in the EPA actions, will be served by the Regional Administrator's responsibility...
to make his concerns known to the State and to air those concerns at any State public hearing. However, where deemed appropriate, the Regional Administrator may request additional public comment on the draft permit transmitted by the State and the exercise of veto authority. In some circumstances, the use of these public notice procedures might be mandatory. For example, if the Regional Administrator sought to consider documentary material which was not before him, he must be given an opportunity to review such material. Otherwise, the Regional Administrator will be limited under §124.48(c) (4) to the record made before the State.

B. SCOPE OF REVIEW

The permissible grounds on which an objection by the Regional Administrator may be based are listed in the proposed §124.48. As noted above, the grounds for objection listed involve legal determinations, not factual determinations. The Regional Administrator will not attempt, in most cases, to challenge factual determinations, except as provided in proposed §124.48(b) (4) and (5). Thus, if the Regional Administrator finds under proposed §124.48(b) (4) that determinations made by the Director are "arbitrary and capricious, or an abuse of discretion," the Regional Administrator is not reredetermining facts, but engaging in a legal review analogous to that performed by the courts. Thus, it will not be necessary to engage in this review because the Regional Administrator cannot determine whether the "guidelines and requirements" of the Act are met unless there is assurance that the State has assembled a full and complete factual record, and made careful and accurate determinations on the basis of that record.

C. CONSIDERATION OF TERMS

The Regional Administrator's authority to object in the case of "pre-guidelines" permits is limited. Frequently permits must be issued before the promulgation of effluent guidelines for a given category or subcategory. Section 402(a) (1) of the Act authorizes the Administrator to issue permits in these cases under "such conditions as the Administrator determines are necessary to carry out the provisions of this section." Where effluent limitation guidelines represent BPT have not been promulgated, for example, the Administrator has interpreted this section of the Act as requiring a determination of "individualized" BPT on a case-by-case basis for incorporation into the discharger's permit. See, e.g., Decision of the General Counsel No. 38 (January 28, 1976); "United States Steel Corp. v. Train," 566 F. 2d 822, 844 (7th Cir. 1977). The present regulations (40 CFR §124.42(a) (5)) authorize the State to issue such "pre-guidelines" permits. However, these regulations have been misconstrued by a few States as committing the effluent limitations in these permits to the absolute discretion of the Director. The proposed regulations, therefore, §124.42(c) (2) to eliminate ambiguity on this point, and, in proposed §124.48, clarify the authority of the Regional Administrator to veto "pre-guidelines" permits where the State improperly determines the limitations necessary to meet the provisions of the Act.

C. CONTENTS OF RECORD

In the existing regulations, States are required to transmit to the Regional Administrator for review only the draft permit and documents which are part of the permit or which affect the determination of these effluent limitations. The proposed amendments require the transmission of a more complete record to the Regional Administrator for review in some cases. Thus, in the circumstances identified in proposed §124.47(c) (2) as constituting the "applicable effluent standard or limitation," the Regional Administrator will have the full 90 days authorized by section 124(d) (2) of the Act or longer period, if specified by agreement with the State for review when the State supplied the requested record or documents.

As noted above, in certain limited circumstances, the Regional Administrator may consider material outside this record after making it available for public comment by review of the record by the State and the discharger.

Note.—The Environmental Protection Agency has determined that this document does not constitute a major regulation requiring preparation of a "Environmental Impact Statement under Executive Order 11902, as amended by Executive Order 11949," and under OMB Circular A-107.


DOUGLAS M. COSTLE, Administrator.

Subpart D—Notice and Public Participation

§124.31 Formulation of Tentative Determinations and Draft NPDES Permits.

(c) The Administrator determinations prepared pursuant to paragraph (a) of this section and the draft NPDES permit prepared pursuant to paragraph (b) of this section shall be transmitted to the Regional Administrator for review less than thirty (30) days prior to publication of the public notice provided for by §124.32. The Regional Administrator may, by agreement with the State, modify the requirements of this subsection, provided that the agreement ensures the Regional Administrator's opportunity to comment on, object to, or make recommendations with respect to, the tentative determination and draft NPDES permit prior to public notice.

(d) The Regional Administrator may comment upon, object to or make recommendations with respect to the draft NPDES permit prior to circulation of such public notice and may request that such circulation be postponed until the Director has had an opportunity to review and consider the terms of the draft NPDES permit in light of such comments, objections or recommendations.

Subpart E—Terms and Conditions of NPDES Permits

1. Section 124.42 is proposed to be amended by revising paragraph (a) (6) to read as follows:

§123.4j Application of effluent standards and limitations, water quality standards and other requirements.

(a) (6) Prior to promulgation by the Administrator of applicable effluent standards and limitations pursuant to sections 208, 301, 302, 306 and 307, such conditions as are necessary to carry out the provisions of the Act.

2. Section 124.47 is proposed to be renumbered as §124.49 and §124.48 is proposed to be deleted and replaced by new §§124.46, 124.47 and 124.48 as follows:

§124.46 Requirements under consent decree.

(a) As used in this section, the term "Consent Decree" shall mean the Settlement Agreement approved by the United States District Court for the District of Columbia and issued on June 8, 1976, in "Natural Resources Defense Council, Inc. v. Russell E. Train," 2 ERC 2120 (D.D.C. 1976).

(b) Any permit issued to a discharger within any industrial category listed in Appendix B of the Consent Decree shall apply, and assure compliance with, all applicable effluent standards and limitations promulgated pursuant to the Consent Decree. Where applicable standards or limitations required by the Consent Decree have not yet been issued, the Director shall include in the permit a condition stating that if an applicable effluent standard or limitation is issued under the Consent Decree, and such effluent standard or limitation is more stringent than any effluent limitation in
the permit, or controls a pollutant or pollutant parameter not limited in the permit, or controls a pollutant or pollutant parameter not limited in the permit, or controls a significant comment adverse to the tentative determination of the Regional Administrator.

The Regional Administrator may, by agreement at the time an NPDES permit is submitted for approval, waive certain requirements different from or less stringent than those embodied in the proposed permit, and which are a part of any proposed permit or that are a part of any proposed permit or that are a part of any proposed permit or that is inadequate to determine whether, the proposed permit is erroneous in the application of the Act, by the guidelines and requirements set forth in paragraph (b) of this section. Any such waivers which may thereafter be granted, shall apply to any permit which is subject to §124.46(b), and which does not comply with that subsection.

§124.48 Objections to proposed permits. (a) Within the period of time provided pursuant to §124.47(d), the Regional Administrator may reopen and revise the record of an objection to issue of the proposed permit. Such notification shall be set forth in writing the nature of the objection, the section of the Act or regulations that support the objection, and any objections that must be taken by the Director in order to eliminate the objection. (b) An objection by the Regional Administrator may be based on one or more of the following grounds: (1) The permit fails to apply, or to ensure compliance with, any applicable requirements of sections 208, 301, 302, 304, 306, 307, and 403, or of any applicable regulations promulgated thereunder. (2) In the case of any proposed permit for which notification to the Administrator is required under section 402(b)(5) of the Act, the written recommendations of an affected State have not been accepted by the permitting State and the Regional Administrator finds adequate the reasons for nonacceptance. (3) The procedures followed in connection with formulations of the proposed permit failed in a material respect to comply with procedures required by the Act or regulations and guidelines thereunder or required by any agreement between the State or interstate agency and the Regional Administrator; (4) Any findings of fact made by the Director, or necessarily implied by the Director's determination to issue the proposed permit are arbitrary and capricious, or an abuse of discretion; (5) With respect to the interpretation of the Act or any guideline or regulation thereunder, or of the application of the Act, guidelines and regulations; the facts found by the Director, or any conclusion made by the Director or necessarily implied by his determination to issue the proposed permit is erroneous in the judgment of the Regional Administrator;

(6) Any provisions of the proposed permit relating to the maintenance of records, reporting, monitoring, sampling, or the provision of any other information by the permitting State have not yet been promulgated by the Regional Administrator, or the Regional Administrator has not received copies of the permit; or

(7) In the case of any proposed permit with respect to which applicable effluent standards and limitations pursuant to sections 208, 301, 302, 306 and 307 of the Act have not yet been promulgated by the Regional Administrator, the permit is not issued in accordance with such effluent standards or limitations pursuant to paragraphs (b) and (c) of this section.

(8) In the case of any proposed permit with respect to which applicable effluent standards and limitations pursuant to sections 208, 301, 302, 306 and 307 of the Act have not yet been promulgated by the Agency, the proposed permit, in the judgment of the Regional Administrator, fails to carry out the provisions of the Act; or

(9) Issuance of the proposed permit would in any other respect be outside the requirements of the Act, or regulations and guidelines thereunder.

(a) Within the period of time provided pursuant to §124.47(d), the Regional Administrator may reopen and revise the record of an objection to issue of the proposed permit. Such notification shall be set forth in writing the nature of the objection, the section of the Act or regulations that support the objection, and any objections that must be taken by the Director in order to eliminate the objection. (b) An objection by the Regional Administrator may be based on one or more of the following grounds: (1) The permit fails to apply, or to ensure compliance with, any applicable requirements of sections 208, 301, 302, 304, 306, 307, and 403, or of any applicable regulations promulgated thereunder. (2) In the case of any proposed permit for which notification to the Administrator is required under section 402(b)(5) of the Act, the written recommendations of an affected State have not been accepted by the permitting State and the Regional Administrator finds adequate the reasons for nonacceptance. (3) The procedures followed in connection with formulations of the proposed permit failed in a material respect to comply with procedures required by the Act or regulations and guidelines thereunder or required by any agreement between the State or interstate agency and the Regional Administrator; (4) Any findings of fact made by the Director, or necessarily implied by the Director's determination to issue the proposed permit are arbitrary and capricious, or an abuse of discretion; (5) With respect to the interpretation of the Act or any guideline or regulation thereunder, or of the application of the Act, guidelines and regulations; the facts found by the Director, or any conclusion made by the Director or necessarily implied by his determination to issue the proposed permit is erroneous in the judgment of the Regional Administrator;

(6) Any provisions of the proposed permit relating to the maintenance of records, reporting, monitoring, sampling, or the provision of any other information by the permitting State have not yet been promulgated by the Regional Administrator, or the Regional Administrator has not received copies of the permit; or

(7) In the case of any proposed permit with respect to which applicable effluent standards and limitations pursuant to sections 208, 301, 302, 306 and 307 of the Act have not yet been promulgated by the Agency, the proposed permit, in the judgment of the Regional Administrator, fails to carry out the provisions of the Act; or

(8) Issuance of the proposed permit would in any other respect be outside the requirements of the Act, or regulations and guidelines thereunder.

(a) Within the period of time provided pursuant to §124.47(d), the Regional Administrator may reopen and revise the record of an objection to issue of the proposed permit. Such notification shall be set forth in writing the nature of the objection, the section of the Act or regulations that support the objection, and any objections that must be taken by the Director in order to eliminate the objection. (b) An objection by the Regional Administrator may be based on one or more of the following grounds: (1) The permit fails to apply, or to ensure compliance with, any applicable requirements of sections 208, 301, 302, 304, 306, 307, and 403, or of any applicable regulations promulgated thereunder. (2) In the case of any proposed permit for which notification to the Administrator is required under section 402(b)(5) of the Act, the written recommendations of an affected State have not been accepted by the permitting State and the Regional Administrator finds adequate the reasons for nonacceptance. (3) The procedures followed in connection with formulations of the proposed permit failed in a material respect to comply with procedures required by the Act or regulations and guidelines thereunder or required by any agreement between the State or interstate agency and the Regional Administrator; (4) Any findings of fact made by the Director, or necessarily implied by the Director's determination to issue the proposed permit are arbitrary and capricious, or an abuse of discretion; (5) With respect to the interpretation of the Act or any guideline or regulation thereunder, or of the application of the Act, guidelines and regulations; the facts found by the Director, or any conclusion made by the Director or necessarily implied by his determination to issue the proposed permit is erroneous in the judgment of the Regional Administrator;
FRIDAY, JANUARY 6, 1978
PART V

DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions
NOTICES

MODIFICATIONS AND SUPERSEDES DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being modified and their dates of publication in the Federal Register are listed with each State.

AL77-1003; AL77-1004; AL 77-1006 ......... May 13, 1977.
AL77-1009 ......... July 8, 1977.

AQ-4109 ......... June 14, 1974.
GA76-1095 ......... Apr. 11, 1975.
GA76-1119 ......... Dec. 12, 1975.

IN77-2134 ......... June 24, 1977.


MD77-3130 ......... Sept. 23, 1977.

MS76-1076 ......... July 16, 1976.
MS77-1055; MS77-1066 ......... May 6, 1977.
MS77-1078 ......... June 17, 1977.


New Mexico: NM77-4103 ......... May 20, 1977.


NC76-1068 ......... May 20, 1976.
NCC77-1017; NCC77-1018 ......... Feb. 11, 1977.
NCC77-1145 ......... Nov. 18, 1977.


SC76-1068 ......... Jan. 9, 1976.
SC77-1019 ......... Nov. 25, 1977.


TX77-4026; TX77-4029 ......... Feb. 19, 1977.
TX77-4103; TX77-4117; TX77-4201 ......... Aug. 19, 1977.
TX77-4221; TX77-4233 ......... Sept. 23, 1977.
TX77-4239; TX77-4240; TX77-4248 ......... Sept. 30, 1977.
TX77-4248; TX77-4252; TX77-4256; TX77-4257; TX77-4258; TX77-4260; TX77-4261; TX77-4268; TX77-4264; TX77-4295; TX77-4286. 

FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978
NOTICES

SUPERSEDEAS DECISIONS TO GENERAL
WAGE DETERMINATION DECISIONS

The numbers of the decisions being superseded and their dates of publication in the Federal Register are listed with each State.

Superseded Decision numbers are in parentheses following the numbers of the decisions being superseded.

Louisiana:

Signed at Washington, D.C., this 30th day of December 1977.

RAY J. DOLAN,
Assistant Administrator,
Wage and Hour Division.
### Notices

**State:** North Carolina  
**County:** Guilford  
**Decision No.:** NC78-1005  
**Date of Publication:**

**Description of Work:** Building construction (does not include single family homes and garden type apartments up to and including 4 stories).

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**Power Equipment Operators:**

- Backhoe: 4.45
- Bulldozer: 4.25
- Cranes, derrick, derrickline: 6.00
- Distributor: 4.75
- Finishing machine: 4.75
- Fork lift operators: 4.00
- Front end loader: 4.25
- Motor grader: 4.76
- Roller: 4.03

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**Footnotes:**

- Employer contributes 6% of basic hourly rate for 5 years or more of service and 6% of basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.
- 7 paid holidays: New Year’s Day; Christmas Day; 4th of July; Labor Day; Memorial Day; Thanksgiving Day; and Friday after Thanksgiving Day.
### NOTICES

#### MODIFICATIONS P. 1

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#### MODIFICATIONS P. 2

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**Summary of Changes**:
- **Laborers**: $2.65
- **Mason tenders**: 2.65
- **Roofers**: 2.65
- **Truck drivers**: 2.65

*FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978*
###適用於異議人

####異議事項

**異議人:**
- 建築工人
- 鍛鐵工人
- 專業層

**地點:**
- 阿倫, 莎克塔, 本頓, 柏林, 約翰遜, 格雷恩, 范登堡, 納森, 提皮卡米, 威廉斯, 與威戈郡, 印第安納州

####異議**: 8月1日

| 工種       | 基本時薪 | 萬用/週薪 | 複製工資 | 養老金 | 薪資補償 | 就業和/or 執行年
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####異議事項

**異議人:**
- 建築工人
- 鍛鐵工人
- 專業層

**地點:**
- 阿蘭, 莎克塔, 本頓, 柏林, 約翰遜, 格雷恩, 范登堡, 納森, 提皮卡米, 威廉斯, 與威戈郡, 印第安納州

####異議**: 8月1日

| 工種       | 基本時薪 | 萬用/週薪 | 複製工資 | 養老金 | 薪資補償 | 就業和/or 執行年
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####異議**: 8月1日

| 工種       | 基本時薪 | 萬用/週薪 | 複製工資 | 養老金 | 薪資補償 | 就業和/or 執行年
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####異議**: 8月1日

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####異議**: 8月1日

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### DECISION 51/220 - Mod. 24

(62 FR 5157 - February 16, 1997)
Gueyvah Parish, Louisiana

**Change:**
- Laborers: $2.65

### DECISION 51/220 - Mod. 24

(62 FR 49068 - September 23, 1997)
Boesier, Caddo & Calcasieu Parish, Louisiana

**Change:**
- Laborers: $2.65

### DECISION 51/220-MOD. 24

(62 FR 49068 - September 23, 1997)
Boesier, Caddo & Calcasieu Parish, Louisiana

**Change:**
- Laborers: $2.65
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**FEDERAL REGISTER, VOL. 45, NO. 4—FRIDAY, JANUARY 6, 1978**
### Modifications P. 11

#### Decision No. NY77-3003-Mod. 81

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<th>Fringe Benefits Payments</th>
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**Footnotes:**

- a. Paid Holidays: A through F plus the day after Thanksgiving.
- b. Employer contributes 8% of basic hourly rate for 5 or more years of service or 6% of basic hourly rate for 6 months to 5 years of service as a Vacation Credit.

---

### Modifications P. 12

#### Decision No. NY77-3003-Mod. 81

**Continued...**

<table>
<thead>
<tr>
<th>Line Construction</th>
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**Federal Register, Vol. 43, No. 4—Friday, January 6, 1978**
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<th>Vacation</th>
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<td>Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Christmas Day.</td>
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</table>

**NOTES:**

- Paid Holidays: A through F, Election Day for President of State, provided the employee works the day before and after the holiday.

**Decision # NC-75-1048 - Mod. # 3**

- Chatham, Harnett, Lee, and Moore Counties, North Carolina
- Laborers
- 2.65

**Decision # NC-71-1042 - Mod. # 1**

- Camden, Currituck, Dare, Pasquotank, Perquimans, and Tyrrell Counties, North Carolina.
- Laborers
- 2.65

**Decision # NC-76-1068 - Mod. # 2**

- Wilkes County, North Carolina
- Laborers
- 2.65

**Decision # NC-77-1017 - Mod. # 1**

- Forsyth and Surry Counties, North Carolina.
- Laborers
- 2.65

**Decision # NC-77-1018 - Mod. # 3**

- Burke, Catawba, Cleveland, Lincoln, Polk, and Rutherford Counties, North Carolina.
- Laborers
- 2.65

**Decision # NC-77-1145 - Mod. # 2**

- Halifax, Columbus, Richmond, Robeson, and Scotland Counties, North Carolina.
- Laborers
- 2.65

**Decision # NC-77-1145 - Mod. # 2**

- Laborers
- 2.65

**Decision # NC-77-1145 - Mod. # 2**

- Laborers
- 2.65

- Laborers
- 2.65

**Decision # NC-77-1145 - Mod. # 2**

- Laborers
- 2.65
### MODIFICATIONS P. 15

<table>
<thead>
<tr>
<th>DECISION NO. OK77-4036 - Mod. 01</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
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<tbody>
<tr>
<td>(62 FR 10261 - February 16, 1977)</td>
<td>Bryan County, Oklahoma</td>
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<td><strong>CHANGE:</strong></td>
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<td>GLAZERS</td>
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<td>TRUCK DRIVERS</td>
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| DECISION NO. OK77-4038 - Mod. 01 | | |
|---------------------------------|-------------------------|
| (62 FR 10262 - February 18, 1977) | Oklahoma, Cleveland, Canadian, Lincoln and Pottawatomie Counties, Oklahoma |
| **CHANGE:** | | |
| TILE SETTERS HELPER | 2.30 | |
| **ADD:** | | |
| TILE SETTERS FINISHERS | 2.65 | |

<table>
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<th>DECISION NO. OK77-6060 - Mod. 01</th>
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<td>(62 FR 13786 - March 11, 1977)</td>
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<th>Fringe Benefits Payments</th>
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<td>(62 FR 44465 - September 1, 1977)</td>
<td>Stantonville, Oklahoma (except heavy construction within the city of Muskogee)</td>
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<td>Education and/or Appr. Tr.</td>
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<tr>
<td><strong>ZONE B</strong></td>
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<tr>
<td>WELL DRILLER HELPER</td>
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### MODIFICATIONS P. 16

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<th>DECISION NO. SC75-1029 - Mod. 02</th>
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<td>(40 FR 10900 - March 7, 1975)</td>
<td>Aiken, Barnwell, and Edgefield Counties, South Carolina</td>
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<td><strong>CHANGE:</strong></td>
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<tr>
<td>Mason tenders &amp; mortar mixers</td>
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<tr>
<td>Power Equipment Operators:</td>
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<tr>
<td>Asphalt distributor</td>
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<td>Asphalt finisher</td>
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<td>Asphalt rakers &amp; oilers</td>
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<td>Steel wheel roller</td>
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<td><strong>ADD:</strong></td>
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<td>Truck Drivers</td>
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<td>(40 FR 12058 - March 14, 1975)</td>
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<td>Power Equipment Operators:</td>
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<td>Asphalt planter helper</td>
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<td>Truck driver (single-rear axle)</td>
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<td>Weighman scales</td>
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<td>Allendale, Bamberg, Calhoun, and Orange Counties, South Carolina</td>
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<tr>
<td>Mortar mixers</td>
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## MODIFICATIONS P. 17

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<td>Decision # 8785-1058 - Mod. # 2</td>
<td>(41 FR-20146 - May 14, 1976)</td>
<td>Abbeville, Cherokee, Laurens, Maulberry, and Union Counties, South Carolina.</td>
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<td>Decision # 977-1115 - Mod. # 1</td>
<td>(41 FR-20146 - October 6, 1976)</td>
<td>Anderson, Greenville, Oconee, and Pickens Counties, South Carolina.</td>
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## MODIFICATIONS P. 18

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<th>Basic Hourly Rates</th>
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<td>(41 FR-47907 - October 29, 1976)</td>
<td>Lexington and Highand Counties, South Carolina.</td>
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| **Decision # TN76-1140 - Mod. # 1** |
| 41 FR 56593 - December 20, 1976 |
| Dyer, Gibson, Lake, Lauderdale, Obion, and Weakley Counties, Tennessee |
| **Changes** |
| Laborers |
| Hortz mixers |
| 2.65 |
| 2.65 |

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| **DECISION #7077-4026 - Mod. #1** |
| (41 FR 10270 - February 16, 1977) |
| Bastrop, Blanco, Caldwell, Fayette, Hays, Llano, Travis & Williamson Counties, Texas |
| **Changes** |
| Laborers |
| 2.65 |

| **DECISION #7077-4029 - Mod. #2** |
| (41 FR 10271 - February 16, 1977) |
| Tarrant County, Texas |
| **Changes** |
| Laborers: Laborers |
| Truck drivers |
| 2.65 |
| 2.65 |

| **DECISION #7077-6193 - Mod. #3** |
| (41 FR 4221L - August 19, 1977) |
| Bexar County, Texas |
| **Changes** |
| Carpenters: Carpenters. |
| Plasterers |
| 8.69 |
| 10.00 |

| **DECISION #7077-6197 - Mod. #4** |
| (41 FR 42127 - August 19, 1977) |
| Colllm, Dallas, Denton, Ellis, Grayson, Hood, Hunt, Johnson, Kaufman, Palo Pinto, Rockwall, Tarrant & Wise Cos., Texas |
| **Changes** |
| Carpenters: |
| Zone 1 - Carpenters |
| Millwrights |
| Electricians |
| 10.225 |
| 10.625 |
| 10.725 |

**FEDERAL REGISTER, VOL. 42, NO. 4—FRIDAY, JANUARY 6, 1978**
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<td>b = Paid Holidays A thru G</td>
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<td>Add = G-tho Friday after Thanksgiving Day</td>
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<th>DECISION 67477-6257 - Mod. 63</th>
<th>Basic Hourly Rates</th>
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<tr>
<td>(62 FR 53155 - September 30, 1977)</td>
<td>El Paso County, Texas</td>
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<tr>
<td>c = Paid Holidays A thru G</td>
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<td>Paid Holidays for elevator constructors:</td>
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<tbody>
<tr>
<td>(62 FR 53159 - September 30, 1977)</td>
<td>Galveston &amp; Harris Co., Texas</td>
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<tr>
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<td>Bricklayers</td>
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<td>Carpenters - Carpenters</td>
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<td>Bricklayers &amp; stonemasons</td>
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FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978
## MODIFICATIONS P. 25

### DECISION 69X7-4261 - Mod. 64

**Lubbock County, Texas**

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
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<tr>
<td>Structural; Ornamental; Reinforcing</td>
<td>8.83</td>
<td>.55</td>
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<td>All Ironworkers on jobs 50 miles or more from the city of Lubbock</td>
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### DECISION 69X7-4263 - Mod. 62

**Taylor County, Texas**

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<th>Education and/or Approx. Tr.</th>
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<tr>
<td>Painters:</td>
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<tr>
<td>Brush, tape &amp; bedding, paperhanger</td>
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<td>Spray</td>
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<td>Plumbers &amp; pipefitters</td>
<td>8.82</td>
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### DECISION 69X7-4264 - Mod. 62

**Tom Green County, Texas**

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### DECISION 69X7-4265 - Mod. 63

**Wichita County, Texas**

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<tr>
<td>b = Paid Holidays A thru C</td>
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<td>Paid Holidays for elevator constructors:</td>
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<tr>
<td>Add = 6-the Friday after Thanksgiving Day</td>
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<td>Ironworkers on jobs 50 miles or more from the city of Wichita Falls</td>
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<td>Plumbers</td>
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<td>Sheet metal workers</td>
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<td>Truck drivers</td>
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### MODIFICATIONS P. 26

### DECISION 69X7-4266 - Mod. 62

**Cameron, Hidalgo, Starr & Willacy Counties, Texas**

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<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
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<tr>
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<td>Mortar mixers</td>
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<td>Plasterers' tenders</td>
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<td>Truck drivers</td>
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## NOTICES

### SUPERFEDERALS

**STATE:** Louisiana  
**PARISH:** St. Tammany

**DECISION NO.:** L476-4001  
**DATES:** Date of Publication: August 24, 1977

**DESCRIPTION OF WORK:** Building Construction (does not include single family homes & garden type apartments up to 6 including 5 stories) & Construction of Highways, Roads, Streets (does not include building structures in rest area projects) & Parking Area (except those let with a building contract). Building Construction includes construction of sheltered enclosures with walk-in access for the purpose of providing sheltering for persons, machinery, equipment or supplies. It includes all construction of such structures including the installation of utilities & the installation of equipment, both above & below ground level, as well as excavation & foundation, includes site preparation & incidental paving & utilities outside the building.

### NOTICES

- ZONE 1: Acadia, Allen, Beauregard, Calcasieu, Cameron, Franklin, Jefferson Davis, Rapides, Vermilion & Vernon Parishes
- ZONE 2: Assumption, Ascension, East Baton Rouge, East Feliciana, Iberville, Lafayette, Jefferson, Lafourche, LaSalle, Livingston, Orleans, Plaquemines, Pointe Coupee, St. Bernard, St. Charles, St. Helena, St. James, St. John the Baptist, St. Landry, St. Martin, St. Mary, St. Tammany, Tangipahoa, Terrebonne, Washington, West Baton Rouge & West Feliciana Parishes
- ZONE 3: East Carroll, Franklin, Madison, Natchitoches, Rapides, Richland, Tensas & West Carroll Parishes

### BOILERSMAKERS

<table>
<thead>
<tr>
<th>Zone</th>
<th>Rate</th>
<th>Hours</th>
<th>Fringe Benefits Payments</th>
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### BRICKLAYERS & STONEMASTERS

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### CARPENTERS

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### FEDERAL REGISTER

**Volume 43, No. 4—Friday, January 6, 1978**
### Notices

**Decision No. 479-6001**

**Zone 1** - Natchitoches & Sabine Parishes  
Zone 2 - East Baton Rouge, St. Landry, Washington, West Carroll & Union Parishes

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**Fencing Benefits Payments**

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### Decision No. 479-6001

**Zone 1** - Ascension, Assumption, East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, St. Helena, St. James, Tangipahoa, Union, West Baton Rouge & West Feliciana Parishes

<table>
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<th>Zone 6</th>
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**NOTES FOR ELEVATOR CONSTRUCTION**

- a = 1st 6 mos. = none; 6 mos. to 3 yrs. = $31 over 3 yrs. = 4% of basic hourly rate
- b = Paid Holidays: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day; the Friday after Thanksgiving; Christmas Day
- c = ZONE 1 - Ascension, Assumption, East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, St. Helena, St. James
- d = ZONE 2 - East Baton Rouge, St. Landry, Washington, West Carroll & Union Parishes
- e = ZONE 3 - East Baton Rouge, St. Landry, Washington, West Carroll & Union Parishes
- f = ZONE 4 - East Baton Rouge, St. Landry, Washington, West Carroll & Union Parishes
- g = ZONE 5 - East Baton Rouge, St. Landry, Washington, West Carroll & Union Parishes
- h = ZONE 6 - East Baton Rouge, St. Landry, Washington, West Carroll & Union Parishes
- i = ZONE 7 - East Baton Rouge, St. Landry, Washington, West Carroll & Union Parishes
- j = ZONE 8 - East Baton Rouge, St. Landry, Washington, West Carroll & Union Parishes
- k = ZONE 9 - East Baton Rouge, St. Landry, Washington, West Carroll & Union Parishes

**Federal Register, Vol. 43, No. 4 — Friday, January 6, 1978**
###NOTICES

####ZONE 1 - Allen (except northeast corner), Beauregard, Calcasieu, Cameron, Jefferson, Rapides & Vernon Parishes

####ZONE 2 - Acadia, Ascension, Assumption (north & west of Hou. 22), Assumption (north of Grand Bayou), East Baton Rouge, East Feliciana, Iberville, Jefferson, Lafayette, Livingston (north & west of Hou. 22), Pointe Coupee, St. Helena, St. Landry (north half), St. Martin, St. Mary (except Morgan City Area), Tangipahoa (west of Hou. 51), Vermilion, West Baton Rouge & West Feliciana Parishes

####ZONE 3 - Assumption (east & south of Hou. 22), Assumption (south of Grand Bayou), Jefferson, Lafayette, Livingston (east & south of Hou. 22), Orleans, Plaquemines, St. Bernard, St. Charles, St. James, St. John the Baptist, St. Mary (north of Hou. 31), St. Tammany, (southern portion) & Terrebonne Parishes

####ZONE 4 - Bienville (eastern half), Caldwell, Concordia, East Carroll, Franklin, Jackson, Lincoln, Natchitoches, Rapides, Richland, Tensas, Union, West Carroll & Winn (north half) Parishes

####ZONE 5 - St. Tammany (northern portion), Tangipahoa (east of Hou. 51) & Washington Parishes

###TOWNSHIPS (BUILDING CONSTRUCTION)

<table>
<thead>
<tr>
<th>ZONE</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
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<th>Education and/or Appr. Tr.</th>
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####ZONE 1 - All of Jefferson, Orleans, Plaquemines, St. Bernard, St. Charles, St. John the Baptist & St. Tammany Parishes, Parts of Lafayette, Livingston, St. Mary, St. Martin, Assumption, Ascension, Assumption (south of Grand Bayou), East Baton Rouge, East Feliciana, Iberville, Jefferson, Lafayette, Livingston (east & south of Hou. 22), Pointe Coupee, St. Helena, St. Landry, St. Martin, St. Mary (south of Hou. 31), St. Tammany, Tangipahoa, Vermilion, West Baton Rouge & West Feliciana Parishes

####ZONE 2 - Assumption (south of Grand Bayou), Assumption (south of Hou. 22), Livingston, Livingston (north & west of Hou. 22), Orleans, Plaquemines, St. Bernard, St. Charles, St. James, St. John the Baptist, St. Mary, St. Martin, St. Martin (north of Hou. 31), St. Tammany, Tangipahoa, Vermilion, Washington, West Baton Rouge & West Feliciana Parishes

####ZONE 3 - Assumption, Ascension, Bienville, Cameron, Caldwell, Catahoula, Claiborne, Concordia, East Carroll, East Feliciana, Iberville, Jefferson, Lafayette, Livingston, Orleans, Plaquemines, St. Bernard, St. Charles, St. John the Baptist, St. Martin, St. Martin, (north of Hou. 31), St. Tammany, Tangipahoa, Vermilion, Washington, West Baton Rouge & West Feliciana Parishes

####ZONE 4 - Bienville (eastern half), Caldwell, Concordia, East Carroll, Franklin, Jackson, Lincoln, Natchitoches, Rapides, Richland, Tensas, Union, West Carroll & Winn (north half) Parishes

####ZONE 5 - St. Tammany (northern portion), Tangipahoa (east of Hou. 51) & Washington Parishes

###TOWNSHIPS (HIGHWAY CONSTRUCTION)

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####ZONE 1 - Jefferson & Orleans Parishes

####ZONE 2 - Plaquemines, St. Bernard & St. Charles Parishes

####ZONE 3 - East Baton Rouge Parish

####ZONE 4 - Calcasieu Parish

####ZONE 5 - Bossier & Caddo Parishes

####ZONE 6 - Lafayette, Orleans & Rapides Parishes

####ZONE 7 - Assam, Ascension, Bienville, Cameron, Caldwell, Catahoula, Claiborne, Concordia, East Carroll, East Feliciana, Iberville, Jefferson, Lafayette, Livingston, Orleans, Plaquemines, St. Bernard, St. Charles, St. John the Baptist, St. Martin (north of Hou. 31), St. Tammany, Tangipahoa, Vermilion, Washington, West Baton Rouge & West Feliciana Parishes

###LANDESIS (BUILDING CONSTRUCTION)

| ZONE 1 | GROUP 1 | 6.15 | .15 |
| ZONE 2 | GROUP 1 | 6.15 | .15 |
| ZONE 3 | GROUP 1 | 7.35 | .15 |
| ZONE 4 | GROUP 1 | 6.77 | .15 |
| ZONE 5 | GROUP 1 | 6.77 | .15 |

###LANDESIS (HIGHWAY CONSTRUCTION)

| ZONE 1 | GROUP 1 | 6.07 | .15 |
| ZONE 2 | GROUP 1 | 6.07 | .15 |
| ZONE 3 | GROUP 1 | 7.15 | .15 |
| ZONE 4 | GROUP 1 | 6.77 | .15 |
| ZONE 5 | GROUP 1 | 6.77 | .15 |

###LANDESIS (HIGHWAY CONSTRUCTION)

<p>| ZONE 1 | GROUP 1 | 6.07 | .15 |
| ZONE 2 | GROUP 1 | 6.07 | .15 |
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<th>CLASSIFICATION DEFINITIONS</th>
<th>NOTES</th>
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<td>GROUP 1 - Building &amp; labor construction</td>
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<tr>
<td>GROUP 2 - Stone mason helpers; mechanical tool operators; sewerman (bottom men, caulkers, tenders, joint wrappers, hot pot, grade carriers, layers &amp; ditchers &amp; ft. or over); tender of all crafts; sandblaster (not mason); sandblaster (pot tender); laying non-metallic pipe over 4 ft. deep, including sewer, drain &amp; underground tile; septic tank diggers &amp; installers, over 4 ft. deep; gas &amp; oil pipeline laborers &amp; wrappers</td>
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<td>GROUP 3 - Gigantic tool operators</td>
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<td>LANDLORDS - ZONE 2</td>
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<tr>
<td>GROUP 1 - Building laborers; rotary drill laborers; foundation drill crewmen</td>
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<tr>
<td>GROUP 2 - Mason mixer; plaster mixer; mechanical tool ops; sandblaster; laying concrete, clay, plastic, asbestos cement, casing &amp; corrugated metal pipe, as sewer, drain &amp; underground tile (caulkers, joint wrappers, hot pot &amp; pipe layers); gas &amp; oil pipeline laborers, wrappers &amp; dokers</td>
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<tr>
<td>LANDLORDS - ZONE 3</td>
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<tr>
<td>GROUP 2 - Air tool ops. (except jackhammers); interior of closed tanks &amp; vessels power equip.</td>
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<tr>
<td>GROUP 3 - Mason mixers &amp; jackhammer ops.</td>
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<td>GROUP 4 - Blaster helpers; concrete cutters behind paving machine &amp; pudleers; form setters &amp; finisher asphalt worker</td>
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<td>GROUP 5 - Wiping joints, laying pipe &amp; tile from pumpcarts</td>
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<td>GROUP 6 - Interior of closed tanks &amp; vessels manually</td>
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| LANDLORDS ZONE 4 & 5 | | |
| GROUP 1 - Building & general laborer, carpenter tenders | |
| GROUP 2 - Power tool ops. (hammer men, tamper, vibrator, power buggies, concrete chippers or cutters, chain saw ops., etc.); pipelayers (non-metalllic) | |
| GROUP 3 - Mason tenders, plaster tenders, cement mix (wet or dry) tenders, hod carrier tenders; mortar mixers & cement mixers (wet or dry) | |

FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978
### DECISION NO. LA70-4001

<table>
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<th>PAGE 11</th>
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### Notices

**ZONE 4** Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Natchitoches, Rapides, St. Landry, St. Martin, and St. Landry (southwest of the Red River) & Vermilion Parish

**ZONE 5** Ascension, East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, St. Helena, St. Landry, St. Martin, and St. Martin (northern section) & Vermilion Parish

**ZONE 6** Ascension, East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, St. Helena, St. Landry, St. Martin, St. Martin (northern section), and Vermilion Parish

**ZONE 7** Calcasieu, Jefferson, Lafayette, and Vermilion Parish

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### Decision No. LA70-4001

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#### ZONE 1 - Group 1

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<th><strong>GROUP 2</strong></th>
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### FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978

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NOTICES.

FLAIMERS & FIREFIGHTERS - ZONE 1

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**POWERS EQUIPMENT OPERATORS (BUILDING CONSTRUCTION)**

| Zone 1 | GROUP 1 | 7.70 | .70 | .70 | .70 |
| Zone 2 | GROUP 2 | 7.70 | .70 | .70 | .70 |
| Zone 3 | GROUP 3 | 7.70 | .70 | .70 | .70 |
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| Zone 5 | GROUP 5 | 7.70 | .70 | .70 | .70 |
| Zone 6 | GROUP 6 | 7.70 | .70 | .70 | .70 |
| Zone 7 | GROUP 7 | 7.70 | .70 | .70 | .70 |

FEDERAL REGISTER, VOL. 43, NO. 4 — FRIDAY, JANUARY 6, 1978
### DECISION NO. LATH-6001

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**POW. EQUIPMENT OPERATORS - ZONE 6, 7, 8, 9 (CLASSIFICATION DEFINITIONS)**

- **GROUP 1 - Operator**
- **GROUP 2 - Mechanic helper**
- **GROUP 3 - Oil Vendor**
- **GROUP 4 - Scaleman**
- **GROUP 5 - Air compressor; Asphalt plant; Bulldozers; D-4 & equivalent & under; Bullfloats; Concrete spreaders**
- **GROUP 6 - Snatch mast; Pumps; 3 inch suction or more**
- **GROUP 7 - Asphalt plant; Boom truck; Bullfloats; Concrete spreaders; Farm-type front end loaders; Pneumatic conveyors (cement, sand, etc.); Rollers (other than plant mix asphalt); Scabbled buggies; Winch truck with A-frame (under 5 tons); Work boat not requiring licensed operator**

**NOTICES**

- **GROUP 8 - Snatch mast; Pump; 3 inch suction or more**
- **GROUP 9 - Pumps, under 3 inch suction; Mechanic helper**
- **GROUP 10 - Snatch mast; Pump; 3 inch suction or more**

**POW. EQUIPMENT OPERATORS - ZONE 7**

- **GROUP 1 - Scale Op.; Oil Vendor on motor crane; Batch plant**
- **GROUP 2 - Pumps under 3 inch suction; Mechanic helper**
- **GROUP 3 - Oil Vendor**
- **GROUP 4 - Fireman**
- **GROUP 5 - Combination oil-compressor; Combination oil-fireman; Asphalt spreaders; Backhoes (all types); Bulldozers; Cabayas; Cherry pickers (all types); Concrete mixers (over 1 yard); Cranes; Deck winches (2 drums or over); Derrick; Ditching or trenching machines (riding type); Draglines; Dragways; Fork lifts (other than farm type) outside warehouses; Foundation drill; Front end loaders (except farm type); Gravel screen; Holist-1 drum (40 ft. or under on structures other than buildings); Holist-1 drum (over 40 ft. on structures other than buildings); Holist-2 drums (under 4 stories); Holist-2 drums (over 4 stories); Rollers (plant mix asphalt); Scarpers; Shovel; Sidewalks; Unit op.; Winch, journymen; Wall point systems; Winch truck; Winch truck A-frame (any steel pipe)**
- **GROUP 6 - Snatch mast; Pump; 3 inch suction or more**
- **GROUP 7 - Snatch mast; Pump; 3 inch suction or more**
- **GROUP 8 - Snatch mast; Pump; 3 inch suction or more**
- **GROUP 9 - Snatch mast; Pump; 3 inch suction or more**
- **GROUP 10 - Snatch mast; Pump; 3 inch suction or more**

**NOTICES**

- **GROUP 11 - Scale Op.; Oil Vendor on motor crane; Batch plant**
- **GROUP 12 - Mechanic helper; Oil Vendor**
- **GROUP 13 - Batch plant; Oil Vendor; Mechanic helper; Oil Vendor (drivers)**
- **GROUP 14 - A-frame truck; except when working with ironworkers or pipefitters; Air compressor; Asphalt plant engineer; Asphalt finisher; Backhoe; Blade graders; Blading machines; Bulldozers; Bucket trucks; Chain trucks; Concrete joining machines; Concrete mixers, 16 & under; Concrete spreaders; Creosoting machines; Deck winches (1); Distributors, asphalt "Ditch Witch" & similar equipment; Electric elevators (1); Electric hoists; Finished, motorized; Firemen; Force graders; Fork lifts; Holist-1 drum; Holist-2 drums; Horse draw; Horse grease carriers; Mechanical; Mechanic; Miscellaneous; Motor graders; Motor trucks; Motor vehicles; Operators; Painters; Plant mix asphalt; Scarpers; Shovel; Sidewalks; Unit op.; Winch, journymen; Wall point systems; Winch truck; Winch truck A-frame (any steel pipe); Work boats requiring licensed op.**

**NOTICES**

- **GROUP 15 - Scale Op.; Oil Vendor on motor crane; Batch plant**
- **GROUP 16 - Mechanic helper; Oil Vendor**
- **GROUP 17 - Batch plant; Oil Vendor; Mechanic helper; Oil Vendor (drivers)**
- **GROUP 18 - A-frame truck; except when working with ironworkers or pipefitters; Air compressor; Asphalt plant engineer; Asphalt finisher; Backhoe; Blade graders; Blading machines; Bulldozers; Bucket trucks; Chain trucks; Concrete joining machines; Concrete mixers, 16 & under; Concrete spreaders; Creosoting machines; Deck winches (1); Distributors, asphalt "Ditch Witch" & similar equipment; Electric elevators (1); Electric hoists; Finished, motorized; Firemen; Force graders; Fork lifts; Holist-1 drum; Holist-2 drums; Horse draw; Horse grease carriers; Mechanical; Mechanic; Miscellaneous; Motor graders; Motor trucks; Motor vehicles; Operators; Painters; Plant mix asphalt; Scarpers; Shovel; Sidewalks; Unit op.; Winch, journymen; Wall point systems; Winch truck; Winch truck A-frame (any steel pipe); Work boats requiring licensed op.
## DECISION NO. L78-5001

### ZONE 1 - Mirrilla, Warrier, Gadda, Cluthera, Batea, End River & Wharton Parishes

### ZONE 2 - Avondale, Rosedale, Grant, Lelia, Hatchet, Mountain, Labrador, St. Landry & Vermillion Parishes

### ZONE 3 - All of Acadia, Lafayette & Vernon Parishes; Parts of Iberville, St. Martin & St. Mary Parishes (west of a line drawn from the city of Berwick to the Junction of the Iberville-St. Landry Parishes, border)

### ZONE 4 - Caldwell, Catahoula, Concordia, East Carroll, Franklin, Jackson, Lincoln, Madison, Natchitoches, Richland, Tensas, Union & West Carroll Parishes

### ZONE 5 - Allen, Beauregard, Calcasieu, Cameron, Jefferson Davis & Vernon Parishes

### ZONE 6 - All of Ascension, East Baton Rouge, East Feliciana, Iberville, Pointe Coupee, St. Helena, West Baton Rouge & West Feliciana Parishes; Parts of Assumption & St. James Parishes (northeast of a straight line drawn from the city of Breaux to the city of Lutcher); Parts of Iberville southern & southern St. Martin Parishes (east of a line from the city of Berwick north to the eastern boundary of the city of Kotla Springs); Parts of East Feliciana, Tensas, & Washington Parishes (west of a line drawn north from the city of Lutcher to the east side of the city of Hammond to the La.-Miss. border)

### ZONE 7 - All of Jefferson, Lafourche, Orleans, Plaquemines, St. Bernard, St. Charles, St. John the Baptist, St. Tammany & Terrebonne Parishes; Parts of Assumption, Livingston, St. James, St. Martin, St. Mary, Taneytown & Washington Parishes (that portion of southeastern La. northward by the State of Miss. on the east by the State of Miss. & the Miss. Sound, on south by the Gulf of Mexico & on the west by a line drawn as follows: beginning at a point on the La.-Miss. boundary in Washington Parish due north of the town of Hackley, thence southeasterly in a straight line to a point on the accretion bank of the Miss. River at the southernmost point of Lutcher (including Government in the area); thence in a southeasterly direction in a straight line to midstream of the Achaflaya River at Morgan City-Berwick (including Morgan City in this area) thence southeasterly on a line following midstream of the Achaflaya River to Achaflaya Bay & in a line due south to the Gulf of Mexico)

### POWER EQUIPMENT OPERATORS (HIGHWAY CONSTRUCTION)

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### FEDERAL REGISTER, VOL. 43, NO. 4—FRIDAY, JANUARY 6, 1978
### Decision No. L78-4001

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### Zone 1 - Allen, Baton Rouge, Calcasieu, Cameron, Evangeline, Jefferson Davis, Vermilion

### Zone 2 - Assumption, Jefferson, Lafourche, Orleans, Plaquemines, St. Bernard, St. Charles, St. John the Baptist, South St. Martin, St. Mary, St. Tammany, Terrebonne & Washington Parishes

### Zone 3 - Acadia, Ascension, East Baton Rouge, East Feliciana, Iberville, Lafayette, Livingston, Pointe Coupee, St. Helena, St. Landry, North St. Martin, Tangipahoa, West Baton Rouge & West Feliciana Parishes

### Zone 4 - Avoyelles, Calcasieu, Catahoula, Concordia, East Carroll, Franklin, Grant, Jackson, LaSalle, Lincoln, Madison, Morehouse, Ouachita, Rapides, Richland, Tensas, Union, West Carroll & Winn Parishes

### Zone 5 - Neville, Bossier, Caddo, Claiborne, DeRidder, Natchitoches, Red River, Sabine & Webster Parishes

### Decision No. L78-4001

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### Zone 2 - Jefferson, Lafourche, Orleans, Plaquemines, St. Bernard, St. Charles, St. John the Baptist, St. Tammany, Terrebonne & Washington Parishes

### Zone 3 - Acadia, Allensville, Ascension, Assumption, Beauregard, Cameron, East Baton Rouge, East Feliciana, Evangeline, Iberville, Jefferson Davis, Lafayette, Livingston, Pointe Coupee, St. Helena, St. Landry, St. Martin, St. Mary, Tangipahoa, Vermilion, West Baton Rouge & West Feliciana Parishes

### Zone 4 - Avoyelles, Evangeline, Franklin, Grant, Jackson, LaSalle, Lincoln, Madison, Morehouse, Natchitoches, Ouachita, Rapides, Red River, Richland, Sabine, Tensas, Union, Webster, West Carroll & Winn Parishes

### Zone 6 - Calcasieu, Jefferson, Orleans, Plaquemines, St. Bernard, St. Charles Parishes

### Zone 7 - Assumption, East Baton Rouge, Iberville, West Baton Rouge Parishes

### Zone 8 - Ascension, Lafayette, St. Martin, St. Mary, St. Tammany, Washington & St. Charles Parishes

### Zone 9 - Calcasieu Parish

### Zone 10 - Fellow on crane using air to drive piles

### Group 1 - 60 ton crane & over; Crane with 125' boom

### Group 2 - Crane with 175' boom

### Group 3 - Crane all types; deck cranes; (2) Hi-lift & similar type equipment; 2 cranes (or more) stabilizers; poles all types; concrete mixer 1 yd. & over; overhead dishing or trenching machines (track type); machinery & equipment welders; well point systems; hoses, 2 cranes or more; hoses, 1 crane, 80 vertical ft. or more; scrapers; bulldozers, rubber-tired or track other than farm-type; dump trucks; graders; rollers; graders on hot mix; asphalt paving machines; front end loaders, other than farm-type, 1 cu. yd. or over; shovels & backhoes, all types, & equivalent equipment; pusher-drivers; skid loader; A-frame truck when handling steel or pipe; work boats required licensed ops.; supertanks; fork lifts 10 ton capacity; foundation drilling machines

### Group 4 - 2 cranes stabilizers; front end loaders under 1 cu. yd.; A-frame truck except when handling steel or pipe; finishing machines (concrete); power graders; top tractor (crawler type); 1 crane hoist under 40 vertical ft.; fillers; concrete spreaders; pugmills; bituminous distributor on surface treatment & equivalent; bulldozers & equivalent; job grassers men; unit ops.; work boats not requiring licensed ops.; inboard motorized crew boats

### Group 5 - Single 1 yard stabilizers; concrete mixer under 1 yd.; spray curing machines; rollers on subgrade; 1 air compressor over 125 cu. ft.; form graders; asphalt finisher spreaders; pump crane; crane hoist over 40; scale op.; crane & equipment mixer; concrete saw; tack machines & equivalent equipment; pump crete; electric elevator (inside); oiler-drivers; farm-type, rubber-tired cranes, with attachments, except backhoes; kalam buff & similar equipment; fork lifts, 10 ton capacity & under, onboard crew boats

### Group 6 - Mechanic helper; Batch plant operator

### Group 7 - Loader

### Group 8 - Fireman

### Group 9 - Fireman operating steam valve

### Group 10 - Fellow on crane using air to drive piles

### Group 11 - Dredger & barge Parishes

### Group 12 - Lafayette, Ouachita & Red River Parishes

### Group 13 - Cameron, Jefferson Davis & Red River Parishes

### Group 14 - Ascension, Iberville, Warren, Iberville, Livingston, Richland, St. James, St. John the Baptist, St. Landry, St. Martin, Tangipahoa, Terrebonne, Washington & St. Charles Parishes

### Group 15 - Ascension, Assumption, Evangeline, Franklin, Grant, Jackson, Lafayette, LaSalle, Lincoln, Madison, Morehouse, Natchitoches, Ouachita, Rapides, Red River, Richland, Sabine, Tensas, Union, Webster, West Carroll & Winn Parishes

### Sprinkler Fitters

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**Notes:**

- **Zone 1:** Jefferson, Orleans, Plaquemines, St. Bernard & St. Charles Parishes
- **Zone 2:** East Baton Rouge Parish
- **Zone 3:** Baton & Caddo Parishes
- **Zone 4:** Calcasieu Parish
- **Zone 5:** Lafayette, St. Martin & Vermilion Parishes
- **Zone 6:** Ascension, Assumption, East Baton Rouge, East Feliciana, Iberville, Livingston, Pointe Coupee, St. James, St. Tammany, Washington, West Baton Rouge & West Feliciana Parishes

**Federal Register, Vol. 43, No. 4—Friday, January 6, 1978**
NOTICES

ZONE A - Ascension, Assumption, Avoyelles, Caddo, Catahoula, Bossier, De Soto, Webster, Harrison, Jefferson Davis, Livingston, Red River, Richland, St. James, St. John the Baptist, St. Landry, St. Martin (north of Iberville Par.), St. Tammany, Tangipahoa, Vermilion, Washington, Webster & West Baton Rouge Parishes

ZONE B - Allen, Acadia, Avoyelles, Beauregard, Calcasieu, Caldwell, Claiborne, Concordia, East Carroll, East Feliciana, Evangeline, Franklin, Grant, Jackson, Lafourche, Labette, Lincoln, Madison, Morehouse, Natchitoches, Pointe Coupee, Sabine, St. Helena, St. Martin (south of Iberville Par.), St. Mary, Tangipahoa, Terrebonne, Tensas, Vernon, West Feliciana & Winn Parishes

WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.
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