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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 950

Solicitation of Federal Civilian and Uniformed Services Personnel for Contributions to Private Voluntary Organizations; Correction

Note.—This document originally appeared in the Federal Register of Thursday, July 8, 1982. It is reprinted in this issue to meet requirements for publication on the Tuesday/Friday schedule assigned to the Office of Personnel Management.

AGENCY: Office of Personnel Management.

ACTION: Final rule; correction.

SUMMARY: In publishing final regulations on the solicitation of Federal civilian and uniformed services personnel for contributions to private voluntary organizations in the Federal Register on Tuesday, July 6, 1982 (47 FR 29496), the Office of Personnel Management (OPM) inadvertently omitted from the Supplementary Information section a statement explaining why good cause was found not to delay the effectiveness of the regulations. Publication of the statement is required by 5 U.S.C. 553(d)(3). Accordingly, OPM is correcting this omission by publishing the statement below. The effective date of the regulations is also changed to correspond with publication of this document.

EFFECTIVE DATE: The regulations published on July 6, 1982 (47 FR 29496) become effective July 8, 1982.

FOR FURTHER INFORMATION CONTACT: Joseph S. Patil, Special Assistant for Regional Operations, (202) 632-5544.

SUPPLEMENTARY INFORMATION: The following statement was unintentionally omitted from the Supplementary Information section of final regulations adding Part 950 to Title 5 of the Code of Federal Regulations, published July 6, 1982:

"Pursuant to 5 U.S.C. section 553 and section 1103, the Director of OPM finds that, because of the needs of government managers, military commanders, employee representatives, federated groups, and voluntary agencies to commence preparations immediately for an effective and timely 1982 CFC; because delay in the effectiveness of these regulations would work undue hardships upon all applicants, participants, and Federal employees in the CFC and jeopardize their abilities to raise funds in the Federal work place in 1982; and because considerations of practicality, necessity, and the public interest require the immediate effectiveness of these regulations; good cause exists for making these regulations effective immediately upon this publication."

"The Director of OPM has further determined, consistent with both the former Manual and these regulations, that the deadline for submission by Federated groups and voluntary agencies of applications for admittance to the 1982 campaign is extended until ten (10) days after this publication."

Donald J. Devine, Director.

[FR Doc. 82-18631 Filed 7-8-82; 8:45 am]
BILLING CODE 6255-01-M

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 2

Delegations of Authority by the Secretary of Agriculture and General Officers of the Department; Local Search and Rescue Operations

AGENCY: USDA.

ACTION: Final rule; correction.

SUMMARY: This document corrects a paragraph number and authority citation in a rule appearing in the Federal Register of April 28, 1982 (47 FR 18111) regarding the delegation of authority to implement the local search and rescue operations provisions of the Agriculture and Food Act of 1981.

EFFECTIVE DATE: July 9, 1982.


SUPPLEMENTARY INFORMATION: In the Federal Register of April 28, 1982 (47 FR 18111) the language amending 7 CFR 2.62 added a new paragraph incorrectly numbered (a)(12). The correct new paragraph number should be (a)(13). Additionally, the specific authority citation in 7 CFR 2.19 and 7 CFR 2.62 should be Section 1550, Pub. L. 97-98, 95 Stat. 1344 (7 U.S.C. 2273).

Accordingly, 7 CFR 2.19 and 2.62 are corrected to read as follows:

§ 2.19 Delegations of authority to the Assistant Secretary for Natural Resources and Environment.

* * * * *

(f) * * *


* * * * *

§ 2.62 Chief, Soil Conservation Service.

(a) * * *


* * * * *

Dated: June 28, 1982.
John R. Block,
Secretary.

John B. Crowell, Jr.,
Assistant Secretary, Natural Resources and Environment.

[FR Doc. 82-18631 Filed 7-8-82; 8:45 am]
BILLING CODE 3410-01-M

Agricultural Marketing Service

7 CFR Part 908

[Valencia Orange Reg. 698; Valencia Orange Reg. 697, Amdt. 1]

Valencia Oranges Grown in Arizona and Designated Part of California; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.
SUMMARY: This action establishes the quantity of fresh California-Arizona Valencia oranges that may be shipped to market during the period July 9–15, 1982, and increases the quantity of such oranges that may be so shipped during the period July 2–8, 1982. Such action is needed to provide for orderly marketing of fresh Valencia oranges for the periods specified due to the marketing situation confronting the orange industry.

DATES: This regulation becomes effective July 9, 1982, and the amendment is effective for the period July 2–8, 1982.


SUPPLEMENTARY INFORMATION: Findings. This rule has been reviewed under Secretary's Memorandum 1512–1, and Executive Order 12291 and has been designated a “non-major” rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has determined that this action will not have a significant economic impact on a substantial number of small entities. It would not substantially affect costs for the directly regulated handlers. This action is designed to promote orderly marketing of the California-Arizona Valencia orange crop.

This regulation and amendment are issued under the marketing agreement, as amended, and Order No. 908, as amended (7 CFR Part 908), regulating the handling of Valencia oranges grown in Arizona and designated part of California. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The action is based upon the recommendation and information submitted by the Valencia Orange Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy for 1981–82. The marketing policy was recommended by the committee following a public meeting on February 5, 1982. The committee met again publicly on July 6, 1982, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of Valencia oranges deemed advisable to be handled during the specified weeks. The committee reports the demand for Valencia oranges has improved. 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 30 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 Valencia oranges. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 908

§ 908.998 Valencia Orange Regulation 698.

The quantities of Valencia oranges grown in Arizona and California which may be handled during the period July 9, 1982, through July 15, 1982, are established as follows:

(1) District 1: 235,000 cartons;
(2) District 2: 255,000 cartons;
(3) District 3: Unlimited cartons.

§ 908.997 Valencia Orange Regulation 697.

The lemon crop.

(1) District 1: 329,000 cartons;
(2) District 2: 371,000 cartons;
(3) District 3: Unlimited cartons.

Dated: July 7, 1982.
D. S. Kurylofski,
Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.

EFFECTIVE DATE: The regulation becomes effective July 11, 1982.


SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291, and has been designated a “non-major” rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has determined that this action will not have a significant economic impact on a substantial number of small entities. It would not substantially affect costs for directly regulated handlers. This action is designed to promote orderly marketing of the California-Arizona lemon crop.

This final rule is issued under 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. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The action is based upon the recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy for 1981–82. The marketing policy was recommended by the committee following a discussion at a public meeting on July 8, 1981. The committee met again publicly on July 7, 1982, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons has improved somewhat.

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 30 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 is based and the effective date necessary to effectuate the declared purposes of the act.

Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is...
necessary to effectuate the declared purposes of the act to make these
regulatory provisions effective as specified, and handlers have been
apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910
Agricultural Marketing Service,
Marketing Agreements and Orders,
California, Arizona, Lemons.

Section 910.667 is added as follows:
§ 910.667 Lemon Regulation 367.

The quantity of lemons grown in
California and Arizona which may be handled during the period July 11, 1982,
through July 17, 1982 is established at
290,000 cartons.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C.
601-674)

Dated: July 8, 1982.
D. S. Kuryloksi,
Acting Director, Fruit and Vegetable
Division, Agricultural Marketing Service.

Federal Register
31, Friday, July 9, 1982 / Rules and Regulations

Farmers Home Administration

7 CFR Part 1942

Community Programs Interest Rates

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: This action amends, FmHA regulations to provide alternative
interest rates for water and waste disposal and community facility loans,
depending on the median income of families in the service area. Under
present regulations, certain loans for facilities required to meet health or
sanitary standards where the median family income is below the poverty line
bear interest at the rate of five percent. Other loans bear interest at a rate based
on the current market yield on municipal obligations. This action is necessary to
maintain the concept of interest rates based on market yield for higher income
communities and provide reduced interest rates for additional lower
income communities. The intended effect of this action is to create three
interest rates for community facility and water and waste disposal loans instead
of the two rates not provided for.

EFFECTIVE DATE: July 9, 1982.

FOR FURTHER INFORMATION CONTACT: Wayne Stansberry, Loan Officer,
Community Facilities Loan Division, Farmers Home Administration, Room 6316, South Agriculture Building,
Washington, DC 20250, telephone (202) 382-4900, or Howard Henderson, Loan
Officer, Water and Waste Disposal Loan Division, Farmers Home Administration,
Room 6316, South Agriculture Building, Washington, DC 20250, telephone (202) 382-9586.

SUPPLEMENTARY INFORMATION:

Classification
This action has been reviewed under
USDA procedures established in
Secretary's Memorandum No. 1512-1
which implements Executive Order
12291 and has been determined to be
nonmajor. The rule will not have:
(a) An annual effect on the economy
of $100 million or more; or
(b) A major increase in costs or prices
for consumers, individual industries,
Federal, State, or local government
agencies, or geographic regions; or
(c) Significant adverse effects on
competition, employment, investment,
productivity, innovation, or on the
ability of United States based
enterprises to compete with foreign
based enterprises in domestic or export
markets.

This action requires no change in
recordkeeping or reporting requirements
imposed upon the public.

Clearinghouse Review
The FmHA programs and projects
which are affected by this instruction are subject to State and local
clearinghouse review, in the manner delineated in FmHA Instruction 1901-H.

Environmental Impact
This document has been reviewed in accordance with 7 CFR Part 1901,
Subpart G, "Environmental Impact Statement." It is the determination of
FmHA that this action does not constitute a major Federal action significantly affecting the quality of the
human environment and in accordance with the National Environmental Policy
Act of 1969, Pub. L. 91-190, an Environmental Impact Statement is not
required.

Programs Affected
Catalogue of Federal Domestic Assistance (CFDA) No. 10.423,
Community Facilities Loans; CFDA No.

Background
On September 30, 1981, FmHA
published a final rule to implement
requirements of the Omnibus Budget
Reconciliation Act of 1981. That rule
increased the interest rate on most
income communities while maintaining
somewhat lower interest rates in low
income communities. The new intermediate rate will
apply to projects not required to meet a health or
sanitary standard.

Alternatives
The major alternatives considered and a brief evaluation of each are as follows:
1. Develop additional criteria for
determining that applicants are of low income, thereby allowing more applicants to qualify for the five percent rate. This would not help applicants for projects not required to meet a health or sanitary standard.

2. Establish a sliding scale of interest rates depending on the median family
income of the service area. This alternative would be complicated to administer, confusing to applicants, and might result in substantial subsidies.

3. Establish two additional interest rates, one between five percent and market
rate depending on the median family
income of the service area. This would also be confusing to applicants and
difficult to administer and could result in an excessive percentage of loans
being made at a reduced interest rate.

4. The alternative selected will
maintain the two rates now in use and establish one additional rate halfway between five percent and the market rate. The new intermediate rate will be applied to projects that do not meet the requirements for the five percent rate when the median family income of the service area is not greater than 85 percent of the nonmetropolitan median family income of the State.

This alternative will provide some interest rate reduction to communities with incomes significantly below the median in their State, regardless of whether the income is below the poverty
line or the project is required to meet a health or sanitary standard. It will allow the interest rate to vary with the income of the applicant community, yet limit the number of different interest rates. It will preserve the concept of market rate for a large percentage of the loans and thereby limit the subsidy cost of the programs. FmHA believes this option will maximize the net benefit to society.

Comments

A proposed rule based on alternative number four was published in the Federal Register dated March 30, 1982, page 13366, with a 30 day comment period. Thirty three letters of comments on the proposed rule were received prior to the deadline. Twenty eight additional letters received later were also considered. During a total of 61 comment letters that have been considered in the development of this final rule. Thirty three of the commenters expressed general support for the concept of establishing an intermediate rate. The major issues contained in the comment letters are summarized as follows:

Twenty six commenters felt the figure of 85 percent of Statewide nonmetropolitan median family income, as the maximum for eligibility for the intermediate interest rate, is too low. The most commonly suggested alternative figure was 100 percent. FmHA selected the 85 percent figure based on projections of the percentage of applicants that would qualify, and feels that a higher limit could result in an excessive percentage of loans being made at the reduced interest rate and an excessive subsidy cost for the programs.

Eleven commenters suggested a revised definition of low income be developed, allowing more applicants to qualify for the five percent interest rate. FmHA feels the intermediate rate will be a more effective method of reducing the interest cost for low income communities. The five percent rate requires the additional criterion, not required for the intermediate rate, that the project be required to meet an applicable health or sanitary standard.

Seven commenters felt the eligibility for the intermediate rate should be based on a comparison of service area median family income to the Nationwide median family income rather than the Statewide median family income. FmHA feels the use of a National income standard creates an unfair disadvantage for communities in States with higher overall incomes, operating costs, and living expenses.

Six commenters suggested changing or further defining the source of income data used to make the determinations of which interest rate is applicable to particular projects. FmHA desires to use the most recent and accurate information that is available and administratively feasible for use and to primarily use objective, published data. FmHA further desires to maintain flexibility to adjust exact procedures as new information becomes available and more expertise is developed in using the information.

Five commenters thought the market, or highest, interest rate should be reduced. FmHA believed that would not comply with the spirit of the Omnibus Budget Reconciliation Act of 1981 or the desire of the Administration to reduce the subsidy cost of the programs.

Two commenters suggested the interest rate be established annually rather than quarterly. While this would be much easier to administer it would not be responsive to changing market conditions.

One commenter requested the time of loan approval and time of establishment of the interest rate for each loan be clarified. The language has been revised slightly from the proposed rule to clarify when the interest rate is established. FmHA is considering other regulation changes to clarify what constitutes loan approval.

List of Subjects in 7 CFR Part 1942

Community development, Community facilities, Loan programs—Housing and Community Development, Loan security, Rural areas, Waste treatment and disposal, Water supply.

PART 1942—ASSOCIATIONS

Accordingly, Subpart A of Part 1942, Chapter XVIII, Title 7, Code of Federal Regulations, is amended by revising §1942.17(f) to read as follows:

§1942.17 Appendix A—Community Facilities

(f) Rates and terms.—(1) General.

Each loan will bear interest at the appropriate rate prescribed in FmHA Instruction 440.1, Exhibit B (which is available in any FmHA office). The interest rates will be set by FmHA at least for each quarter of the fiscal year. All rates will be adjusted to the nearest one-eighth of one per centum. The interest rate for each loan will be the rate in effect on the date the signed copy of Form FmHA 1940-1, "Request for Obligation of Funds," is mailed to the applicant. The interest rate to be charged on each loan will be enter on Form FmHA 1940-1 on the date the form is mailed to the applicant. For each loan, the basis for determining what interest rate is appropriate will be completely documented on Form FmHA 442-43, "Project Summary—Community Facilities, (Other Than Utility-Type Projects)," or Form FmHA 1942-45, "Project Summary—Water and Waste Disposal and Other Utility-Type Projects."

(2) Market rate. The market interest rate will be set using as guidance the average of the Bond Buyer Index for the four weeks prior to the first Friday of the last month before the beginning of the quarter. The market rate will apply to all loans that do not qualify for a different rate under paragraphs (3) or (4) of this section. It may be adjusted as provided in paragraph (5) of this section.

(3) Poverty line rate. The poverty line interest rate will not exceed five per centum per annum. It will apply to loans for which the loan approval official determines both the following conditions exist:

(i) The primary purpose of the loan is to upgrade existing facilities or construct new facilities required to meet applicable health or sanitary standards. Documentation will be obtained from the appropriate regulatory agency with jurisdiction to enforce the standard, to verify that a bona fide standard exists, what that standard is, and that the proposed improvements are needed and required to meet the standard; and

(ii) The median family income of the service area is below the poverty line for a nonfarm family of four as prescribed by the Office of Management and Budget (OMB), as adjusted under Section 624 of the Economic Opportunity Act of 1964 (42 U.S.C. 2971d).

(4) Intermediate rate. The intermediate interest rate will be set at the poverty line rate plus one-half of the difference between the poverty line rate and the market rate. It will apply to loans that do not meet the requirements for the poverty line rate and for which the median family income of the service area is not more than 85 percent of the nonmetropolitan median family income of the State.

(5) Prime farmland. For essential community facilities loans, the rate indicated by paragraphs (1), (2), (3), or (4) of this section will be increased by two per centum per annum if the project being financed will involve the use of, or construction on, prime or unique farmland in accordance with FmHA Instruction 440.1, Exhibit B and J (which are available in any FmHA office).

(6) Income determination. The income data used to determine median family income should be that which most accurately reflects the income of the service area. The service area is the
area reasonably expected to be served by the facility being financed by FmHA. The median family income of the service area and the nonmetropolitan median family income for the State will be determined from the U.S. Department of Commerce, Bureau of Census, Publication PC (1)-C Series, or from unpublished Bureau of Census data for individual enumeration districts. If there is reason to believe that the census data is not an accurate representation of the median family income within the area to be served, the reasons will be documented and the applicant may furnish, or FmHA may obtain, additional information regarding such median family income. Such information will consist of reliable data from local, regional, State or Federal sources or from a survey conducted by a reliable impartial source. The nonmetropolitan median family income of the State should be updated, using reliable data from State or Federal sources as such data becomes available.

(7) Repayment terms. Loans will ordinarily be scheduled for repayment on terms similar to those used in the State for financing such facilities but in no case shall they exceed the useful life of the facility or 40 years from the date of the note(s) or bond(s), whichever is less. In all cases, including those in which the FmHA is jointly financing with another lender, the FmHA payments of principal and interest should approximate amortized installments.

(i) If the borrower will be retiring other debts the repayment on such debts may be considered in developing the repayment schedule for the FmHA loans.

(ii) Principal payments may be deferred in whole or in part for a period not to exceed the end of the third full year after the estimated date of loan closing. If for any reason it appears necessary to permit a longer period of deferment, the State Director may authorize such deferment with the prior approval of the National Office. Deferments of principal will not be used to:

(A) Postpone the levying of taxes or assessments.

(B) Delay the collection of the full rates which the borrower has agreed to charge users for its services as soon as major benefits or the improvements are available to those users.

(C) Create reserves for normal operation and maintenance.

(D) Make any capital improvements except those approved by FmHA determined to be essential to the repayment of the loan or to the obtaining of adequate security thereof.

(E) Accelerate the payment of other debts.

(iii) Payment date. Loan payments will be scheduled to coincide with income availability and be in accordance with State law. Monthly payments will be required if consistent with the foregoing, and will be enumerated in the bond, other evidence of indebtedness, or other supplemental agreement. Insofar as practical monthly payments will be scheduled one full month following the date of loan closing; or semiannual or annual payments will be scheduled six or twelve full months respectively, following the date of loan closing or any deferment period. Due dates falling on the 29th, 30th or 31st day of the month will be avoided.

(7 U.S.C. 1986; 7 CFR 2.23; 7 CFR 2.70)

Dated: June 18, 1982.

Frank W. Naylor, Jr.,
Under Secretary for Small Community and Rural Development.

Food Safety and Inspection Service
9 CFR Parts 312 and 381

Official Export Certificates, Marks, and Devices

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations (9 CFR 301.1 et seq.) and the poultry products inspection regulations (9 CFR 381.1 et seq.) to provide for a new "Application for Export Certificate" (MP Form 130-A), which will be used as the basis for granting meat and poultry export certificates. This new form will replace MP Form 412, which is currently used for making applications for meat exports, and will provide an application form for poultry exports (currently, there are no application forms used for poultry exports). A poultry export certificate may also be obtained upon request. In this instance, the inspector will complete the application form based on information supplied by the poultry exporter. A new official export certificate (MP Form 130) will also be used and will replace MP Form 412-3 and MP Form 566, which are respectively used currently for meat and poultry exports. The new export certificate will eliminate the necessity of using three of the four official export marks described in the poultry products inspection regulations. A new letterhead will also be used as part of this new form to replace the current legends on the meat and poultry export certificates.

EFFECTIVE DATE: August 9, 1982.


SUPPLEMENTARY INFORMATION:

Executive Order 12291

This final rule is issued in conformance with Executive Order 12291 and has been determined to be not a "major rule". No significant additional costs on industry are foreseen. This action will provide for a reduction in the existing number of forms and provide uniformity in their use. Consequently, it will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Effect on Small Entities

The Administrator, Food Safety and Inspection Service, has determined that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act, Pub. L. 99-365 (5 U.S.C. 601 et seq.), because the information obtained with respect to the issuance of export certificates is presently required or necessary. Therefore, the new application and export forms are not imposing any significant additional economic impact upon small entities. For instance, poultry exporters will still be able to request a certificate as they do now. In fact, the reduction in number and uniformity in use in regard to the current forms should ease the existing burden. Additionally, the export certificates are required by most foreign countries.

Background

On July 21, 1981, the Food Safety and Inspection Service published a proposal (46 FR 37514) to amend the Federal meat and poultry products inspection regulations to provide for (1) the use of a uniform application for all meat and
poultry export certificates (MP Form 130-A) when an application is used, (2) the use of a uniform meat and poultry export certificate (MP Form 130) to replace the two separate certificates currently in use for meat and poultry exports, (3) the elimination of three of the four official export marks currently described in the poultry products inspection regulations, and (4) the deletion of the certificate legends that now appear on meat and poultry export certificates.

Currently, both the meat and poultry products inspection regulations prescribe how exporters may obtain export certificates, but the regulations are not consistent with one another. Under the Federal meat inspection regulations (9 CFR 322.2), exporters of meat and meat food products must submit an application (MP Form 412) to the inspector in charge in order to obtain an export certificate. However, under the Federal poultry inspection regulations (9 CFR 361.105), exporters of poultry products need only "request" an export certificate. Therefore, to eliminate the inconsistent provisions in regard to the submission of formal applications for an export certificate and to provide for a uniform manner of obtaining export certificates, FSIS has designed a new application form (MP Form 130–A) for use by both exporters of meat and poultry food products and exporters of poultry products.

Information on the application will be reviewed by the inspector prior to issuing an export certificate. However, comments on the proposal have indicated that the requirement that poultry exporters complete an application form imposes a potential burden on the poultry industry. The Agency has accordingly amended this final rule to provide that an export certificate may be obtained by application, or by request. Upon request, the inspector will complete the application form based on information supplied by the poultry exporter.

Additionally, to provide consistency and cost savings, a new official export certificate, MP Form 130, for issuance in connection with meat and poultry exports, has been developed. The new form will combine the information now contained on MP Form 412–3, "Meat Export Certificate", and MP Form 506, "Poultry Export Certificate", on to one form. MP Forms 412–3 and 506 will be discontinued. Therefore, only two forms will be needed for meat and poultry exports—the application (MP Form 130–A) and the official export certificate (MP Form 130). The reduction in the number of forms will provide a projected savings of approximately $1,700 annually, while providing for uniformity in connection with the issuance of export certificates.

Three official marks, shown in figures 8, 9, and 10 of section 381.104 of the poultry products inspection regulations (9 CFR 381.104) and used to identify where the product was inspected and passed for export, are no longer necessary and will be eliminated because of the provisions in the new export certificate. This official export certificate includes blocks for checking where the product was inspected and passed for export, such as slaughter plants, processing plants, warehouses or docksites. Only one mark, figure 11 of § 381.104 of the poultry products inspection regulations (9 CFR 381.104), which is also specified in § 312.8 of the Federal meat inspection regulations and prescribed in § 322.1 of the Federal meat inspection regulations (9 CFR 312.8 and 322.1), will continue to be used to mark outside containers of any products inspected and passed for export.

Additionally, the certificate legend, "United States Department of Agriculture, Animal and Plant Health Inspection Service, Meat and Poultry Products Inspection" prescribed in § 312.8 of the Federal meat inspection regulations (9 CFR 312.8), and the similar legend prescribed in § 361.106 of the poultry products inspection regulations (9 CFR 381.106), will be replaced by a requirement that the certificate bear a letterhead of this Department. This will avoid the necessity for amending the regulations in the event of future Agency name changes.

Comments
The Department received nine comments on the proposal. Comments from the National Meat Association and Tama Meat Packing Corporation supported the proposal in its entirety.

Rocco Farms, Rockingham Poultry Marketing Cooperative, Inc. National Broiler Council, Poultry and Egg Institute of America, and Gold Kist, Inc., indicated support for that portion of the proposal dealing with the use of a uniform export certificate and eliminating three of the four official export marks described in the poultry products inspection regulations. However, these comments opposed the proposed use of an application form to obtain an export certificate for poultry exports, because they believed completing the form would be burdensome for the applicant.

The Agency has carefully considered the burden on the poultry industry of introducing a formal application form for obtaining an export certificate. In the past, poultry exporters have not had to fill out applications to obtain certificates. The applicants have been able to transmit the information orally. Since the PPFA does not specifically require the use of official export certificates for poultry products, the Agency has granted certificates "upon request", in accordance with the requirements of the importing country. Upon further consideration of this issue, the Agency agrees that requiring the submission of written applications rather than permitting oral transmission would be a new and potentially burdensome paperwork requirement on poultry exporters. Therefore, the final rule has been amended to provide that a poultry export certificate may be obtained either by submission of an MP Form 130–A or upon request. In the case of an oral request, the inspector will obtain the information orally and fill out the MP Form 130-A to serve as the basis for the poultry export certificate.

Two comments suggested changes in wording on the export certificate. Spring Valley Farms suggested that the words "Health Certificate", "Veterinary Certificate", or "Sanitary Certificate" be printed on top of the export certificate so the exporter could check the title that best describes the wording used by the foreign country. Swift and Company suggested the words "wholesome and fit for human consumption" be used instead of "sound and wholesome." The Agency notes that the new export certificate has a "Remarks" section where these and other specific statements required by individual foreign countries can be readily added.

In consideration of the foregoing, and pursuant to the authority granted in section 21 of the Federal Meat Inspection Act (21 U.S.C. 621) and section 14(b) of the Poultry Products Inspection Act (21 U.S.C. 441(b)), the Federal meat and poultry products inspection regulations are amended as follows:
Information Collection Requirements

Information collection requirements contained in this regulation (§ 312.17) have been approved by the Office of Management and Budget under the provisions of 44 U.S.C. Chapter 35 and have been assigned OMB number 40R-2297.

Indexing Terms

As required by 1 CFR 18.20 (46 FR 7161, January 22, 1981) the following are the index terms for this regulation:

List of Subjects

9 CFR Part 312

Meat inspection, Official inspection marks, devices, Certificates.

9 CFR Part 381

Poultry inspection, Official inspection marks, devices, Certificates.

Part 312 of the Federal meat inspection regulations (specifically, 9 CFR 312.8(b)) and Part 381 of the poultry products inspection regulations (specifically, 9 CFR 381.104, 381.105(a), and 381.106) are revised as follows:

PART 312—OFFICIAL MARKS, DEVICES AND CERTIFICATES

1. The authority citation for Part 312 reads as follows:


2. Section 312.8(b) of the Federal meat inspection regulations ([9 CFR 312.8(b))] is amended by deleting the words "the legend: United States Department of Agriculture, Animal and Plant Health Inspection Service, Meat and Poultry Products Inspection" and adding the words "a letterhead" to the first sentence to read as follows:

§ 312.8 Official export inspection marks, devices, and certificates.

(a) * * *

(b) The official export certificate required by Part 322 of this subchapter is a paper certificate form for signature by a Program employee, bearing a letterhead and the seal of the United States Department of Agriculture, with a certification that the slaughtered poultry and other poultry products described on the form came from birds that were officially given an ante-mortem and post-mortem inspection and passed in accordance with the regulations of the Department that such products are wholesome and fit for human consumption. The certificate also bears a serial number, such as "MPA 002805", and shows the respective names of the exporter and consignee, the destination, the shipping marks, the names of such products, the total net weight thereof, and such other information as the Administrator may prescribe or approve in specific cases.

Done at Washington, D.C., on: June 23, 1982.

Donald L. Houston,
Administrator, Food Safety and Inspection Service.

[FR Doc. 82-10736 Filed 7-4-82; 8:45 am]
BILLING CODE 3410-DM-M

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

12 CFR Part 5

[Docket No. 82-13]

Rules, Policies, and Procedures for Corporate Activities: Establishment of a Domestic Branch, Seasonal Agency, CBCT (Customer-Bank Communication Terminal) Branches, and Change in Location of a Head Office, Domestic Branch, or CBCT

AGENCY: Office of the Comptroller of the Currency, Treasury.
ACTION: Final rule.

SUMMARY: The Office of the Comptroller of the Currency (Office) is adopting amendments to its policy statements, procedures and forms concerning applications to establish domestic branches, seasonal agencies, CBCT (customer-bank communication terminal) branches and to change the location of head offices, domestic branches, and CBCTs. These amendments reflect the Office's desire to streamline the application process and eliminate unnecessary regulatory analysis and application filing burdens.

EFFECTIVE DATE: August 9, 1982.

FOR FURTHER INFORMATION CONTACT:

Further information also may be obtained from the Regional Director for Corporate Activities in any office of the Regional Administrator of National Banks.

SUPPLEMENTARY INFORMATION: The primary drafter of this document is James E. Brennan, Manager, Policy and Procedures, Bank Organization and Structure Division.

Special Analyses
The Office has determined that under the provisions of the Regulatory Flexibility Act, a regulatory flexibility analysis is not required. The amendments deal with general statements of policy and agency procedures which are exempt from the Act's coverage.

The Office has also considered the requirements of Executive Order 12291. The amendments cover the Office's policies and procedures for applications to establish or relocate domestic branches and CBCT (customer-bank communication terminal) branches, and to relocated head offices. The amendments will clarify that the Office's role in deciding these applications is to assure that the proposal is legal, and that, with respect to the applicant, there are no significant supervisory or Community Reinvestment Act (CRA) concerns that should preclude approval. The Office will reduce substantially the amount of information that must be filed with each application. In particular, the Office will no longer require extensive economic and competitive data. This amendment should reduce considerably the cost to applicants of preparing applications and the cost to the agency of processing them.

It is the Office's opinion that none of the proposals will result in:
1. an annual effect on the economy of $100 million or more;
2. a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions;
3. significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Background
The Office's Corporate Applications Review and Evaluation (CARE) Program, described in 48 FR 66588, dated October 15, 1983, involves a comprehensive review of the Office's rules, policies, procedures and forms governing filings for corporate expansion and structural changes for national banks. The goals of the CARE Program are to minimize costs and burdens on applicants, the agency and the public; to provide a better understanding of policies; to modify or eliminate rules, policies, procedures and forms which are unnecessary or lead to inefficiencies; and to remove barriers to competition. As part of the ongoing program, in the first half of 1981 the Office undertook the extensive review of its policies, regulations, procedures, and forms concerning branching and relocation activities. All national banks should be aware that revised application forms and filing instructions will be available from the regional offices 15 days prior to the effective date of this final rule and applications may be filed with the regional office on the revised form as of the effective date.

Requests for Comments
The proposed rulemaking on branching and relocation activities was published on July 30, 1981 (46 FR 38925), and comments were invited for 60 days, ending September 30, 1981. Over fifty comments were received from national banks, bank holding companies, banking trade associations, consultants, attorneys, Office personnel, and other interested parties.

General Support for the Proposals
Nearly all of the comment letters expressed support for the proposed amendments, especially the provisions that would eliminate the necessity for applicants to submit lengthy economic and competitive information. However, a number of commenters suggested other changes, some of which are incorporated into the final rule and are discussed below.

1. Several commenters noted that the proposed definition of a CBCT branch did not include a further definition or clarification of a "point-of-sale terminal." The commenters noted that "point-of-sale" devices generally act only as sophisticated telephone substitutes in providing a check or credit authorization or verification link to the customer's bank. Such devices (for example) allow merchants to verify immediately with a customer's bank that a proposed purchase, to be effected through the use of a credit or debit card, will be honored or has been previously authorized.

The final rule clarifies that the Office considers a "point-of-sale terminal" to be a CBCT branch if it performs one of the three branching functions stated in 12 U.S.C. 36(f). (In part, 12 U.S.C. 36(f) states that a "branch" is "* * * at which deposits are received, or checks paid, or money lent.") The Office does not consider the type of transaction described in the previous paragraph as within the purview of section 36(f), and concludes that such devices are not CBCT branches.

The Office notes that the continuing developments in the electronic funds transfer field make it impractical to provide a definition of a CBCT branch that will cover all devices that might be presented in the future. In devising its definition, the Office was guided by section 36(f) and the decision reached in Independent Bankers Assn. v. Smith, 534 F. 2d 921, 951-952 (D.C. Cir. 1976), cert. denied, 429 U.S. 802 (1976). The Office believes that the definition will allow banks to determine whether or not a proposed installation will be a CBCT branch in most instances. However, in some instances it may be appropriate and helpful for the bank to contact the regional office for additional guidance.

2. Several comments noted that the proposed amended rules do not provide for the possible elimination or substitution of CBCT locations in multiple-site CBCT applications. The Office does not intend to permit substitution of proposed CBCT sites after the application has been accepted for filing, since it is considered administratively less burdensome to file a separate application rather than to request a substitution. However, the Office will permit elimination of sites from a multiple-site application after it has been accepted for filing; this will be accomplished through internal procedures and application instructions.
3. One comment recommended that the Office further expand its proposed CBCT rules to allow unlimited interstate CBCT branching, as was recently adopted by the Federal Home Loan Bank Board (FHLBB) for federally chartered savings and loan associations. As early as 1974, the Office promoted the view that CBCTs are not branches and thus can be established by national banks without reference to geographic restrictions. An Interpretive Ruling issued to that effect (12 CFR 7.491, 39 FR 44416) was called into question in IBAA v. Smith, cited above. Holding that CBCTs constitute branches under federal law, the court ordered recision of the ruling in 1976 (41 FR 36198).

The Office recognizes the competitive advantage afforded savings and loan associations by the FHLBB’s action, and continues to hold the view that the deployment of CBCTs should not be as limited as that for domestic branches. However, the referenced court action restricts the establishment of CBCTs by national banks to only those locations that would be authorized to similarly situated state chartered banks under state law.

4. Several comments expressed a concern over the requirement in the CBCT application process that the required newspaper notice be published within 5 days after mailing the application (the date placed in the mail is also the acceptance-for-filing date). Although this provision is not a change from current procedures, the commenters have apparently encountered difficulty in arranging for the newspaper publication, especially in areas where the newspaper is published weekly only. To resolve this, the Office will revise its application filing instructions to advise that before the application is mailed the bank should make the arrangements to have the required notice published. In this way, the applicant will be able to determine in advance the date (or approximate date) that the notice will appear, and can mail the application on that date or any time within the preceding five days. The Office anticipates that, by following these instructions, no additional unwarranted delays will be encountered in the application process.

5. One comment stated that the proposed CBCT procedure does not go far enough in streamlining the process. The commenter suggested that national banks be permitted to use the same application process that is required of state banks in the particular state involved. The Office has given considerable thought to this concept in the past and has decided not to adopt such procedures at this time.

In an effort to determine the most expedient process that may be available for national banks, given the constraints imposed by IBAA v. Smith, the Office compared its proposed CBCT application process with that required of state chartered banks. Many states require some form of “30-day prior notice” before establishing CBCTs. In addition, state-chartered non-member insured banks are also required to file with the FDIC a notice, acceptance of which begins a 30-day advance notice process. As the Office’s proposed process was developed, the staff considered the fact that most state banks can receive approval for routine CBCT installations in about 30 days. Therefore, without adopting a “pure notice” process, the Office’s application process for routine CBCT proposals was structured to allow for a decision in as timely a manner as possible. The Office anticipates that the process will provide for a decision in 30 days or less from the time the application is mailed to the regional office in routine cases. While implementing this procedure, the Office is continuing to consider other methods to further shorten the CBCT application process and information requirements.

6. Several comments requested that the Office retain its current procedure of allowing 18 months within which time approved de novo domestic branches and relocations must be accomplished, rather than reducing the time to 12 months. The same comments also suggested that the 18-month period, rather than the proposed 6-month period, apply to CBCTs as well. The commenters noted that in many instances the reduced time would not be sufficient to allow for unanticipated delays due to property acquisition, lease negotiations, construction difficulties, etc. The Office has considered these comments and decided to retain the 18-month period for the establishment and relocation of domestic branches and the relocation of head offices. In addition, the Office has decided to extend from 6 to 9 months the time for establishment or relocation of CBCTs. The Office has also decided to extend, from 6 to 9 months, the time allowed in cases where a bank submits a multiple-site CBCT application.

7. A few comments, including one from a banking trade organization, recommended that guidelines governing CBCT and branch applications include an adequate analysis of the market area. One comment noted further that experience has shown that an institution’s operating plan must be stronger in markets where economic conditions are marginal or in which competition is intense. The Office agrees with the commenter’s views concerning the need for stronger operating plans with respect to proposals for new banks in certain markets. However, except where possibly required by state law, the Office believes that a market or competitive analysis of branch proposals by the Office is not necessary. Through the examination process, the Office analyzes and appraises the extent to which an institution is being managed in a safe and sound manner. This analysis includes an appraisal of the management capabilities, earnings trends, and asset/funds management of the bank. By assigning satisfactory ratings to these and other related factors, the Office is stating that the bank’s overall condition enables it to establish branches and engage in similar expansionary activities, without the need for the Office to analyze the applicant’s market area study at a later date.

8. Several comments objected to the Office’s proposal to require the applicant to submit a revised CRA statement with any application which would change the bank’s existing community delineation. The comments stated that this requirement is onerous and premature because the bank does not know if the application will be approved. The comments noted also that this requirement would be redundant, since 12 CFR 25 requires the bank’s board of directors to revise its CRA statement at its next meeting after the change in the delineation is effectuated. The Office has considered these comments and has changed the regulation so as not to require the applicant to submit a revised CRA statement with the application.

In addition, the Office has determined that its consumer compliance examination and CRA performance appraisal processes provide the Office with all data needed to adequately consider the applicant’s record of helping to meet the credit needs of its entire community, including low- and moderate-income neighborhoods. The revised application form will request the bank to indicate in what ways it intends to vary its lending policy, procedures, or services at the proposed branch, if at all. With this information, the Office may supplement its CRA performance appraisal of the applicant for those proposals that may require further review.
income neighborhoods, consistent with the safe and sound operation of the bank, is less than satisfactory; or 
(ii) Any financial or other business arrangement, direct or indirect, involving the proposed branch or seasonal agency and bank insiders (directors, officers, employees, and shareholders owning or controlling, directly or indirectly, 10 percent or more of any class of the subject bank's voting stock) involves terms and conditions more favorable to the insiders than would be available in a comparable transaction with unrelated parties. 
(d) Community. (1) In order to comply with 12 CFR 25.4(d), if the proposed branch or seasonal agency will change the bank's existing community delineation, the applicant's board of directors must act upon any material change at its next regular meeting after the change, i.e., the establishment of the branch. In the application, the bank must indicate the ways its intends to vary its lending policy, procedures or services at the proposed branch, if at all. 
(2) For the purpose of any market area analysis that may be required by state law referred to in paragraph (c)(1) above, the bank's community as delineated in its CRA statement should be used. 
(e) Fees. A filing fee of $900 is required for each application. 
(f) Decision. Written notification of the decision will be issued in accordance with § 5.13. 
(g) Commencement of business. The branch approval will expire if the branch has not commenced business within 18 months after the date of preliminary approval. Extensions to this period generally are not granted; however, in the event of extraordinary circumstances, renewal requests for extension may be submitted to the regional office. 
(h) Authorization. When all requirements and conditions for opening are satisfied, authorization for operation of the branch or seasonal agency at the location described in the application, will be granted. 
(i) Forms. 
(1) Form to be used by applicant: 
(a) CC 7021-01: Instructions for Filing and Application to Establish: Domestic Branch/CBTC Branch 
(b) CC 7021-02: Confidential Memorandum—Branch/CBTC/Relocation Application 
(c) CC 7021-03: Regional Office Procedures—Applications to Establish Domestic Branches and Applications to Relocate Head Offices or Domestic Branches
the bank's existing community
delineation, the applicant's board of
directors must act upon any material
change at its first regular meeting after
the change, i.e., the establishment of the
branch.

(2) For the purpose of any market area
analysis that may be required by state
law referred to in paragraph (c)(1)
above, the bank's community as
delineated in its CRA statement should
be used.

(e) Rules of General Applicability.
Sections 5.8(a), 5.10, 5.11 and 5.13 do not
apply to this section.

(f) Fees. A filing fee of $500 is required
with each application.

(g) Application filing requirements. (1)
The applicant shall mail an application
form, or a document containing the
information requested in the application
form, to the appropriate regional office.
For the purposes of this section, the
filing date of the application shall be the
date upon which the application was
placed in the United States mail,
postage prepaid, certified or registered
mail, return receipt requested,
within 5 days after filing an
application, applicant shall publish
once, in a newspaper of general
circulation in the community in which
the applicant's head office is located,
and once in a newspaper(s) of general
circulation in the community(ies) in
which the applicant proposes to
establish a CBCT branch(es), a notice
containing the name of the applicant, the
subject matter of the application, the
date on which the application was filed,
and a statement that written comments
on the application must be submitted by
interested persons within 10 days after
the newspaper publication date to the
appropriate regional administrator.
Immediately thereafter, the applicant
shall furnish the regional administrator
with a clipped copy of the newspaper
notice that indicates the publication
dates.

(3) The applicant may request
approval, through a single application,
for as many CBCT branches as the
applicant proposes to establish within
nine months after the preliminary
approval date. Each proposed location
must be listed in the application.

(4) If a national bank proposes to
establish a CBCT branch jointly with
one or more national banks or other
financial institutions, only one of the
national banks must submit an
application as agent for all the national
banks in the group of financial
institutions proposing to share the CBCT
branch. The application must indicate in
an attachment the names and head
office addresses of all the national
banks that propose to establish jointly
the CBCT branch. A national bank that
arranges for its customers to use another
financial institution's automated
teller device on a transactional fee basis
does not require a separate CBCT branch
application.

(h) Written comments on CBCT
branch applications. Within 10 days
after publication of the notice described
in section 5.31(g)(2), any interested
person may submit to the Regional
Administrator written comments
concerning the application. Written
requests for a hearing before the
regional administrator or designee will
be considered only by direction of the
Comptroller.

(i) Decisions. For those CBCT branch
applications that meet delegated
authority criteria (§ 5.3(c)(3) of this
Part), on or before the tenth day after
the end of the comment period a
decision will be made (1) to approve the
application, or (2) that further
consideration of the application is
warranted. If the applicant has not
received notification on or before the
eleventh day after the end of the
comment period that further
consideration of the application is
required, the applicant may conclude
that the application was approved and
may proceed with establishing the CBCT
branch. Written notification of
approvals will be forwarded to all
interested parties within 30 days after
the end of the comment period. If the
application is disapproved, the applicant
will be informed of the basis for the
decision.

(j) Expiration of preliminary approval.
CBCT branch approvals will expire if the
CBCT is not in operation within nine
months after the date of preliminary
approval.

(k) Authorization. (1) The CBCT
branch will be considered established
on the date it becomes operational for
customer use. Except as noted in
paragraph (k)(2) of this section, the bank
must notify the regional office by letter,
confirming the location(s) of the CBCT
branch and the date of establishment
within seven days after the establishment
date.

(2) If preliminary approval is granted
subject to satisfaction of conditions,
authorization for the establishment and
operation of the CBCT branch(es) at the
location(s) described in the application
will be granted following satisfaction of
the conditions. In these instances, the
applicant must advise the regional office
at least two weeks in advance of the
establishment date of the CBCT(s)
branch(es) so that the proper
authorization can be issued.

(l) Forms.
(1) Form to be used by applicant:
CC 7021-01: Instructions for Filing and
Application to Establish: Domestic
Branch/CBCT Branch

(2) Forms to be used by Office:
CC 7021-02: Confidential
Memorandum—Branch/CBCT/
Relocation Application
CC 7021-03: Regional Office
Procedures—CBCT Branch
Applications
CC 7021-04: Branch/CBCT/Relocation
Processing Checklist
CC 7021-05: Branch/CBCT/Relocation—
Review for Accuracy and
Completeness

§ 5.40 Change in location of head office,
domestic branch or CBCT branch.

(a) Authority. A national bank may,
with the approval of this Office, change
the location of its head office in
accordance with 12 U.S.C. 30 or change
the location of a branch office in
accordance with 12 U.S.C. 36(a), and 12
U.S.C. 2901 et seq., subject to the
additional requirements below.

(b) Definition. (1) A relocation of a
head office is one that involves a move to a
location that would be permitted

(2) A domestic branch is defined in
§ 5.30(b). A relocation of a domestic
branch is one that involves a move to a
location to which a branch of a similarly
situated state chartered bank would be
permitted to relocate under applicable
state law governing establishment of or
relocation of state chartered bank
branches.

(3) The legal permissibility of CBCT
branch relocations will be evaluated in
the same manner as relocations of
domestic branches. However, for
procedural and administrative purposes
only, the applicant must follow the filing
procedures described in § 5.31.

(c) Establishment of CBCT branches.

(d) Policy. (1) It is the general policy of
the Office to approve applications to
relocate a head office or a branch office,
provided that approval is consistent
with applicable law.

(2) As provided in section 5.13, the
Office reserves the right to deny
applications, or to grant approval,
supplementary to fulfillment of certain
conditions, if:

(i) There are significant supervisory
concerns with respect to the applicant or
any affiliated organizations as defined
by 12 U.S.C. 221a; or,

(ii) The applicant's record of helping
to meet the credit needs of its entire
community, including low- and moderate-income neighborhoods, consistent with the safe and sound operation of the bank, is less than satisfactory; or,

(iii) Any financial or other business arrangement, direct or indirect, involving the proposed branch or seasonal agency and bank insiders (directors, officers, employees, and shareholders owning or controlling, directly or indirectly, 10 percent or more of any class of the subject bank’s voting stock) involves terms and conditions more favorable to the insiders than would be available in a comparable transaction with unrelated parties.

(d) Community. In order to comply with 12 CFR 25.7(a), if the proposed relocated office will change the bank’s existing community delineation, the applicant’s board of directors must act upon any material change at its first regular meeting after the change, i.e., the relocation of the office. In the relocation, the bank must indicate ways it intends to vary its lending policy, procedures or services at the proposed relocated office, if at all, and must discuss the extent to which services to the community surrounding the present location will be diminished, if at all.

(e) Rules of General Applicability. In addition to the publication requirement of § 5.8(a), a notice must be published on the same day of two consecutive weeks in a newspaper of general circulation in the community in which the office to be relocated is located. In addition, a notice identical to that required by § 5.8(a) must be posted in the lobby of the office to be relocated on the date of the first publication in the newspaper, and must remain posted for 28 days.

(f) Fees. A filing fee of $500 is required with each application.

(g) Decision. Written notification of the decision will be issued in accordance with § 5.13, except for CBCT branches, in which case the same procedures as stated in § 5.31(i) apply.

(h) Commencement of business. The relocation approval will expire if the subject office has not opened at the relocated site within 18 months (nine months for CBCT branches) after the date of preliminary approval. Extensions to this period generally are not granted; however, in the event of unusual circumstances, requests for extension may be submitted to the regional office.

(i) Authorization. When all requirements and conditions for the relocation are satisfied, authorization for the relocation to the location described in the application will be granted.

(j) Forms.

(1) Forms to be used by applicant:
CC 7027-01: Instructions for Filing and Application to Relocate: Head Office/Domestic Branch

(2) Forms to be used by Office:
CC 7021-02: Confidential Memorandum—Branch/CBCT/Relocation Application
CC 7021-03: Regional Office Procedures—Applications to Establish Domestic Branches and for Applications to Relocate Head Office or Domestic Branches
CC 7021-04: Branch/CBCT/Relocation Processing Checklist

Prior to this rulemaking, the official U.S. import and export statistics reflected the movement of merchandise into and out of the Customs territory of the United States and thus excluded merchandise admitted to U.S. Foreign Trade Zones and reexported having never been entered into U.S. Customs territory.

When U.S. Foreign Trade Zone procedures were established (during the 1960’s), there were about a half dozen Foreign Trade Zones in the United States with a very low volume of activity. This number has now increased to over 50 U.S. Foreign Trade Zones, some with related subzones. In addition, the nature of the activities taking place in U.S. Foreign Trade Zones has undergone substantial change. In the earlier years, the activities of U.S. Foreign Trade Zones were confined largely to sorting, grading, marking, and repackaging of merchandise. Current activities are expanding to include major manufacturing, assembling, testing, and other merchandise processing functions. Accordingly, notification was given to members of the ad hoc Interagency Committee on Foreign Trade Statistical Matters, Customs, the Foreign Trade Zone Board, and the Foreign Trade Zones Operators of the Bureau of the Census’ intention to expand the coverage of its foreign trade statistics to include the movement of merchandise into and out of U.S. Foreign Trade Zones.

The information collected in association with this rule will be obtained from Customs Form 214 (O.M.B. No. 1515-0080). Customs requires this form for Zone tenants’ use in applying for admission of merchandise into a U.S. Foreign Trade Zone. Thus, their action does not require any new forms or the collection of any additional information. These documents will serve as the basic source for including in the general import statistics foreign merchandise admitted into U.S. Foreign Trade Zones in terms of the condition of such merchandise when admitted. If such merchandise enters the Customs territory of the United States from U.S. Foreign Trade Zones, it will be included in the import for consumption statistics in terms of its condition when entering the U.S. Customs territory. The procedures will also afford information on movements of domestic merchandise out of the U.S. Customs territory into U.S. Foreign Trade Zones.

Formerly, Form 7513, Shipper’s Export Declaration for Intransit Goods, was used for exports of foreign merchandise from U.S. Foreign Trade Zones but is not
included in the regular export statistics. The inclusion of exports of merchandise from U.S. Foreign Trade Zones in the regular export statistics will simply require that Form 7525-V instead of Form 7513 be used to reflect such movements. If foreign merchandise is exported from the U.S. Foreign Trade Zone in the same condition as when admitted, it will be included in the export statistics as an export of foreign merchandise. If the merchandise has been subjected to processing while in the Zone, such as refining, assembling, manufacturing, and so forth, it will be reflected in the export statistics as an export of domestic merchandise. This is not a major rule in accordance with the criteria set forth in Executive Order 12291. Therefore, no Regulatory Impact Analysis is required. Moreover, the amendment imposes no additional reporting burden on the public, thus satisfying the requirements of the Paperwork Reduction Act of 1980.

Discussion of major comments:
No comments were received.

AMENDMENTS TO THE REGULATIONS: The Foreign Trade Statistics Regulations (15 CFR Part 30) are amended as set forth below.

PART 30—FOREIGN TRADE STATISTICS

1. Section 30.3(a)(2) is hereby amended by removing the words "or from the Foreign Trade Zones" so that as amended the initial sentence reads as follows:

§ 30.3 Shipper's export declaration form.

(a) * * *

(2) For merchandise shipped in transit through the United States, Puerto Rico, or the Virgin Islands of the United States from one foreign country or area to another, including such merchandise destined from one foreign place to another and transshipped in ports of the United States, Puerto Rico, or the Virgin Islands of the United States, and for foreign merchandise exported from General Order Warehouses, the Shipper's Export Declaration for Intransit Goods (Commerce Form 7513) shall be filed.

§ 30.7 Information required on shipper's export declarations.

(a) Port of export. The name of the U.S. Customs port of exportation shall be entered in terms of Schedule D, Classification of Customs Districts and Ports. (See § 30.20(c) for definition of port of exportation.)(The boxes for District and Port codes in the upper portion of the form are to be completed by Customs except where the Customs Director requests that they be completed by the person preparing the declaration.) For shipments by mail, the name of the post office where the package is mailed shall be inserted in the space for U.S. port of export. For merchandise exported after having been in a U.S. Foreign Trade Zone, the letters "PTZ" followed by the Foreign Trade Zone number shall be inserted in lieu of the U.S. port of export.

(b) Importing vessel or carrier. (Not required for merchandise entering U.S. Customs territory from U.S. Foreign Trade Zones.)

5. Section 30.70(c)(1) is hereby revised by inserting between the first and second sentences the statement "This information is not required for merchandise entering the U.S. Customs territory from a U.S. Foreign Trade Zone." As revised, § 30.70(c)(1) reads as follows:

(c) * * *

(1) (Customs Forms 7501, 7502, 7512 and 7521.) For merchandise arriving in the United States by vessel or air, the name and country of the foreign port at which the merchandise was actually loaded on the vessel or aircraft that carried the merchandise to the United States is required. This information is not required for merchandise entering the U.S. Customs territory from a U.S. Foreign Trade Zone. For shipments originating in either Canada or Mexico by rail, truck, pipeline, or other nonvessel/nonair mode of transportation, supply the name of the province (Canada) or state (Mexico) where the merchandise was first loaded for exportation to the United States.

6. A new § 30.70(c)(3) is hereby added immediately following § 30.70(c)(2) to read as follows:

(c) * * *

(3) For merchandise entering the U.S. Customs territory from a U.S. Foreign Trade Zone, the number of the Foreign Trade Zone, preceded by the letters "FTZ" shall be shown in this space.

7. The heading for § 30.70(d) is hereby revised by adding the parenthetical note "(Not required for merchandise entering U.S. Customs territory from U.S. Foreign Trade Zones.)" so that as revised the heading for § 30.70(d) reads as follows:

(d) * * *
FEDERAL TRADE COMMISSION

16 CFR Part 460

Trade Regulation Rule: Labeling and Advertising of Home Insulation

AGENCY: Federal Trade Commission.

ACTION: Temporary partial stay of rules and request for comments.

SUMMARY: The Federal Trade Commission is issuing a temporary partial stay of certain requirements on labeling and advertising of home insulation insofar as those requirements apply to new home sellers. The temporary stay is being issued pending the receipt and evaluation of comments on whether or not to permanently exempt new home sellers from those requirements. The Commission is taking this action based on its tentative determination on a petition filed by the National Association of Home Builders.

DATES: The temporary stay is effective July 9, 1982. Written comments regarding the Commission’s tentative decision to grant a partial exemption to new home sellers will be accepted until September 7, 1982.

ADDRESS: Written comments should be addressed to the Secretary, Federal Trade Commission, 6th and Pennsylvania Avenue, NW., Washington, D.C. 20580. All comments should be captioned: “Comment on petition for exemption for new home sellers—Home Insulation Rule, FTC File No. 215–59.”


SUPPLEMENTARY INFORMATION: The National Association of Home Builders (NAHB) has filed a petition on behalf of all builders and sellers of new of substantially rehabilitated homes (hereafter referred to as “new home sellers”) requesting exemption from the Commission’s Rule.

The petition from NAHB, Bureau of the Census, Pennsylvania Avenue, NW., 7, 1982.

Bruce Chapman, Assistant Secretary, Department of the Treasury.

List of Subjects in 15 CFR Part 30

Census Bureau, Economic statistics, Foreign trade, Reporting requirements.


§ 30.80 [Reserved]

8. Section 30.80 is hereby removed in its entirety and that section number is reserved for future use.

(Title 13, United States Code, section 302; and title 5, United States Code, section 301; Reorganization Plan No. 5 of 1950; Department of Commerce Organization Order No. 35–2A, August 4, 1973, 40 FR 4275.)

List of Subjects in 15 CFR Part 30

Census Bureau, Economic statistics, Foreign trade, Reporting requirements.

Bruce Chapman, Bureau of the Census.

I concur:

J. M. Walker, Jr., Assistant Secretary, Department of the Treasury.

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BILLING CODE 3510–07–M

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1 The petition from NAHB, dated April 15, 1981, has been placed on the public record and is available for public inspection. It has been filed as Document No. X–18 in FTC File No. 215–59.

The Commission is persuaded, however, that the disclosures required by §§ 460.18(a) and 460.18(c) may not be necessary to prevent the unfair or deceptive acts or practices to which the Rule relates. In insulation advertising, R-value information is material information because thermal performance is the major criterion in the insulation purchase and can only be measured by R-value. While R-value information is material to new home buyers, and therefore must be disclosed to them under § 460.18 in the sales contract, R-value information in new home advertising is less material than in insulation advertising. Consequently, any harm to consumers flowing from the failure to disclose R-value information in new home advertisements is likely to be relatively minor and cured by the disclosure of such information at the time of sale. Indeed, it is possible that such disclosures in new home advertisements would confuse or mislead consumers or discourage reference to helpful energy-savings information. Consequently, the Commission has tentatively determined that new home sellers should be exempted from §§ 460.18(a) and 460.18(c).

Section 460.18(a) also requires ads giving insulation R-values to explain R-values by stating: "The higher the R-value, the greater the insulating power. Ask your seller for the fact sheet on R-values." This provision is based on the Commission's belief that consumers do not understand the R-value concept. The FTC staff's compliance guidelines, noting that the Rule does not require new home sellers to make fact sheets available to consumers, permit advertisers of new homes to delete the reference to fact sheets from the disclosure. Thus, FTC staff has given an opinion that the following disclosure required by § 460.18(a) is appropriate for new home sellers: "The higher the R-value, the greater the insulating power." The Commission has tentatively determined that it is appropriate to formalize the staff's advice and to exempt new home sellers from the second sentence of the disclosure requirement. This exemption would apply whenever the seller is required to make the § 460.18(a) statement.

Upon review of the other paragraphs of Section 460.18, the Commission does not believe that there are adequate grounds for the granting of an exemption. The Commission believes that the reasoning behind those requirements, as discussed in detail in the Rule's Statement of Basis and Purpose, applies to new home sellers. Therefore, the Commission has tentatively decided to grant an exemption only from the disclosure requirements of §§ 460.18(a) and 460.18(c). All other requirements of § 460.18 will continue to apply to new home sellers who make the triggering claims about insulation products defined in that section of the Rule.

NAHB also has petitioned for an exemption from Section 460.19, or at least from § 460.19(c). Section 460.19 sets forth the Rule's requirements pertaining to savings claims. There are six subparts in this section. Section 460.19(a) requires insulation materials that make a savings claim to have a reasonable basis for the claim. Section 460.19(b) requires promotional materials containing savings claims to contain the following statement: "Savings vary. Find out why in the seller's fact sheet on R-values. Higher R-values mean greater insulating power." If promotional materials state that a combination of products can cut fuel bills or use, § 460.19(c) requires the advertiser to list the combination of products and to state how much of the savings is due to each product. If exact figures are not possible, the products must be ranked. Section 460.19(d) explains what disclosures are required in promotional materials which contain claims of savings. Section 460.19(e) permits nonmanufacturers to rely on information provided by the manufacturer as a reasonable basis for their savings claims. Section 460.19(f) requires advertisers to keep records of all data on savings claims for three (3) years after the claim is made.

Only § 460.19(c) is addressed specifically by the NAHB petition. NAHB argues that § 460.19(c) goes beyond the Rule's stated scope and puts the home builder in the position of having to test building components for their energy savings. According to NAHB, the home builder is likely to use many products with energy saving features in the construction of a new home. Many of these products—for example, storm windows and doors—are not covered under the Rule. These products are not necessarily tested by their manufacturers for their energy savings potential. Yet the Rule requires the home seller making a savings claim to list the products in the order of their savings. According to NAHB, the home builder is, in effect, required to say how much savings come from each product without the necessary information.

NAHB suggests that § 460.19(c) is intended to inhibit installers or contractors who might attempt to reap additional profits by selling the homeowner a retrofit package consisting of one useful conservation product and others having only marginal value. However, according to NAHB, this problem is unlikely in the building industry, where the high cost of housing gives the builder the incentive to reduce costs by eliminating superfluous costs such as energy-saving products of marginal value. NAHB therefore contends that this section of the Rule does not produce benefits that justify the burden it places on the home building industry.

The Commission agrees with NAHB's assertion that this provision was not designed to apply to advertising claims made by new home sellers. Instead, the section was designed to cover energy savings claims made for a combination of products sold by insulation contractors or other retailers. The purpose of the provision is to apprise consumers of the fact that not all of the advertised products contributed equally to the energy savings achieved by the combination. The Rule provision thus enables consumers to make cost-effective purchase decisions concerning the individual products.

A new home builder may use numerous energy conserving products and construction techniques when designing a home package. Because of the number of products in such a package and the overlap in energy savings achieved, it becomes very difficult, if not impossible, for a new home seller to disclose the amount of savings that may be attributed to the various individual products. Thus, the Commission believes that requirements of § 460.19(c), if applied to new home advertising, may have the undesired effect of discouraging the promotion of energy efficient homes.

The Commission's staff has informally advised new home sellers that § 460.19(c) applies only to promotional claims in retrofit situations, and not to those affecting new homes. The Commission recognizes that such staff advice is not consistent with the literal wording of § 460.19(c), but the Commission agrees with the staff that the section should not apply to new
home sellers. Therefore, the Commission has tentatively decided to grant an exemption from § 460.19(c) to new home sellers.

NAHB does not present justification for an exemption from the other provisions of § 460.19. The Commission's analysis of the other provisions suggests that in addition to § 460.19(c) new home sellers should be exempted only from § 460.19(b). Section 460.19(b) requires ads which make savings claims about insulation to state that the savings vary, and to make a reference to the seller's fact sheet for further information. However, as discussed in connection with § 460.18(a), the Rule does not require new home sellers to have fact sheets; for this reason, the Commission staff has advised new home sellers that it is appropriate for them to delete the reference to fact sheets when making the savings disclaimer. The Commission agrees with the staff's reasoning, and has tentatively decided to grant new home sellers an exemption from the reference to fact sheets as it appears in § 460.19(b). Thus, the disclosure required of new home sellers who make savings claims will read: "Savings vary. Higher R-values mean greater insulating power."

Pending a final decision, the Commission has issued a temporary partial stay of §§ 460.18(a), 460.19(c), 460.19(b), and 460.19(c) insofar as they apply to new home sellers. In all other respects, the Commission believes the provisions of §§ 460.18 and 460.19 should continue to apply to new home sellers.

The Commission solicits public comment on the proposed exemption for new home sellers. Following the comment period, the Commission will review the comments received and will make a final decision on the exemption request.

List of Subjects in 16 CFR Part 460
§ 460.18 and § 460.19 [Amended]
Accordingly, the Commission has issued a temporary partial stay of §§ 460.18(a), 460.19(c), 460.19(b) and 460.19(c) insofar as they apply to new home sellers.

By direction of the Commission.
Carol M. Thomas,
Secretary.

SECURITIES AND EXCHANGE COMMISSION
17 CFR Parts 210, 229, 230, 231, 239, 240 and 249
[Release Nos. 33-6413; 34-18842; 35-22547; IC-12504; FR-2; File No. S7-906]

Instructions for the Presentation and Preparation of Pro Forma Financial Information and Requirements for Financial Statements of Businesses Acquired or To Be Acquired

AGENCY: Securities and Exchange Commission.

ACTION: Final rules.

SUMMARY: The Commission announces the adoption of uniform instructions for the presentation and preparation of pro forma financial information in Commission filings. The rules codify existing administrative practices and do not significantly modify the various situations for which pro forma financial presentations are now required or alter the specific disclosures required by existing accounting literature. However, the rules do provide for an optional presentation of a financial forecast in place of certain of the required pro forma information. In addition, the Commission announces adoption of revised requirements for filing financial statements of businesses acquired or to be acquired which provide for variable disclosure depending on the significance of the acquisition to the registrant.

Finally, Form 8-K and various other Commission reporting requirements have been amended to reflect adoption of these rules.

DATE: The rules adopted herein are effective for filings with the Commission after September 30, 1982; early application of these rules in their entirety is permitted.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: The Commission has adopted rules which incorporate in Regulation S-X ("S-X") (17 CFR Part 210) its administrative policies and practices applicable to the presentation and preparation of pro forma financial information included in certain filings with the Commission. The rules are intended to simplify and improve the registration and reporting process by codifying current policies developed by the Commission's Division of Corporation Finance through the comment process as well as those practices generally followed by registrants when presenting pro forma financial information in Commission filings. The rules do not significantly change or expand the various reporting situations for which pro forma financial information has been presented in the past, but they will generate pro forma financial information which distinguishes between the one-time impact and on-going impact of the transaction more clearly than such information has done historically.

Further, as part of the Commission's effort to encourage presentation of projected financial information, the rules permit registrants to present a financial forecast in lieu of certain of the pro forma information.

In addition, the Commission has adopted rules which in certain situations significantly reduce the reporting requirements for financial statements of businesses acquired or to be acquired. The revised requirements are based on the significant subsidiary tests using a sliding scale so that the requirements for filing such financial statements as well as the periods covered by such financial statements will vary with the impact of the acquisition on the registrant.

Finally, Form 8-K has been amended to require the filing of pro forma financial information consistent with the concepts underlying the Commission's integrated disclosure system and to revise the provision relating to extension of time to file required financial statements. Several minor modifications of various Commission reporting requirements have been made to reflect adoption of these rules and to effect certain technical amendments.

Background

Pro forma financial information is principally used to show the effect of certain significant transactions which (a) occur or become probable after the date of the historical financial statements or (b) have occurred during the year and are not fully reflected in the historical financial statements. Pro forma disclosures are specifically required in a number of circumstances under generally accepted accounting principles (GAAP) and are also required in certain filings with the Commission to facilitate investor understanding of certain significant transactions.

Notwithstanding this frequent use, guidance about the presentation and preparation of pro forma financial information is limited, and as a result,
the form and content of these disclosures can vary significantly.

Problems encountered with pro forma disclosures in specific filings have been resolved by the Commission staff on a case-by-case basis. As a consequence, informal policies and practices have developed. The Commission believes that its administrative policies and practices should be set forth as formal regulations so that registrants know when and what pro forma financial information is required. Thus, the Commission has amended S-X to establish uniform instructions for the presentation and preparation of pro forma financial information.

As a part of the development of these new guidelines and in response to commentators' concerns, the Commission has reexamined its rules relating to the presentation of historical financial statements of businesses acquired or to be acquired. As a result of this review, the Commission has adopted amendments which significantly modify the requirements for presentation of these financial statements.

Proposal and Comment

In Securities Act Release No. 6350 (September 24, 1981), the Commission invited comment on uniform instructions for the presentation and preparation of pro forma financial information in Commission filings. In addition, that release proposed to consolidate existing provisions relating to financial statements of companies acquired or to be acquired.

The Commission received 31 letters of comment on these proposals. Although substantially all of the commentators endorsed the objective of the rule proposals, various improvements were suggested and changes in the rules reflect some of these suggestions. The major comments are listed below and the Commission's responses to those suggestions are discussed in the following section.

Pro Forma Financial Information

1. Commentators objected to the proposal to require disclosure of nonrecurring charges and credits in a table immediately following the pro forma condensed income statement because of concern that such disclosure would be inappropriate in some cases and create ambiguity as to whether all nonrecurring items or only those attributable to the transaction had been included in the table. Footnote disclosure of these items was suggested by some as sufficient to highlight the one-time cost or benefit of the transaction to the registrant.

2. Approximately one-third of the commentators opposed the option to present a financial forecast in lieu of a pro forma income statement because of concern that the greater number of assumptions necessary to the preparation of a forecast as compared with a pro forma income statement adversely affects the accuracy of the former and its relevance to the transaction. In addition, in the opinion of most commentators, an independent accountant's review of a financial forecast would subject registrants to increased costs without significantly enhancing the reliability of the forecast.

3. Commentator response to the invitation to comment on whether pro forma financial information should be required in reports on Form 8-K was mixed with most commentators suggesting that inclusion of pro forma financial information in Form 8-K be optional. Those who objected to a requirement primarily cited the time constraint in the filing requirement.

Financial Statements of Businesses Acquired or To Be Acquired

1. Commentators questioned the need for financial statements of acquired businesses for periods prior to their acquisition.

2. In addition, commentators urged the Commission to revise the rules for financial statements of businesses acquired or to be acquired to call for summarized or condensed financial data or no information at all under certain circumstances.

Comments Applicable to Both Pro Forma Financial Information and Financial Statements of Businesses Acquired or To Be Acquired

1. Commentators' responses to the Commission's question relating to the need for a definition of or guidelines on the meaning of the term "business" were mixed. Some argued that a definition might restrict necessary flexibility while others requested that the Commission clarify how it believes a business is involved to facilitate registrants' understanding of when pro forma financial information and financial statements of a business acquired or to be acquired are required.

2. Various commentators objected to the proposal to require pro forma data or financial statements for planned transactions when consummation of the transaction is "probable" even though the transaction may be subject to shareholder approval.

Discussion of Rules

Pro Forma Financial Information

Presentation Requirements

New Rule 11-01 lists various situations for which pro forma financial information is required. In addition to business combinations and dispositions, entities sometimes enter into other types of significant transactions for which pro forma financial information should be presented. Such transactions might include reorganizations, unusual asset exchanges and restructuring of existing indebtedness. It is not possible to anticipate all of the situations for which pro forma financial information should be presented, so a comprehensive listing of situation has not been incorporated in the rules. Registrants must exercise judgment in determining whether pro forma financial information will be meaningful in light of the particular facts and circumstances of the transaction.

Rule 11-01 establishes criteria for determining the significance of a business combination or disposition of a business for purposes of furnishing pro forma financial information. As with new Rule 3-05, the criteria are those used in the definition of significant subsidiary.

Preparation Requirements

Rule 11-02 contains rules and instructions for the preparation of pro forma financial information. These rules have been drafted in a broad fashion since flexibility is necessary to tailor pro forma disclosures to particular events and circumstances.

The presentation requirements for the pro forma condensed statement of income are designed to elicit disclosures that clearly distinguish between the one-time impact and the on-going impact of the transaction and thereby assist investors in focusing on the transaction at hand. Therefore, the rules call for the pro forma condensed income statement to show the impact of the transaction on income from continuing operations of the registrant; any discontinued operations, extraordinary items and the cumulative effects of accounting changes would not be reflected in the condensed historical financial statements used as the starting point for the pro forma presentation.

The rules provide that the only adjustments that are appropriate in the preparation of the pro forma condensed statement of income are those which

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1 The proposing release stated that such point in time is generally reached when an agreement in principal has been reached or when the board of directors has reached agreement on the transaction.

2 The Commission may study the provisions of Rule 370 of the Securities Act as part of its merger proxy project. This rule currently precludes presentation of pro forma data when there is no guarantee that all securities offered will be taken.
give effect to events that are (i) directly attributable to the transaction, (ii) expected to have a continuing impact on the registrant, and (iii) factually supported, nonrecurring charges or credits which result directly from the transaction and which will impact the income statement during the next 12 months should not be reflected in the pro forma condensed income statement, but should be separately disclosed (although not necessarily in a table, as proposed) with a clear indication that such charges or credits were not considered in the pro forma condensed income statement. Thus, the “bottom line” of the pro forma column of the condensed income statement will be “income (loss) from continuing operations before nonrecurring charges or credits directly attributable to the transaction.” If, of course, the transaction for which the pro forma financial information is presented relates to a disposition of a business segment, the material nonrecurring charges or credits directly attributable to the transaction adjusted to give effect to the proposed disposition of the business segment, the “bottom line” caption(s) in the pro forma condensed income statement should be revised accordingly, e.g., “income (loss) from continuing operations before nonrecurring charges or credits directly attributable to the transaction adjusted to give effect to the proposed disposition of company A.” The pro forma condensed balance sheet, on the other hand, should reflect pro forma adjustments for all events which are directly attributable to the transaction and factually supportable regardless of whether the impact is expected to be continuing or nonrecurring since the objective of the pro forma balance sheet is to reflect the impact of the transaction on the financial position of the registrant.

Financial Forecasts

Rule 11-03 permits registrants to file a financial forecast in lieu of the pro forma condensed statements of income. This provision is consistent with the Commission’s goal of encouraging the disclosure of future-oriented information when appropriate. The Commission believes that in certain circumstances the use of a forecast to reflect the impact of a transaction may be more relevant than a pro forma condensed income statement. Thus, the rules provide that this alternative may be used at the option of the registrant.

The Commission understands that there are many factors, in addition to those which are related to the transaction at hand, which must be considered in developing a forecast. The rules provide that when the forecast option is used, the assumptions particularly relevant to the transaction and effects thereof should be clearly set forth so that the effect of the transaction will not be obscured by the other data included in the forecast.

Financial Statements of Businesses Acquired or To Be Acquired

The Commission’s requirements for financial statements of businesses acquired or to be acquired have been consolidated in new Rule 3-05 of S-X.3 The reporting process should be simplified by the Commission’s revision of these requirements which (1) base the number of periods for which financial statements are required on the significance of the acquisition and (2) limit the presentation of financial statements of businesses acquired in the past. The Commission recognizes that certain acquisitions have a greater impact on a registrant than others and, accordingly, has adopted a sliding scale type of requirement which determines the periods for which such financial statements are required.4 The sliding scale test is based on the conditions specified in the definition of significant subsidiary5 and although the percentages used are arbitrary, the Commission believes that they meet the objectives of providing adequate financial information to investors, shareholders and other users while at the same time reducing the reporting burdens of registrants involved in acquisitions.

The revised requirements adopted herein make the waiver procedures set forth in Securities Act Release No. 4950 obsolete. Therefore, the Commission is rescinding that release and the corresponding instruction in Form 8-K at this time.

The Commission has also reexamined the need for furnishing financial statements for businesses acquired in the past and has determined to codify the present staff practice of generally not insisting on the presentation of separate financial statements of an acquired business once the operating results of the acquired business have been reflected in the audited consolidated financial statements of the registrant for a complete fiscal year. The one exception to this general rule is when the acquired business is of such significance to the registrant that omission of its financial statements would materially impair an investor’s ability to understand the historical financial results of the registrant.

Codification of this practice will mean that registrants will be required to present separate financial statements of an acquired business when (1) the acquisition of the business is probable, (2) the business has been acquired during the latest fiscal year for which audited financial statements of the registrant are required or during the period between the end of the latest fiscal year and the filing date or (3) the business acquired was extremely significant to the registrant.

The Commission considered reducing the required disclosures to a condensed or summarized financial information level, but concluded that this level of disclosure would not be adequate for two reasons. First, there is important information contained in the notes to the financial statements which would not be reflected in condensed or summarized financial information. Second, there is currently no provision in the existing auditing literature which permits an independent auditor to issue a report on condensed or summarized financial information of nonpublic companies, and the Commission believes that certification of this financial information is essential in acquisition situations.

Requirements Applicable to Both Pro Forma Financial Information and Financial Statements of Businesses Acquired or To Be Acquired

Guidance About What Is a “Business”

A recurring problem in deciding whether separate historical financial statements and pro forma financial information is required for business combinations is the determination of whether a “business” has been acquired. In order to assist registrants, the Commission has included in new Rule 11-01 guidelines which are relevant to that determination; however, the Commission cautions registrants that these guidelines may not be all inclusive or determinative. Registrants must continue to exercise judgment in this area.

Businesses To Be Acquired and Other Transactions not yet Consummated

Frequently, a registration statement is filed at a time when management is
considering a transaction (e.g., a business combination) which is unrelated to the reason for which the registration statement is being filed. In these situations, a question arises about whether historical financial statements of the business to be acquired and pro forma financial information reflecting the unrelated transaction should be included in the filing. The rules provide that these disclosures are required when it is probable that the transaction will be consummated. Guidance as to when consummation of a transaction is probable cannot be given because such a determination is dependent upon the facts and circumstances. In essence, however, consummation of a transaction is considered to be probable whenever the registrants’ financial statements alone would not provide investors with adequate financial information with which to make an investment decision.

Form 8-K

Form 8-K plays a critical role in the integrated disclosure system which is intended to provide investors with a continuous stream of corporate information. Reports on Form 8-K are used to disclose material information concerning certain specified events that have occurred since the latest annual report on Form 10-K or quarterly report on Form 10-Q was filed.

In light of the enhanced role this Exchange Act report plays in the continuous stream of corporate information, the Commission has amended this form to require reporting of pro forma financial information pursuant to Article 11 of Regulation S-X whenever a significant business combination or disposition of a business is consummated. The Commission believes that investors should be informed of the potential financial statement impact in these circumstances. The Commission has also amended Form 8-K to be consistent with the new requirements for filing financial statements of a business acquired or to be acquired. Thus, when reporting business acquisitions on Form 8-K or in certain registration statements, registrants need only look to one test to determine the need for and periods to be covered by financial statements of a business acquired or to be acquired. In addition, the Commission has amended Form 8-K to make clear that the required financial statements and pro forma financial information should be included, if practicable, in the Form 8-K report filed within 15 days of the occurrence of the acquisition or disposition. Thus, the Form provides that the required financial statements and information shall be presented in the report on Form 8-K, but also provides that, if it is impracticable to file the required statements or information at the time the Form 8-K is filed, the Commission may, upon written request, grant an extension of time. While some commentators expressed concern about the time constraints imposed by a requirement for pro forma financial information in Form 8-K, the Commission believes that, once required historical financial statements are available, preparation of pro forma financial information does not involve significantly more preparation time. Moreover, any time constraints which do exist should be ameliorated, where necessary and appropriate, by the granting of specific extensions.

Other Changes

Regulation S-X

Several housekeeping changes have been made to Regulation S-X. For example, the substance of former Article 11, “Contents of Statements of Other Stockholders’ Equity” [17 CFR 210.11], which specifies reporting requirements for changes in other stockholders equity, has been moved to Rule 3-04. In addition, the Commission has deleted Article 11A, “Statement of Source and Application of Funds” [17 CFR 210.11A] because that article required disclosure substantially similar to the information required by Accounting Principles Board Opinion No. 19, “Reporting Changes in Financial Position.”

Forms S-1, S-2, S-3 and S-18

Forms S-1, S-2, S-3 and S-18 have been amended to reflect the adoption of Rule 3-05 and Article 11. Additionally, several technical amendments to cross references in Form S-18 have been made.

Form 10-K and Annual Reports to Security Holders

Form 10-K has been amended to specify that the information required by Rule 3-05 and Article 11 need not be disclosed. (This exemption was previously in Rules 3-07 and 3-08.) Annual reports to security holders continue to be exempt from these disclosures.

Technical Amendments

The Commission is also adopting technical amendments which, among other things, (1) revise Rule 3-05 of Regulation S-X to clarify that the conditions under which separate financial statements of unconsolidated subsidiaries and 50 percent or less owned persons need not be audited for prior years are to be based on 20 percent measurements and (2) conform Schedule III under Rule 7-05 of Regulation S-X with the revised requirements for condensed parent company financial information.

Codification Update

The “Codification of Financial Reporting Policies” announced in Financial Reporting Release 1 (April 15, 1982) (47 FR 21028) is updated to:

1. Add a new section, Section 506, entitled as follows:

506 Pro Forma Financial Information and Financial Statements of Businesses Acquired or to be Acquired

2. Include in Section 506 the sections of this release entitled “Background,” “Discussion of Rules” and “Form 8-K” numbered as specified below:

.01 Background

.02 Discussion of Rules

a. Pro Forma Financial Information

i. Presentation Requirements

ii. Preparation Requirements

iii. Financial Forecasts

b. Financial Statements of Businesses Acquired or to be Acquired

c. Requirements Applicable to Both Pro Forma Financial Statements of Businesses Acquired or to be Acquired

i. Guidance About What is a “Business”

ii. Businesses to be Acquired and Other Transactions not yet Consummated

.03 Form 8-K

Regulatory Flexibility Act Certification

Pursuant to Section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Chairman of the Commission
has certified that the adopted amendments will not have a significant economic impact on a substantial number of small entities. This certification, including the reasons therefore, is attached to this release.

List of Subjects in 17 CFR Parts 210, 229, 230, 231, 239, 240 and 249

Accounting, Reporting requirements, Securities.

Text of Rules

In accordance with the foregoing, 17 CFR Chapter II is amended as follows:

PART 210—FORM AND CONTENT OF AND REQUIREMENTS FOR FINANCIAL STATEMENTS, SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934, PUBLIC UTILITY HOLDING COMPANY ACT OF 1935, INVESTMENT COMPANY ACT OF 1940, AND ENERGY POLICY AND CONSERVATION ACT OF 1975

1. By revising paragraph (v)(1) of § 210.1-02 to read as follows:

§ 210.1-02 Definitions of terms used in Regulation S-X (17 CFR Part 210).

• • • •

(v) Significant subsidiary.

• • • •

(1) The registrant’s and its other subsidiaries’ investments in and advances to the subsidiary exceed 10 percent of the total assets of the registrant and its subsidiaries consolidated as of the end of the most recently completed fiscal year (for purposes of determining whether financial statements of a business acquired or to be acquired in a business combination accounted for as a pooling of interests are required pursuant to § 210.3-05, this condition is also met when the number of common shares exchanged by the registrant exceeds 10 percent of its total common shares outstanding at the date the combination is initiated); or

• • • •

2. By revising paragraph (a) of § 210.3-02 to read as follows:

§ 210.3-02 Consolidated statements of income and changes in financial position.

(a) There shall be filed, for the registrant and its subsidiaries consolidated and its predecessors, audited statements of income and changes in financial position for each of the three fiscal years preceding the date of the most recent audited balance sheet being filed.

• • • •

§ 210.3-06 Redesignated as § 210.3-03

3. By redesignating § 210.3-06 as § 210.3-03.

§ 210.11-01 and § 210.11-02 [Removed]

4. By removing §§ 210.11-01 and 210.11-02 (Article 11) and combining their substance in a new § 210.3-04 to read as follows:

§ 210.3-04 Changes in other stockholders’ equity.

An analysis of the changes in each caption of other stockholders’ equity presented in the balance sheets shall be given in a note or separate statement. This analysis shall be presented in the form of a reconciliation of the beginning balance to the ending balance for each period for which an income statement is required to be filed with all significant reconciling items described by appropriate captions. State separately the adjustments to the balance at the beginning of the earliest period presented for items which were retroactively applied to periods prior to that period. With respect to any dividends, state the amount per share and in the aggregate for each class of shares.

5. By adding § 210.3-05 to read as follows:

§ 210.3-05 Financial statements of businesses acquired or to be acquired.

(a) Financial statements required.

(1) Financial statements prepared and audited in accordance with this regulation should be furnished for the periods specified in paragraph (b) below if any of the following conditions exist:

(i) Consumption of a business combination accounted for as a purchase has occurred or is probable (for purposes of this rule, the term "purchase" encompasses the purchase of an interest in a business accounted for by the equity method); or

(ii) Consumption of a business combination to be accounted for as a pooling of interests is probable.

(2) For purposes of determining whether the provisions of this rule apply, the determination of whether a "business" has been acquired should be made in accordance with the guidance set forth in § 210.11-01(d).

(3) If consumption of more than one transaction has occurred or is probable, the required financial statements may be presented on a combined basis, if appropriate.

(4) This rule shall not apply to a business which is totally held by the registrant prior to consummation of the transaction.

(b) Periods to be presented. (1) If securities are being registered to be offered to the security holders of the business to be acquired, the financial statements specified in §§ 210.3-01 and 210.3-02 shall be furnished for the business to be acquired, except as provided otherwise for filings on Forms S-14 and S-15. In all other cases, financial statements of the business acquired or to be acquired shall be filed for the periods specified in this paragraph or such shorter period as the business has been in existence. The financial statements covering fiscal years shall be audited except as provided in Item 15 of Schedule 14A, § 240.14a-01 with respect to certain proxy statements. The periods for which such financial statements are to be filed shall be determined using the conditions specified in the definition of significant subsidiary in § 210.1-02. The determination shall be made by comparing the most recent annual financial statements of each such business to the registrant’s most recent annual consolidated financial statements filed at or prior to the date of acquisition.

(i) If none of the conditions exceeds 10 percent, financial statements are not required. However, if the aggregate impact of the individually insignificant businesses acquired since the date of the most recent audited balance sheet filed for the registrant exceeds 20%, financial statements covering at least the substantial majority of the businesses acquired, combined if appropriate, shall be furnished. Such financial statements shall be for at least the most recent fiscal year and any interim periods specified in §§ 210.3-01 and 210.3-02.

(ii) If any of the conditions exceeds 10 percent, but none exceed 20 percent, financial statements shall be furnished for at least the most recent fiscal year and any interim periods specified in §§ 210.3-01 and 210.3-02.

(iii) If any of the conditions exceeds 20 percent, but none exceed 40 percent, financial statements shall be furnished for at least the two most recent fiscal years and any interim periods specified in §§ 210.3-01 and 210.3-02.

(iv) If any of the conditions exceeds 40 percent, the full financial statements specified in §§ 210.3-01 and 210.3-02 shall be furnished.

2(1) Notwithstanding the requirements in (b)(1) above, separate financial statements of the acquired business need not be presented once the operating results of the acquired business have been reflected in the audited consolidated financial statements of the registrant for a complete fiscal year unless such
financial statements have not been previously filed or unless the acquired business is of such significance to the registrant that omission of such financial statements would materially impair an investor's ability to understand the historical financial results of the registrant. For example, if, at the date of acquisition, the acquired business met at least one of the conditions in the definition of significant subsidiary in §210.1-02 at the 80 percent level the income statements of the acquired business should normally continue to be furnished for such periods prior to the purchase as may be necessary when added to the time for which audited income statements after the purchase are filed to cover the equivalent of the period specified in §210.3-02. A separate audited balance sheet of the acquired business is not required when the registrant's most recent audited balance sheet filed by the registrant as management information of registrant. By revising paragraph (d) of §210.3-02 to read as follows:

§210.3-02 [Amended] 9. By deleting paragraph 31(c) of §210.5-02.
10. By revising paragraph 26(c) of §210.6-22 to read as follows:

§210.6-22 Balance sheets.
* * * * * * * * * * * * * 
26 Surplus.
* * * * * * * * * * * * * 
(c) An analysis of each surplus account set forth the information prescribed by §210.3-04 shall be given for each period for which a profit and loss or income statement is filed, as a continuation of the related profit and loss or income statement or in the form of a separate statement of surplus, and shall be referred to in the balance sheet.
11. By revising paragraph (a) of §210.7-05 and revising Schedules III, IV and V to read as follows:

§210.7-05 What schedules are to be filed.
(a) Except as expressly provided otherwise in the applicable form—
(1) The schedules specified below as Schedules I and VII shall be filed as of the dates of the most recent audited balance sheet for each person or group.
(2) Other schedules specified below as Schedules II, IV, VI, VIII and IX shall be filed for each period for which an audited income statement is required to be filed for each person or group.
(3) Schedules III and V shall be filed as of the dates and for the periods specified in the schedule.
* * * * * * * * * * * * * 
Schedule III—Condensed financial information of registrant. The schedule prescribed by §210.12-04 shall be filed when the restricted net assets (§210.4.08(e)(3)) of consolidated subsidiaries exceed 25 percent of consolidated net assets as of the end of the most recently completed fiscal year. For purposes of the above test, restricted net assets of consolidated subsidiaries shall mean that amount of the registrant's proportionate share of net assets of consolidated subsidiaries other than intercompany eliminations which as of the end of the most recent fiscal year may not be transferred to the parent company by subsidiaries in the form of advances or cash dividends without the consent of a third party (i.e., lender, regulatory agency, foreign government, etc.). Where restrictions on the amount of funds which may be loaned or advanced differ from the amount restricted as to transfer in the form of cash dividends, the amount least restrictive to the subsidiary shall be used. Redeemable preferred stocks (§210.7-03.21) and minority interests shall be deducted in computing net assets for purposes of this test.
Schedule IV—Indebtedness of and to related parties—not current. The schedule prescribed by §210.12-05 shall be filed in support of captions 3(b) and 17 of the balance sheet. This schedule may be omitted if (1) either the sum of captions 3(a) and 3(b) in the related balance sheet or the amount of caption 17 in such balance sheet exceeds five percent of total assets as shown by the related balance sheet at either the beginning or end of the period or (2) there have been no material changes in the information required to be filed from that last previously reported.
Schedule V—Supplementary insurance information. The schedule prescribed by §210.12-16 shall be filed giving segment detail in support of various balance sheet and income statement captions. The required balance sheet information shall be presented as of the date of each audited balance sheet filed, and the income statement information shall be presented for each period for which an audited income statement is required to be filed, for each person or group.
* * * * * * * * * * * * * 
12. By adding new Article 11 and §§210.11-01, 210.11-02 and 210.11-03 to read as follows:

Pro Forma Financial Information

§210.11-01 Presentation requirements.
(a) Pro forma financial information shall be furnished when any of the following conditions exist:
(1) During the most recent fiscal year or subsequent interim period for which a balance sheet is required by §210.3-01, a significant business combination accounted for as a purchase has occurred (for purposes of these rules, the term “purchase” encompasses the purchase of an interest in a business accounted for by the equity method);
(2) After the date of the most recent balance sheet filed pursuant to §210.3-01, consumption of a significant business combination to be accounted for by either the purchase method or pooling-of-interests method of accounting has occurred or is probable;
(3) Securities being registered by the registrant are to be offered to the security holders of a significant business to be acquired or the proceeds from the sale of the offered securities will be applied directly or indirectly to the purchase of a specific significant business;
(4) The disposition of a significant portion of a business either by sale, abandonment or distribution to shareholders by means of a spin-off, split-up or split-off has occurred or is probable and such disposition is not fully reflected in the financial statements of the registrant included in the filing.
(5) The registrant previously was a part of another entity and such presentation is necessary to reflect operations and financial position of the registrant as an autonomous entity; or
(6) Consumption of other events or transactions has occurred or is probable for which disclosure of pro forma financial information would be material to investors.

(b) A business combination or disposition of a business shall be considered significant if:
(1) A comparison of the most recent annual financial statements of the business acquired or to be acquired and the registrant's most recent annual consolidated financial statements filed at or prior to the date of acquisition indicates that the business would be a significant subsidiary pursuant to the conditions specified in § 210.1-02; or
(2) The business to be disposed of meets the conditions of a significant subsidiary in § 210.1-02.

(c) When consumption of more than one transaction has occurred or is probable during a fiscal year, the tests of significance in paragraph (b) above shall be applied to the cumulative effect of those transactions. If the cumulative effect of the transactions is significant, pro forma financial information shall be presented.

(d) For purposes of this rule, the term business should be evaluated in light of the facts and circumstances involved and whether there is sufficient continuity of the acquired entity's operations prior to and after the transactions so that disclosure of prior financial information is material to an understanding of future operations. A presumption exists that a separate entity, a subsidiary, or a division is a business. However, a lesser component of an entity may also constitute a business. Among the facts circumstances which should be considered in evaluating whether an acquisition of a lesser component of an entity constitutes a business are the following:
(1) Whether the nature of the revenue-producing activity of the component will remain generally the same as before the transaction; or
(2) Whether any of the following attributes remain with the component after the transaction:
   (i) Physical facilities,
   (ii) Employee base,
   (iii) Market distribution system,
   (iv) Sales force,
   (v) Customer base,
   (vi) Operating rights,
   (vii) Production techniques, or
   (viii) Trade names.

(e) This rule does not apply to transactions between a parent company and its totally held subsidiary.

§ 210.11-02 Preparation requirements.
(a) Objective. Pro forma financial information should provide investors with information about the continuing impact of a particular transaction by showing how it might have affected historical financial statements if the transaction had been consummated at an earlier time. Such statements should assist investors in analyzing the future prospects of the registrant because they illustrate the possible scope of the change in the registrant's historical financial position and results of operations caused by the transaction.

(b) Form and content. (1) Pro forma financial information shall consist of a pro forma condensed balance sheet, pro forma condensed statements of income, and accompanying explanatory notes. In certain circumstances (i.e., where a limited number of pro forma adjustments are required and those adjustments are easily understood), a narrative description of the pro forma effects of the transaction may be furnished in lieu of the statements described herein.

(2) The pro forma financial information shall be accompanied by an introductory paragraph which briefly sets forth a description of (i) the transaction, (ii) the entities involved, and (iii) the periods for which the pro forma information is presented. In addition, an explanation of what the pro forma presentation shows shall be set forth.

(3) The pro forma condensed financial information need only include major captions (i.e., the numbered captions) prescribed by the applicable sections of this Regulation. Where any major balance sheet caption is less than 10 percent of total assets, the caption may be combined with others. When any major income statement caption is less than 15 percent of average net income of the registrant for the most recent three fiscal years, the caption may be combined with others. In calculating average net income, loss years should be excluded unless losses were incurred in each of the most recent three years, in which case the average loss shall be used for purposes of this test.

Notwithstanding these tests, de minimis amounts need not be shown separately.

(4) Pro forma statements shall ordinarily be in columnar form showing condensed historical statements, pro forma adjustments, and the pro forma results.

(5) The pro forma condensed income statement shall disclose income (loss) from continuing operations before nonrecurring charges or credits directly attributable to the transaction. Material nonrecurring charges or credits and related tax effects which result directly from the transaction and which will be included in the income of the registrant within the 12 months succeeding the transaction shall be disclosed separately. It should be clearly indicated that such charges or credits were not considered in the pro forma condensed income statement. If the transaction for which pro forma financial information is presented relates to the disposition of a business, the pro forma results should give effect to the disposition and be presented under an appropriate caption.

(6) Pro forma adjustments related to the pro forma condensed income statement shall be computed assuming the transaction was consummated at the beginning of the fiscal year presented and shall include adjustments which give effect to events that are (i) directly attributable to the transaction, (ii) expected to have a continuing impact on the registrant, and (iii) factually supportable. Pro forma adjustments related to the pro forma condensed balance sheet shall be computed assuming the transaction was consummated at the end of the most recent period for which a balance sheet is required by § 210.3-01 and shall include adjustments which give effect to events that are directly attributable to the transaction and factually supportable regardless of whether they have a continuing impact or are nonrecurring. All adjustments should be referenced to notes which clearly explain the assumptions involved.

(7) Historical primary and fully diluted per share data based on continuing operations (or not issued) of the registrant does not report either discontinued operations, extraordinary items, or the cumulative effects of accounting changes for the registrant, and primary and fully diluted pro forma per share data based on continuing operations before nonrecurring charges or credits directly attributable to the transaction shall be presented on the face of the pro forma condensed income statement together with the number of shares used to compute such per share data. For transactions involving the issuance of securities, the number of shares used in the calculation of the pro forma per share data should be based on the weighted average number of shares outstanding during the period adjusted to give effect to shares subsequently issued or assumed to be issued had the particular transaction or event taken place at the beginning of the
period presented. If a convertible security is being issued in the transaction, consideration should be given to the potential dilution of the pro forma per share data.

(6) If the transaction is structured in such a manner that significantly different results may occur, additional pro forma presentations shall be made which give effect to the range of possible results.

**Instructions.** 1. The historical statement of income used in the pro forma financial information shall not report operations of a segment that has been discontinued, extraordinary items, or the cumulative effects of accounting changes. If the historical statement of income includes such items, only the portion of the income statement through “income from continuing operations” (or the appropriate modification thereof) should be used in preparing pro forma results.

2. For a purchase transaction, pro forma adjustments for the income statement shall include amortization of goodwill, depreciation and other adjustments based on the allocated purchase price of net assets acquired. In some transactions, such as in financial institution acquisitions, the purchase adjustments may include significant discounts of the historical cost of the acquired assets to their fair value at the acquisition date. When such adjustments will result in a significant effect on earnings (losses) in periods immediately subsequent to the acquisition which will be progressively eliminated over a relatively short period, the effect of the purchase adjustments on reported results of operations for each of the next five years should be disclosed in a note.

3. For a disposition transaction, the pro forma financial information shall begin with the historical financial statements of the existing entity and show the deletion of the business to be divested along with the pro forma adjustments necessary to arrive at the remainder of the existing entity. For example, pro forma adjustments should include adjustments similar in nature to those referred to in Instruction 3 above. Adjustments may also be necessary when charges for corporate overhead, interest, or income taxes have been allocated to the entity on a basis other than one deemed reasonable by management.

5. When consummation of more than one transaction has occurred or is probable during a fiscal year, the pro forma financial information may be presented on a combined basis; however, in some circumstances (e.g., depending upon the combination of probable and consummated transactions, and the nature of the filing) it may be more useful to present the pro forma financial information on a disaggregated basis even though some or all of the transactions would not meet the tests of significance individually. For combined presentations, a note should explain the various transactions and disclose the maximum variances in the pro forma financial information which would occur for any of the possible combinations. If the pro forma financial information is presented in a proxy or information statement for purposes of obtaining shareholder approval of one of the transactions, the effects of that transaction must be clearly set forth.

6. Tax effects, if any, of pro forma adjustments normally should be calculated at the statutory rate in effect during the periods for which pro forma condensed income statements are presented and should be reflected as a separate pro forma adjustment.

(c) **Periods to be presented.** (1) A pro forma condensed balance sheet as of the end of the most recent period for which a consolidated balance sheet of the registrant is required by § 210.3-01 shall be filed unless the transaction is already reflected in such balance sheet.

(2)(i) Pro forma condensed statements of income shall be filed for only the most recent fiscal year and for the period from the most recent fiscal year end to the most recent interim date for which a balance sheet is required. A pro forma condensed statement of income may be filed for the corresponding interim period of the preceding fiscal year. A pro forma condensed statement of income shall not be filed when the historical income statement reflects the transaction for the entire period.

(ii) For a business combination accounted for as a pooling of interests, the pro forma income statements (which are in effect a restatement of the historical income statements as if the combination had been consummated) shall be filed for all periods for which historical income statements of the registrant are required.

(3) Pro forma condensed statements of income shall be presented using the registrant’s fiscal year end. If the most recent fiscal year end of any other entity involved in the transaction differs from the registrant’s most recent fiscal year end by more than 90 days, the other entity’s income statement shall be brought up to within 90 days of the registrant’s most recent fiscal year end, if practicable. This updating could be accomplished by adding subsequent interim period results to the most recent fiscal year-end information and deducting the comparable preceding year interim period results. Disclosure shall be made of the periods combined and of the sales or revenues and income for any periods which were excluded from or included more than once in the condensed pro forma income statements (e.g., an interim period that is included both as part of the fiscal year and the subsequent interim period). For investment companies subject to §§ 210.8-01 to 210.8-10, the periods covered by the pro forma statements must be the same.

(4) Whenever unusual events enter into the determination of the results shown for the most recently completed fiscal year, the effect of such unusual events should be disclosed and consideration should be given to presenting a pro forma condensed income statement for the most recent twelve-month period in addition to those required in paragraph (c)(2)(i) above if the most recent twelve-month period is more representative of normal operations.

§ 210.11-03 Presentation of financial forecast.

(a) A financial forecast may be filed in lieu of the pro forma condensed statements of income required by § 210.11-02(b)(1).

(1) The financial forecast shall cover a period of at least 12 months from the latest of (i) the most recent balance sheet included in the filing or (ii) the consummation date or estimated consummation date of the transaction.

(2) The forecasted statement of income shall be presented in the same degree of detail as the pro forma condensed statement of income required by § 210.11-02(b)(3).

(3) Assumptions particularly relevant to the transaction and effects thereof should be clearly set forth.

(4) Historical condensed financial information of the registrant and the business acquired or to be acquired, if any, shall be presented for at least a recent 12 month period in parallel columns with the financial forecast.

(b) Such financial forecast shall be presented in accordance with the guidelines established by the American Institute of Certified Public Accountants.

(c) Forecasted earnings per share data shall be substituted for pro forma per share data.

(d) This rule does not permit the filing of a financial forecast in lieu of pro forma information required by generally accepted accounting principles.

§ 210.11A-01 and 210.11A-02. [Removed]


PART 229—STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933 AND SECURITIES EXCHANGE ACT OF 1934—REGULATION S-K

14. By revising paragraph (b)(2) of § 229.303 to read as follows:
§ 229.303 (Item 303) Management's discussion and analysis of financial condition and results of operations.

(b) Interim periods. 

(2) Material changes in results of operations. Discuss any material changes in the registrant's results of operations with respect to the most recent fiscal year-to-date period for which an income statement is provided and the corresponding year-to-date period of the preceding fiscal year. If the registrant is required to or has elected to provide an income statement for the twelve-month period ended as of the date of the most recent interim balance sheet provided, the discussion also shall cover material changes with respect to that fiscal quarter and the corresponding fiscal quarter in the preceding fiscal year. In addition, if the registrant has elected to provide an income statement for the twelve-month period ended as of the date of the most recent interim balance sheet provided, the discussion also shall cover material changes with respect to that twelve-month period and the corresponding interim balance sheet date of the preceding fiscal year. Notwithstanding the above, if for purposes of a registration statement a registrant subject to paragraph (b) of § 210.3-03 of Regulation S-X provides a statement of income for the twelve-month period ended as of the date of the most recent interim balance sheet provided, the discussion also shall cover material changes with respect to that twelve-month period and the twelve-month period ended as of the corresponding interim balance sheet date of the preceding fiscal year.

PART 231—INTERPRETATIVE RELEASES RELATING TO THE SECURITIES ACT OF 1933 AND GENERAL RULES AND REGULATIONS THEREUNDER


PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

17. By revising Item 11(e) of Form S–1 in § 239.11 to read as follows (Form S–1 does not appear in the Code of Federal Regulations):

§ 239.11 Form S–1, registration statement under the Securities Act of 1933.

Item 11. Information with Respect to the Registrant.

(e) Financial statements meeting the requirements of Regulation S–X (17 CFR Part 210) (Schedules required under Regulation S–X shall be filed as "Financial Statement Schedules" pursuant to Item 10, Exhibits and Financial Statement Schedules, of this Form), as well as any financial information required by Rule 3–05 and Article 11 of Regulation S–X:

18. By revising Items 11(a)(3) and 11(b)(2) of Form S–2 in § 239.12 to read as follows (Form S–2 does not appear in the Code of Federal Regulations):

§ 239.12 Form S–2, for registration under the Securities Act of 1933 of securities of certain issuers.

Item 11. Information with Respect to the Registrant.

(a) 

(3) If not reflected in the registrant's latest annual report to security holders, provide information required by Rule 3–05 and Article 11 of Regulation S–X (17 CFR Part 210).

(b) 

2. Include financial statements and information as required by Rule 14a–3(b)(1) to be included in annual reports to security holders as well as: (i) the interim financial information required by Rule 10–Q of Regulation S–X for a filing on Form 10–Q; (ii) any financial information required by Rule 3–05 and Article 11 of Regulation S–X; and (iii) any financial information required because of a material disposition of assets outside the normal course of business. The financial statements shall be restated if there has been a change in accounting principles or a correction of an error where such change or correction requires a material retroactive restatement of financial statements, or where one or more business combinations accounted for by the pooling of interest method of accounting have been consummated subsequent to the most recent fiscal year and the acquired businesses, considered in the aggregate, are significant pursuant to Rule 11–01(b).

19. By revising Item 11(b) of Form S–3 in § 239.13 to read as follows (Form S–3 does not appear in the Code of Federal Regulations):

§ 239.13 Form S–3, for registration under the Securities Act of 1933 of securities of certain issuers offered pursuant to certain types of transactions.

Item 11. Material Changes.

(b) Include in the prospectus, if not incorporated by reference therein from the reports filed under the Exchange Act specified in Item 12(a), a proxy or information statement filed pursuant to Section 14 of the Exchange Act, a prospectus previously filed pursuant to Rule 424 under the Securities Act, or a Form 8–K filed during either of the two preceding fiscal years: (i) information required by Rule 3–05 and Article 11 of Regulation S–X if there has been a change in accounting principles or a correction in an error where such change or correction requires a material retroactive restatement of financial statements; (ii) restated financial statements prepared in accordance with Regulation S–X if there has been a change in accounting principles or a correction in an error where such change or correction requires a material retroactive restatement of financial statements; (iii) restated financial statements prepared in accordance with Regulation S–X where one or more business combinations accounted for by the pooling of interest method of accounting have been consummated subsequent to the most recent fiscal year and the acquired businesses, considered in the aggregate, are significant pursuant to Rule 11–01(b), or (iv) any financial information required because of a material disposition of assets outside the normal course of business.

20. By revising Form S–16 in § 239.28 to read as follows (Form S–16 does not appear in the Code of Federal Regulations):

§ 239.28 Form S–16, optional form for the registration of securities to be sold to the public by the issuer for an aggregate cash price not to exceed $5,000,000.

General Instructions

I. Rule as to Use of Form S–18

A. 

(3) Is not an investment company:

III. Application of General Rules and Regulations

C. Attention is directed to Regulation S–K (17 CFR 229.2001 et seq.) relating to
registration statement content. Where this form specifically references an item within that Regulation, the information need only be furnished to the extent appropriate. Special attention also is directed to paragraphs (b) and (c) of § 229.10 of Regulation S-K which outline the Commission’s policies on projections and securities ratings, respectively.

D. Attention is directed to disclosure provisions set forth in the Industry Guide which are listed in § 229.801 of Regulation S-K (17 CFR 229.801). These Industry Guides represent Division practices with respect to the disclosure to be provided by the affected industries in registration statements.

F. Attention is directed to Form S-11 (17 CFR 239.18), which relates to the registration of securities of certain real estate companies, and particularly Item 13 (Investment Policies of Registrant), Item 14 (Description of Real Estate), and Item 15 (Operating Data) contained therein. To the extent that these items offer enhanced guidelines for disclosure by real estate entities, registrants engaged or to be engaged in real estate operations may wish to consider these items for use in a Form S-10 offering.


(3) Any security holder named in answer to Item 11; or

Instructions. See Instruction 2 to Item 20(a)(1). No information need be given in response to this item as to any remuneration or other transaction reported in response to Item 20 or specifically excluded from Item 20.


(a) *

(2) Regulation S-X (17 CFR 210.1–210.12), Form and Content of and Requirements for Financial Statements, shall not apply to the preparation of such financial statements, except that the report and qualifications of the independent accountant shall comply with the requirements of Article 2 of Regulation S-X (17 CFR 210.2), and registrants engaged in oil and gas producing activities shall follow the financial accounting and reporting standards specified in Article 4–10 of Regulation S-X (17 CFR 210.4–10) with respect to such activities. However, to the extent that Article 10 (17 CFR 210.10) (Interim Financial Statements), Article 11–01 (17 CFR 210.11–01) (Pro Forma Presentation Requirements) and Article 11–02 (17 CFR 210.11–02) (Pro Forma Preparation Requirements) offer enhanced guidelines for the preparation, presentation and disclosure of condensed financial statements and pro forma financial information, registrants may wish to consider these items for use in a Form S-18 offering.

(d) Financial Statements of Businesses Acquired or to be Acquired.

(1) Financial statements for the periods specified in (3) below should be furnished if any of the following conditions exist:

(i) Consummation of a significant business combination accounted for as a purchase has occurred or is probable (for purposes of this rule, the term “purchase” encompasses the purchase of an interest in a business accounted for by the equity method); or

(ii) Consummation of a significant business combination to be accounted for as a pooling of interests is probable.

(2) A business combination shall be considered significant if a comparison of the most recent annual financial statements of the business acquired or to be acquired and the registrant’s most recent annual consolidated financial statements filed at or prior to the date of acquisition indicates that the business would be a significant subsidiary pursuant to the conditions specified in Rule 405 of Regulation C (17 CFR 230.405).

(3)(i) The financial statements shall be furnished for the periods up to the date of acquisition, for those periods for which the registrant is required to furnish financial statements as specified in paragraph (b) and (c)(1).

(ii) The financial statements covering fiscal years shall be audited.

(iii) A separate audited balance sheet of the acquired business is not required when the registrant’s most recent audited balance sheet filed is for a date after the acquisition was consummated.

(iv) If none of the conditions in the definitions of significant subsidiary in Rule 405 exceeds 20%, income statements of the acquired business for only the most recent fiscal year and any interim period need be filed.

(4) If consummation of more than one transaction has occurred or is probable, the tests of significance shall be made using the aggregate impact of the businesses and the required financial statements may be presented on a combined basis, if appropriate.

(5) This paragraph (d) of this section shall not apply to a business which is totally held by the registrant prior to consummation of the transaction.

(e) Pro Forma Financial Information.

(1) Pro forma information shall be furnished if any of the following conditions exist (for purposes of this rule, the term “purchase” encompasses the purchase of an interest in a business accounted for by the equity method):

(i) During the most recent fiscal year or subsequent interim period for which a balance sheet is required by paragraph (b), a significant business combination accounted for as a purchase has occurred;

(ii) After the date of the most recent balance sheet filed pursuant to paragraph (b), consummation of a significant business combination to be accounted for by either the purchase method or pooling of interests method of accounting has occurred or is probable.

(2) The provisions of paragraph (d)(2), (4) and (5) apply to this paragraph (e).

(3) Pro forma statements shall ordinarily be in columnar form showing condensed historical statements, pro forma adjustments, and the pro forma results and should include the following:

(i) If the transaction was consummated during the most recent fiscal year or in the subsequent interim period, pro forma statements of income reflecting the combined operations of the entities for the latest fiscal year and interim period, if any; or

(ii) If consummation of the transaction has occurred or is probable after the date of the most recent balance sheet, a pro forma balance sheet giving effect to the combination as of the date of the most recent balance sheet required by paragraph (b). For a purchase, pro forma statements of income reflecting the combined operations of the entities for the latest fiscal year and interim period, if any, and for a pooling of interests, pro forma statements of income for all periods for which income statements of the registrant are required.

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

21. By revising paragraph (1) of the definition of significant subsidiary in § 240.12b–2 to read as follows:

§ 240.12b–2 Definitions.

Significant Subsidiary.

(1) The registrant’s and its other subsidiaries’ investments in and advance to the subsidiary exceed 10 percent of the total assets of the registrant and its subsidiaries consolidated as of the end of the most recently completed fiscal year (for purposes of determining whether financial statements of a business acquired or to be acquired in a business combination accounted for as a pooling of interests are required pursuant to § 210.3–05, this condition is also met
when the number of common shares exchanged by the registrant exceeds 10 percent of its total common shares outstanding at the date of the combination is initiated; or

22. By revising paragraph (b)(1) of § 240.14a-3 to read as follows:

§ 240.14a-3 Information to be furnished to security holders.

(b) * * *

(1) The report shall include, for the registrant and its subsidiaries consolidated, audited balance sheets as of the end of the two most recent fiscal years and audited statements of income and changes in financial position for each of the three most recent fiscal years prepared in accordance with Regulation S-X (Part 210 of this chapter), except that the provisions of Article 3, other than §§ 210.3-03(e) and 210.3-04, and Article 11 shall not apply and only substantial compliance with Articles 6 and 9 is required. Any financial statement schedules or exhibits or separate financial statements which may otherwise be required in filings with the Commission may be omitted. Investment companies registered under the Investment Company Act of 1940 need include financial statements only for the last fiscal year except for statements of changes in net assets which are to be filed for the two most recent fiscal years. If the financial statements of the registrant and its subsidiaries consolidated in the annual report filed or to be filed with the Commission are not required to be audited, the financial statements required by this paragraph may be unaudited.

23. By revising Items 14(b)(5), (b)(6) and (b)(7); the instructions to Item 14(b); and Item 15(f) of § 240.14a-101 to read as follows:

§ 240.14a-101 Schedule 14A. Information required in proxy statement.

Item 14. Mergers, consolidations, acquisitions and similar matters.

(b) * * *

(5) Furnish selected financial data pursuant to Item 301 of Regulation S-K (§ 229.301) and book value per common share as of the end of the most recent period for which a balance sheet is required by § 210.3-01.

(6) Furnish any pro forma financial information required by Article 11 of Regulation S-X and pro forma book value per common share as of the end of the most recent period for which a balance sheet is furnished pursuant to § 210.3-01.

(7) Furnish the equivalent share information specified in the instructions below for exchange transactions.

* * * * *

Instructions. 1. The historical primary and fully diluted earnings per share before discontinued operations, extraordinary items, or the cumulative effects of accounting changes, as appropriate, and the primary and fully diluted pro forma per share data; cash dividends declared per common share; and book value per common share presented in response to paragraphs (b)(6) and (7) and equivalent share data pursuant to (b)(7) where appropriate shall be set forth in comparative columnar form.

2. Equivalent share amounts of the acquired company shall be calculated by multiplying the pro forma income (loss) per share before nonrecurring charges or credits directly attributable to the transaction, pro forma book value per share, and the historical dividends per share of the acquiring company by the exchange ratio so that the per share amounts are equated to the respective values for one share of the company being acquired. In situations where the fiscal years end of the companies involved are different, additional historical information should be presented so that equivalent share amounts may be compared for equivalent periods. If the impact of the exchange transaction is immaterial to the registrant, all equivalent share amounts furnished should be determined on the basis of the historical per share data of the registrant.

3. Paragraph (b) shall not apply if the plan described in answer to paragraph (a) involves only the issuer and one or more of its totally held subsidiaries.

(c) * Item 15. Financial Information.

* * * * *

(f) The financial statements of an acquired company not subject to the reporting provisions of the Exchange Act required to be furnished pursuant to Regulation S-X shall be certified to the extent practicable. However, if the proxy statement is to be included in a filing on Form S-14 and if any of the securities are to be reoffered to the public by any person who is deemed to be an underwriter thereof, within the meaning of Rule 145(c), the financial statements of the acquired company must be certified for three years.

* * * * *

24. By revising paragraph (a)(1) of § 240.14a-3 to read as follows:

§ 240.14c-3 Annual report to be furnished security holders.

(a) * * *

(1) The report shall include, for the registrant and its subsidiaries consolidated, audited balance sheets as of the end of each of the two most recent fiscal years and audited statements of income and changes in financial position for each of the three most recent fiscal years prepared in accordance with Regulation S-X (Part 210 of this chapter), except that the provisions of Article 3, other than §§ 210.3-03(e) and 210.3-04, and Article 11 shall not apply and only substantial compliance with Articles 6 and 9 is required. Any financial statement schedules or exhibits or separate financial statements which may otherwise be required in filings with the Commission may be omitted. Investment companies registered under the Investment Company Act of 1940 need include financial statements only for the last fiscal year except for statements of changes in net assets which are to be filed for the two most recent fiscal years. If the financial statements of the registrant and its subsidiaries consolidated in the annual report filed or to be filed with the Commission are not required to be audited, the financial statements required by this paragraph may be unaudited.

* * * * *

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

25. By revising instructions 4 and 6 of Item 2 and paragraph (a) of Item 7 of § 249.308 to read as follows (Form 8-K does not appear in the Code of Federal Regulations):

§ 249.308 Form 8-K, for current reports.

* * * * *

Information To Be Included in the Report.

* * * * *

Item 2. Acquisition or Disposition of Assets.

* * * * *

Instructions.

* * * * *

4. An acquisition or disposition shall be deemed to involve a significant amount of assets (i) if the registrant and its other subsidiaries’ equity in the net book value of such assets or the amount paid or received therefor upon such acquisition or disposition exceeded 10 percent of the total assets of the registrant and its consolidated subsidiaries, or (ii) if it involved a business (see § 210.11-01(d)) which is significant (see § 210.11-01(b)).

* * * * *

8. Attention is directed to the requirements in Item 7 of the form with respect to the filing of (i) financial statements for businesses acquired, (ii) pro forma financial information, and (iii) copies of the plans of acquisition or disposition as exhibits to the report.

* * * * *


List below the financial statements, pro forma financial information and exhibits, if any, filed as a part of this report.

(a) Financial statements of businesses acquired.
For any business acquisition required to be described in answer to Item 2 above, financial statements of the business acquired shall be filed for the periods specified in § 210.3-05(b).

(2) The financial statements shall be prepared pursuant to Regulation S-X except that supporting schedules need not be filed. A manually signed accountants' report should be provided pursuant to Rule 2-02 of Regulation S-X (17 CFR 210.2-02).

(3) The Commission may, upon the written request of the registrant and where consistent with protection of investors, extend the time for filing the financial statements herein required if it is impracticable for required audited financial statements to be filed at the time the report on Form 8-K is filed. A written request for such relief setting forth the reason(s) for the impracticability of filing the audited financial statements at that time should be submitted, separately from the subject report or the cover letter to the report, to the Chief of the Division of Corporation Finance. In such circumstances, the registrant may also, at its option, include unaudited financial statements in the report on Form 8-K.

(b) Pro forma financial information.

(1) For any transaction required to be described in answer to Item 2 above, furnish any pro forma financial information that would be required pursuant to Article 11 of Regulation S-X.

(2) The provisions of [a][3] above shall also apply to pro forma financial information relative to an acquired business.

(c) Exhibits. The exhibits shall be furnished in accordance with the provisions of Item 601 of Regulation S-K (§ 229.601 of this chapter).

28. By revising the first paragraph of Item 8 of § 249.310 to read as follows (Form 10-K does not appear in the Code of Federal Regulations):

§ 249.310 Form 10-K. Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934.

* * * * *

Item 8. Financial Statements and Supplementary Data.

Furnish financial statements meeting the requirements of Regulation S-X (§ 210.3-03 and Article 11 thereof, and the supplementary financial information required by Item 302 of Regulation S-K (§ 229.302 of this chapter). Financial statements of the registrant and its subsidiaries consolidated (as required by Rule 14a-2(b)) shall be included under this item. Other financial statements and schedules required under Regulation S-X may be filed as "Financial Statement Schedules" pursuant to Item 13, Exhibits, Financial Statement Schedules, and Reports on Form 8-K, of this Form.

* * * * *

(The amendments are adopted pursuant to authority in Sections 7 and 10a of the Securities Act, 15 U.S.C. 77g, 77j(a), 77aa[25][26] Section 12, 13, 14, 15(d), and 23(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78l, 78m, 78n, 78o[d], 78w[a], Sections 5[b], 10[a], 14, 20[a] of the Public Utility Holding Company Act, 15 U.S.C. 79e[a], 79m, 79[a]; Sections 8, 20, 30, 31[c], 38(a) of the Investment Company Act of 1940, 15 U.S.C. 80a-6, 80a-20, 80a-29, 80a-30[c], 80a-37[a].)

By the Commission.

Dated: June 24, 1982.

George A. Fitzsimmons, Secretary.

Regulatory Flexibility Act Certification

I, John S. R. Shad, Chairman of the Securities and Exchange Commission, hereby certify pursuant to 5 U.S.C. 605(b) that the adopted rules relating primarily to presentation and preparation of pro forma financial information and financial statements of businesses acquired or to be acquired, set forth in Securities Act Release No. 4613 will not have a significant economic impact on a substantial number of small entities. The reasons for this certification are that these rules generally codify existing practice, are limited to specific situations which do not occur regularly for any company and will not significantly change the reporting burdens of a substantial number of small businesses. Although to some extent these rules represent a revision to the requirements and potentially change some reporting burdens, a substantial number of small businesses, which do not occur regularly for any company, are new animal drugs. FDA provided 6 months in which to submit supplements containing adequate documentation (data and information) in support of the labeling used.

American Cyanamid did not submit any data to establish safety and effectiveness for any of the claims reviewed by NAS/NRC. Consequently, the Bureau of Veterinary Medicine (the Bureau) again reviewed the NAS/NRC report for Aureomycin Soluble Oblets (CTC HCI) and the NAS/NRC recommended dosage for CTC in calves and concluded that CTC HCI soluble tablets are effective for certain conditions of use in calves. Those conditions were specified in the Drug Efficacy Study Implementation; Followup Notice and Opportunity for Hearing which was published in the Federal Register of March 30, 1979 (44 FR 19030).

American Cyanamid responded by submitting a supplemental NADA which complies with the Bureau Director’s conclusions as described in the 1979 notice. Accordingly, the supplemental NADA is approved and § 546.110d (21 CFR 546.110d) is amended to reflect the approval. Section 546.110d is further amended to specify a 24-hour preslaughter withdrawal period as required by FDA.

Under the Bureau’s supplemental approval policy (42 FR 64397; December 23, 1977), this is a Category II supplemental approval because (1) the
dosage level is increased. (2) claims and species have been removed, and (3) a 24-hour slaughter withdrawal requirement has been added. The higher dosage poses no increased human risk from exposure to residues of the drug because of the 24-hour withdrawal period. The Bureau has determined, based on tissue residue data, that 24 hours withdrawal will allow for any residues to deplete below tolerance. Therefore, this supplement does not require reevaluation of the human safety data in the original approval.

NADA's that pertain to identical products and that provide for similar labeling for treatment of bacterial enteritis and bacterial pneumonia do not require efficacy data as specified by § 514.1(b)(8)(ii) or § 514.111(a)(5)(vi) (21 CFR 514.1(b)(8)(ii) or 514.111(a)(5)(vi)). In lieu of such data, approval may require bioequivalency or similar data as suggested in the guideline for submitting NADA's for NAS/NRC-reviewed generic drugs. The guideline is available from the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857 from 9 a.m. to 4 p.m., Monday through Friday.

The notice of opportunity for hearing (44 FR 19030) is hereby withdrawn, because the sponsor did not submit a request for hearing, and because the previously approved claims are withdrawn with the approval of this supplement.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 23.24(d)(1)(i) [proposed December 11, 1979; 44 FR 71742] that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.111(e)(2)(ii) (21 CFR 514.111(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch [address above] from 9 a.m. to 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 546

Animal drugs, Antibiotics, Tetracycline.

PART 546—TETRACYCLINE ANTIBiotic Drugs for Animal Use

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512 (f) and (o), 82 Stat. 347, 350–351 (21 U.S.C. 360b (f) and (o)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 546.110d is amended by redesignating existing paragraphs (c)(5) as (c)(6) and revising it, and by adding new paragraph (c)(5), to read as follows:

§ 546.110d Chlortetracycline hydrochloride tablets.

* * * * *

(c) * * *

(5) NAS/NRC status. The conditions of use specified in paragraph (c)(2)(ii) of this section are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalency and safety information.

(b) Conditions of use. Administer orally as chlortetracycline hydrochloride tablets to calves as follows:

(i) Amount. 25 milligrams per tablet.

(a) Indications for use. Aid in reduction of incidence of bacterial scour.

(b) Limitations. 75 milligrams per animal per day.

(ii) Amount. 500 milligrams per tablet.

(a) Indications for use. Treatment of bacterial enteritis (scours) caused by E. coli and Salmonella spp. and bacterial pneumonia associated with Pasteurella spp., Hemophilus spp., and Klebsiella spp. susceptible to chlortetracycline.

(b) Limitations. Administer 1 tablet (500 milligrams) per 100 pounds of body weight twice a day for 3 to 5 days; administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

Effective date: July 9, 1982.

(Sec. 521 (f) and (o), 82 Stat. 347, 350–351 (21 U.S.C. 360b (f) and (o))

Dated: July 7, 1982.

Robert A. Baldwin, Associate Director for Scientific Evaluation.

[FR Doc. 82-18515 Filed 7-8-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed for Heinold Feeds, Inc., providing for use of a 10-gram-per-pound tylosin premix for making complete swine, beef cattle, and chicken feeds in addition to its current use for making certain swine feeds.

EFFECTIVE DATE: July 9, 1982.

FOR FURTHER INFORMATION CONTACT: Jack C. Taylor, Bureau of Veterinary Medicine (HFV–136), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5247.

SUPPLEMENTARY INFORMATION: Heinold Feeds, Inc., P.O. Box 377, Kouts, IN 46347, is sponsor of NADA 65–828 providing for use of 4- and 10-gram-per-pound tylosin premixes for making complete swine feeds for increased rate of weight gain and improved feed efficiency. On behalf of Heinold Feeds, Elanco Products Co. submitted a supplement to the NADA which provides for use of the 10-gram-per-pound tylosin premix for making complete swine, beef cattle, chicken, and layer, broiler, and replacement chicken feed. The swine feed is used, in addition to use for increased rate of weight gain and improved feed efficiency, for prevention, treatment, and control of swine dysentery, and for maintenance of weight gains and promotion of feed efficiency in the presence of atrophic rhinitis; the beef cattle feed for reduction of incidence of certain liver abscesses; the chicken feed for increased rate of weight gain and improved feed efficiency; the layer feed for improved feed efficiency; and the broiler and replacement chicken feed for control of chronic respiratory disease.

Approval of this supplemental NADA relies upon safety and effectiveness data contained in NADA 12–491. Elanco has authorized use of the data in NADA 12–491 to support approval of this supplement. This approval does not change the approved use of the drug. Consequently, approval of this supplement poses no increased human risk from exposure to residues of the animal drug, nor does it change the conditions of the drug’s safe use in the target animal species.

Accordingly, under the Bureau of Veterinary Medicine’s supplemental approval policy (42 FR 94367; December 23, 1977), this is a Category II supplemental approval which does not require reevaluation of the safety and effectiveness data in NADA 12–491.
DEPARTMENT OF LABOR

Employment Standards Administration

29 CFR Part 5


Correction

In FR Doc. 82–18167, appearing on page 28916, in the issue of Friday, July 2, 1982, make the following correction.

- On page 28917, first column, the third and fourth lines of the second complete paragraph reading "Wage and Hour Division on or before August 2, 1982 * * *" should read "Wage and Hour Division within 30 days after * * *".

BILLING CODE 1505–01–M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 211, 221, 231, 250, and 270

Limitation on Adjustments to Statements of Account on Minerals Leases on Federal, Indian, and Outer Continental Shelf Lands

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of final dates for making adjustments to inactive lease accounts.

SUMMARY: The Minerals Management Service (MMS) is in the process of reconciling and closing out lease accounts maintained under the Royalty Accounting System (RAS) as part of its procedures for converting that system to the Auditing and Financial System (AFS). Accounts will be reconciled in each former RAS office as the accounts in that office are converted to AFS. Notice is hereby given that the MMS is establishing a 120-day limitation period during which each lessee/payor may initiate adjustments to the lease accounts or to the RAS Statement(s) of Account (Form 9–1424). This policy will provide incentive to each lessee/payor to review all open RAS accounts and make adjustments to them in a timely fashion, allowing for completion of the MMS program on lease reconciliation within time frames and guidance provided by the General Accounting Office (GAO) and the Commission on Fiscal Accountability of the Nation's Energy Resources.

EFFECTIVE DATE: July 9, 1982.

FOR FURTHER INFORMATION CONTACT: Raymond A. Hicks, Chief, Branch of Rules and Procedures for Royalty Management, Minerals Management Service—Mail Stop 600, 12203 Sunrise Valley Drive, Reston, VA 22091, (703) 860–7311, (FTS) 929–7311.

SUPPLEMENTARY INFORMATION: On January 19, 1982, the Secretary of the Interior established the MMS and transferred to it all functions previously exercised by the Conservation Division, U.S. Geological Survey. Secretarial Order 3071 (47 FR 4751, February 2, 1982).

MMS has the fiscal and financial responsibility to enforce the contractual obligation of each lessee/payor to pay royalties fully, accurately, and timely. Controls over timeliness and accuracy of royalties payments necessitate placing a reasonable time limit on lessee/payor generated adjustments to the RAS Statement(s) of Account.


This notice applies only to those lessees/payors whose RAS lease accounts are being rendered inactive by the MMS conversion of paying responsibility for those leases to the new AFS now operated in Denver, Colorado.

For RAS lease accounts already converted to the AFS, lessee/payor generated adjustments must be received at the MMS Accounting Center in Denver on or before the 120th day after the effective date of this notice. Lessee/payor generated adjustments for those RAS lease accounts that have not been converted from the field paying offices must be received at the Accounting Center on or before the 120th day after the effective date of conversion (or the first workday thereafter). Adjustments received after the final due dates established in the following reconciliation schedule will not be accepted by MMS.

List of Subjects in 21 CFR Part 558

Animal drugs. Animal feeds.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.625 is amended by revising paragraph (b)(9) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(9) To 043727: 4 grams per pound; paragraph (f)(1)(vi)(o) of this section; 10 grams per pound paragraph (f)(1)(i) through (vi) of this section.

* * * * *


(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: June 30, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82–10440 Filed 7–8–82; 8:45 am]

BILLING CODE 4160–01–M
Royalty Management Reconciliation
Schedule of Lease Accounts by Field Office

Oil and gas accounts:
WALA (Washington, Anchorage, Los Angeles), effective date of this notice plus 120 days.
Metairie, effective date of this notice plus 120 days.
Casper, October 29, 1983.

Mining accounts:
All field offices, November 28, 1983.
Any adjustments submitted during a 120-day post conversion period and the reports due on current sales and royalties shall be made by the lessee/payor on Form 9-2014 (Report of Sales and Royalty Remittance). All payor on Form 9-2014 (Report of Sales and Royalty Remittance) shall be made.

Angeles), effective date of this notice plus 120 days.

FOR FURTHER INFORMATION CONTACT:

EFFECTIVE DATE:

47 CFR Part 73
[FR Doc. 82-18005 Filed 7-8-82; 8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73
[BC Docket No. 82-62; RM-3959]

TV Broadcast Stations in Natchez, Mississippi; Changes Made in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Action taken herein assigns UHF television Channel 48 to Natchez, Mississippi, as its first local commercial television assignment, in response to a petition filed by Harold Calish.

EFFECTIVE DATE: August 24, 1982.


FOR FURTHER INFORMATION CONTACT:
Mark N. Lipp, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73
Television.

Television.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714, it is ordered as follows:

1. Public Land Order No. 2354 of April 27, 1961, which withdrew the following described lands for use as a roadside zone is hereby revoked:

Salt Lake Meridian
T. 28 S., R. 1 E., Sec. 27, 5%SW% and SW%SE%.
The area described contains 120 acres in Sevier County.

2. At 10:00 a.m. on August 6, 1982, the lands shall be open to such forms of appropriation as may by law be made of national forest land, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law.

Inquiries concerning the lands should be addressed to the Chief, Branch of Lands and Minerals Operations, Bureau of Land Management, 136 East South Temple, Salt Lake City, Utah 84111. July 1, 1982.

Garrey C. Carruthers,
Assistant Secretary of the Interior.

Federal Register
Vol. 47, No. 132 / Friday, July 9, 1982 / Rules and Regulations

5. It is further ordered, That this proceeding is terminated.

6. For further information concerning this proceeding, contact Mark N. Lipp, Broadcast Bureau, [202] 632-7792.

(Sees. 4, 305, 48 Stat., as amended, 1068, 1082; 47 U.S.C. 154, 303)
Federal Communications Commission.

Roderick K. Porter,
Chief, Policy and Rules Division, Broadcast Bureau.

[FR Doc. 82-18005 Filed 7-8-82; 8:45 am]
BILLING CODE 4310-84-M
47 CFR Part 73
[BC Docket No. 82-75; RM-3963]

TV Broadcast Station in Forest City, North Carolina; Changes Made in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Action taken herein assigns UHF television Channel 66 to Forest City, North Carolina, in response to a petition filed by Rutherford Broadcasting, Inc. The assignment could provide a first television service to Forest City.

DATE: Effective August 31, 1982.


FOR FURTHER INFORMATION CONTACT: Mark N. Lipp, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:
List of Subjects in 47 CFR Part 73
Television.

Adopted: June 28, 1982.
Released: July 2, 1982.

In the matter of amendment of § 73.606(b), Table of Assignments, TV Broadcast Stations (Forest City, North Carolina); BC Docket No. 82-75, RM-3963; Report and order (Proceeding Terminated).

1. The Commission has under consideration a notice of proposed rule making, 47 FR 7462, published February 19, 1982, proposing the assignment of UHF television Channel 66 to Forest City, North Carolina, as its first local television assignment. The notice was issued in response to a petition filed by Rutherford Broadcasting, Inc. ("petitioner"). Supporting comments were filed by petitioner. No oppositions to the proposal were received. Petitioner reaffirmed its interest in applying for the channel, if assigned.

2. Forest City (population 7,668), in Rutherford County (population 53,787), is located in western North Carolina, approximately 90 kilometers (56 miles) west of Charlotte. Forest City presently has no local television channel assignment.

3. In its comments to the proposal, petitioner incorporated by reference the information contained in the notice demonstrating the need for a first television assignment to Forest City. Petitioner restated its intention to apply for the channel, if assigned.

4. The Commission believes that the petitioner has adequately demonstrated the need for a first television assignment to Forest City, and that the public interest would be served by assigning UHF television Channel 66 to that community. The assignment can be made in compliance with the minimum distance separation requirements and other technical criteria.

5. Accordingly, pursuant to the authority contained in Sections 4(l), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.204 and 0.281 of the Commission’s rules, it is ordered, That effective August 31, 1982, the Television Table of Assignments (§ 73.606(b) of the rules), is amended with respect to the following community:

<table>
<thead>
<tr>
<th>City</th>
<th>Channel No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forest City, North Carolina</td>
<td>66+</td>
</tr>
</tbody>
</table>

6. It is further ordered, That this proceeding is terminated.

7. For further information concerning this proceeding, contact Mark N. Lipp, Broadcast Bureau, (202) 632-7792.

(Sec. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303) Federal Communications Commission.

Roderick K. Porter,
Chief, Policy and Rules Division, Broadcast Bureau.

[FR Doc. 82-18623 Filed 7-8-82; 8:45 am]
BILLING CODE 6712-01-M

47 CFR Part 73

[BC Docket No. 82-110; RM-4012]

FM Broadcast Station In Goldendale, Wash.; Changes Made in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Action taken herein assigns Channel 272A to Goldendale, Washington, in response to a petition filed by Klickitat Valley Broadcasting Service. The assigned channel could provide a first FM service to Goldendale.

EFFECTIVE DATE: August 31, 1982.


FOR FURTHER INFORMATION CONTACT: Mark N. Lipp, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:
List of Subjects in 47 CFR Part 73
Radio broadcasting.

In the matter of amendment of § 73.202(b), table of assignments, FM Broadcast Stations (Goldendale, Washington); BC Docket No. 82-110, RM-4012; Report and Order (Proceeding Terminated).

Adopted: June 20, 1982.
Released: July 2, 1982.

1. The Commission has under consideration the Notice of Proposed Rule Making, 47 FR 8796, published March 2, 1982, proposing the assignment of Channel 272A to Goldendale, Washington, as that community’s first FM assignment in response to a petition filed by Klickitat Valley Broadcasting Service ("petitioner"). Comments in support of the proposal were filed by the petitioner.

2. Petitioner incorporated by reference the information in the Notice demonstrating the need for an FM assignment. Petitioner urges the Commission to adopt its proposal, and restated its intention to apply for the channel, if assigned. Additionally, petitioner indicated its preference of a transmitter site more distant than is usually allowed but stated that it would accept a closer one.

3. The Commission has determined that the public interest would be served by assigning Channel 272A to Goldendale, Washington, since it would provide the community with its first local FM broadcast service. The transmitter site is restricted to 2.5 miles south of the city of Goldendale to avoid short spacing to KPQ-FM, Channel 271, in Wenatchee, Washington.

4. Canadian concurrence has been received.

5. Accordingly, pursuant to the authority contained in sections 4(l), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.204(b) and 0.281 of the Commission’s Rules, it is ordered, That effective August 31, 1982, § 73.202(b) of the Commission’s Rules, is amended with respect to the following community:

<table>
<thead>
<tr>
<th>City</th>
<th>Channel No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goldendale, Washington</td>
<td>272A</td>
</tr>
</tbody>
</table>

6. It is further ordered, That this proceeding is terminated.

7. For further information, contact Mark N. Lipp, Broadcast Bureau, (202) 632-7792.
47 CFR Part 73
[BC Docket No. 81-817; RM-3954]

Summary: Action taken herein assigns FM Channel 252A to Pukalani, Hawaii, in response to a petition filed by Minority Broadcasting. The assignment could provide a first local broadcast service to Pukalani.

Agency: Federal Communications Commission.

Action: Final rule.

Summary: Action taken herein assigns FM Channel 252A to Pukalani, Hawaii, in response to a petition filed by Minority Broadcasting. The assignment could provide a first local broadcast service to Pukalani.

Agency: Federal Communications Commission.

Action: Final rule.

47 CFR Part 73
[BC Docket No. 81-817; RM-3954]

FM Broadcast Station in Pukalani, Hawaii; Changes Made in Table of Assignments

Agency: Federal Communications Commission.

Action: Final rule.

Summary: Action taken herein assigns FM Channel 252A to Pukalani, Hawaii, in response to a petition filed by Minority Broadcasting. The assignment could provide a first local broadcast service to Pukalani.

Agency: Federal Communications Commission.

Action: Final rule.

47 CFR Part 73
[BC Docket No. 81-782; RM-3937]

FM Broadcast Station in Cozad, Nebraska; Changes Made in Table of Assignments

Agency: Federal Communications Commission.

Action: Final rule.
5. It is further ordered, That this proceeding is terminated.
6. For further information concerning this proceeding, contact Montrose H. Tyree, Broadcast Bureau (202) 632-7792. (Secs. 4, 303, 48 Stat., as amended 1066, 1082, 47 U.S.C. 154, 303) Federal Communications Commission. Roderick K. Porter, Chief, Policy and Rules Division, Broadcast Bureau. [FR Doc. 82-18113 Filed 7-6-82; 8:45 am] BILLING CODE 6712-01-M

47 CFR Part 73
[BC Docket No. 82-133; RM-4035]

FM Broadcast Station in Shallotte, North Carolina; Changes Made in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Action taken herein assigns Channel 292A to Shallotte, North Carolina, in response to a petition filed by Shallotte Broadcasting Company, Inc. The assigned channel could provide a second FM service to Shallotte, since it would provide a second local FM broadcast service to that community.

5. It is further ordered, That this proceeding is terminated.
6. For further information, contact Mark N. Lipp, Broadcast Bureau, (202) 632-7792. (Secs. 4, 303, 48 Stat., as amended 1066, 1082; 47 U.S.C. 154, 303) Federal Communications Commission. Roderick K. Porter, Chief, Policy and Rules Division, Broadcast Bureau. [FR Doc. 82-18113 Filed 7-6-82; 8:45 am] BILLING CODE 6712-01-M

47 CFR Part 73
[BC Docket No. 82-277; RM-3981]

FM Broadcast Stations in Klamath Falls, Oregon; Changes Made in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This action assigns a third FM channel to Klamath Falls, Oregon, in response to a petition filed by Wyme Broadcasting Company, Inc.

EFFECTIVE DATE: August 31, 1982.


FOR FURTHER INFORMATION CONTACT: Montrose H. Tyree, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73
Radio broadcasting.

Adopted: June 26, 1982.
Released: July 1, 1982.

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations, (Klamath Falls, Oregon); BC Docket No. 82-77, RM-3981; Report and order (proceeding terminated).

1. In response to a petition filed by Wyme Broadcasting Co., Inc. ("petitioner")\(^1\), the Commission adopted a Notice of Proposed Rule Making, 47 FR 7465, published February 19, 1982, proposing the assignment of Channel 240A to Klamath Falls, Oregon. Supporting comments were filed by the petitioner stating its intention to apply for the channel, if assigned. Comments were also filed by 960 Radio, Inc., licensee of AM Station KLAD, Klamath Falls.\(^2\)

2. Since the assignment of Channel 240A could provide a third FM service to Klamath Falls, we believe that the public interest would be served by the requested assignment. Accordingly, pursuant to sections 4(i), 5(d)(1), 303(g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.204(b) and 0.281 of the Commission's Rules, it is ordered, That effective August 31, 1982, § 73.202(b) of the Commission's rules, is amended with respect to the following community:

<table>
<thead>
<tr>
<th>City</th>
<th>Channel No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shallotte, N.C.</td>
<td>228A and 292A</td>
</tr>
</tbody>
</table>

5. It is further ordered, That this proceeding is terminated.
6. For further information concerning this proceeding, contact Montrose H. Tyree, Broadcast Bureau, (202) 632-7792.

3. It is further ordered, That this proceeding is terminated.
4. For further information concerning this proceeding, contact Montrose H. Tyree, Broadcast Bureau, (202) 632-7792.

\(^1\)In comments to the proposal, petitioner submitted preclusion data. However, in view of the action in Revision of FM Policies and Procedures, BC Docket No. 80-130, 47 FR 20824, published June 21, 1982, that information is no longer needed to justify the requested assignment.

\(^2\)The comments of 960 Radio were submitted for the purpose of correcting the record in this proceeding to state that Station KLAD (AM) is a full-time station.
47 CFR Part 73

[BC Docket No. 81-853; RM-3962]

FM Broadcast Station in Amarillo, Texas; Changes Made in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This action assigns a sixth Class C FM channel to Amarillo, Texas, in response to a petition filed by K. T. Wiggins and R. K. Jack.

DATE: Effective August 31, 1982.


FOR FURTHER INFORMATION CONTACT: Montrose H. Tyree, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73
Radio broadcasting.

Adopted: June 28, 1982.
Released: July 2, 1982.

In the matter of Amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations (Amarillo, Texas); BC Docket No. 81-853, RM-3962; Report and Order (proceeding terminated).

1. In response to a petition filed by K. T. Wiggins and R. K. Jack (petitioners), the Commission adopted a notice of proposed rule making, 46 FR 61679, published December 18, 1981. The notice proposed assigning Class C Channel 245 to Amarillo, Texas, as its sixth commercial FM allocation. Supporting comments were filed by the petitioners restating their interest in the channel.

2. In comments, the petitioners restated the information previously submitted demonstrating the need for an additional FM assignment at Amarillo, and provided a list of alternate channels available to the communities precluded by a Channel 245 assignment to Amarillo.1

3. In view of the fact that the assignment could provide a sixth FM station to Amarillo, Texas, the Commission believes that the public interest would be served by assigning Channel 245 to that community. Accordingly, pursuant to the authority contained in Sections 4(f), 5(d)(1), 303(g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.204(b) and 0.281 of the Commission's Rules, it is ordered, That effective August 31, 1982, the FM Table of Assignments, § 73.202(b) of the rules is amended with regard to the following city:

<table>
<thead>
<tr>
<th>City</th>
<th>Channel No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amarillo, Tex.</td>
<td>226, 231, 245, 250, 254, and 270.</td>
</tr>
</tbody>
</table>

4. It is further ordered, That this proceeding is terminated.

5. For further information concerning this proceeding, contact Montrose H. Tyree, Broadcast Bureau, (202) 632-7792.

(Secs. 4, 303, 48 Stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.

Roderick K. Porter,
Chief, Policy and Rules Division, Broadcast Bureau.

[FR Doc. 82-18612 Filed 7-6-82; 8:45 am]
BILLING CODE 6712-01-M
This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 214

Nonimmigrant Classes; Petitions for Aliens Accompanying Nonimmigrant Aliens of Distinguished Merit and Ability

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Proposed rule.

SUMMARY: This proposed rule clarifies the admission requirements for aliens seeking to enter the United States for the purpose of accompanying nonimmigrant entertainers. The rule is needed to ensure that only those persons who are necessary to the success of the performance by an alien of distinguished merit and ability are included in the same classification.

DATE: Written comments will be considered if received on or before August 9, 1982.

ADDRESS: Please submit written comments in duplicate to the Commissioner, Immigration and Naturalization Service, 425 I Street NW., Washington, D.C. 20536.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: On August 4, 1980, the Service published a proposed rule in the Federal Register at 45 FR 51590 to give interested persons the opportunity to comment upon the rule to clarify the admission requirements for those nonimmigrant aliens who accompany aliens of distinguished merit and ability to the United States. The rule proposed that an entertainer’s successful performance must be dependent upon the accompanying alien’s participation in the performance because of their unique qualities, experience, or familiarity with the performance.

Due to the passage of time and a detailed examination of the area of concern, the Service has delayed implementing the proposed rule change and is again proposing a slightly modified change to the existing regulation.

Originally, four comments were received by the Service regarding the proposed rule. Three commenters, representing various labor organizations in the entertainment field, opposed amending the regulation. They believe no accompanying aliens should be allowed to enter as H-1 nonimmigrants unless they also are distinguished in merit and ability.

There are numerous instances where a support staff is essential to the successful performance by a distinguished entertainer, such as: Manager and trainers of an internationally famous boxer, musical accompanist to a celebrated soloist, and assistants to a renowned theatrical magician, among others. The Service proposes to continue to recognize these individuals as accompanying aliens and grant admission under H-1 provided the need to the entertainer for the success of the performance is fully established.

The fourth commenter, noting the economic contributions of foreign film makers, suggested exempting producers and key support personnel coming to the United States as nonimmigrants to produce motion pictures or television commercials or films from the requirements of the H classification. While his statement that such groups contribute to the local economy and often create jobs is well taken, the H nonimmigrant visa classification is currently the only classification available to temporary workers. The Service, in conjunction with the Department of State, is currently studying a similar suggestion relating to rules in this area. That proposal is to classify foreign film makers coming to film other than entertainment films under the visitor for business classification (B-1) if certain other restrictions are met.

In accordance with 5 U.S.C. 605(b), the Commissioner of Immigration and Naturalization certifies that the rule, if promulgated, will not have a significant impact on a substantial number of small entities. The proposed rule will not be a major rule as defined in section 1(b) of E.O. 12291. It will not have an effect on the economy of $100 million or more; result in an increase in costs or prices for consumers, individuals industries, federal, state, or local government agencies, or geographic regions; or have a significant adverse effect on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 8 CFR Part 214

Administrative practice and procedure, Aliens, Crime, Employment, Passports and visas.

After considering the comments received and restudying the proposed amendment, the Service is publishing this new proposed rule to provide a better understanding of the admission requirements and to again allow for public comment.

Accordingly, it is proposed to amend Chapter I of Title 8 of the Code of Federal Regulations as follows:

PART 214—NONIMMIGRANT CLASSES

In § 214.2 it is proposed to revise paragraph (h)(2)(v) to read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

(h) * * *

(v) Accompanying aliens. Managers, trainers, musical accompanists, and other persons determined by the district director to be necessary for successful performance by the beneficiary of a petition approved for classification under section 101(a)(15)(H)(j) of the Act may also be accorded such classification if included in the same or a separate petition. The petitioner must establish that accompanying aliens possess unique qualities, experience, or knowledge of the performance as to render success of the performance dependent upon their participation.

* * *
DEPARTMENT OF AGRICULTURE

Packers and Stockyards Administration

9 CFR Parts 201 and 203

Regulations and Policy Statements

AGENCY: Packers and Stockyards Administration, USDA.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On May 12, 1982, a notice of proposed rulemaking; review of existing regulations was published in the Federal Register (47 FR 20311) advising that the Packers and Stockyards Administration was considering amending and removing certain regulations and policy statements.

That notice provided that comments regarding the proposal should be filed with the Administration on or before July 12, 1982.

Pursuant to a request from interested parties for additional time to prepare their comments, the time for filing comments concerning the proposed revisions and removal of regulations and policy statements is hereby extended to and including July 31, 1982.

DATE: The time for filing comments is hereby extended to and including July 31, 1982.

ADDRESS: Comments may be mailed to the Administrator, Packers and Stockyards Administration, Room 3039, South Building, U.S. Department of Agriculture, Washington, D.C. 20250. Comments received may be inspected during normal business hours in the Office of the Administrator.

FOR FURTHER INFORMATION CONTACT: Jack Brinkmeyer, (202) 447-4366.

Done at Washington, D.C., July 6, 1982.

B. H. (Bill) Jones,
Administrator, Packers and Stockyards Administration.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 271

[Docket No. RM82-34-000]

High-Cost Gas Produced from Tight Formations

June 22, 1982

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of Petition for interpretation and clarification of rule.

SUMMARY: Anderson Petroleum, Inc. has filed a petition for interpretation and clarification of Commission regulations under the Natural Gas Policy Act regarding the definition of recompletion tight formation gas. Anderson states that an ambiguity exists in this definition as it is applied to various tight formations which could discourage the efficient production of available reserves of tight sands gas.

DATE: Comments must be received on or before July 26, 1982.


FOR FURTHER INFORMATION CONTACT: Leslie Lawner, Office of the General Counsel, FERC, (202) 357-8511.

Petition of Anderson Petroleum, Inc. for Interpretation and Clarification of Part 271 of the Commission's Regulations

Take notice that on June 4, 1982, Anderson Petroleum, Inc. (Anderson) filed a petition pursuant to § 1.7 of the Commission's Rules of Practice and Procedure requesting that the Commission interpret and clarify § 271.703 of its regulations implementing sections 107(b) and 107(g)(6) of the Natural Gas Policy Act of 1978 (NGPA), 15 U.S.C. 3301-3432. Anderson requests that the Commission exercise its authority under NGPA sections 501(a), 501(b), 107(b) and 107(c)(5), and issue an interpretation of § 271.703(b)(3) of its regulations to clarify that the definition of “recompletion tight formation gas” includes additional volumes of natural gas produced as a result of enhanced production work undertaken after the filing date of the subject petition, involving perforation, fracturing, and other necessary downhole recompletion work from certain wells completed for production in a designated tight formation prior to July 16, 1979.

Section 271.703(b)(3) of the Commission's regulations defines "recompletion tight formation gas" as "natural gas which is produced from a designated tight formation through a well, the surface drilling of which was begun before July 16, 1979, if such well was not completed for production from such designated formation before July 16, 1979."

Anderson states in its application that it believes that "an ambiguity exists in this definition as it is applied to various tight formations which could discourage the efficient production of available reserves of tight sands gas." Anderson requests that the Commission issue a clarifying rule which would allow recompletions in zones other than the zone in which the well was completed on July 16, 1979, in the designated tight formations, to be permitted the incentive price as this gas is produced as a result of undertaking high risks and costs.

Anderson states that this result is consistent with the regulations which allow a producer to recomplete a single well in separately designated tight formations and to qualify for the incentive price.

Anderson also proposes that in order to prevent premature abandonment of existing reserves, the Commission could stipulate that before recompletion work in undertaken on wells originally completed in a designated tight formation prior to July 16, 1979, the well must have a recorded average daily maximum efficient production of 60 Mcf per day or less for a 120-day which falls entirely within 150 days prior to the date on which the application for recompletion qualification is filed.

Anderson's petition is on file with the Commission and is available for public inspection in the Commission's Office of Public Information. Any persons desiring to participate in this request for clarification should file their comments with the Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before July 26, 1982.

Kenneth F. Plumb,
Secretary.

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

Public Comment Period on Modified Portions of the West Virginia Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.
ACTION: Proposed rule; notice of receipt of permanent program modification and public comment period.

SUMMARY: OSM is announcing a public comment period on the substantive adequacy of a program amendment submitted to satisfy a condition imposed on the approval of the West Virginia permanent regulatory program (hereinafter referred to as the West Virginia program) under the Surface Mining and Reclamation Act of 1977 (SMCRA).

This notice sets forth the times and locations that the West Virginia program and the proposed amendment are available for public inspection and the comment period during which interested persons may submit written comments on the proposed program amendment.

DATE: Written comments must be received on or before 4:00 p.m. on August 8, 1982, to be considered in the Director's decision on whether the proposed amendment satisfies the condition.

ADDRESSES: Written comments should be mailed or hand delivered to: Office of Surface Mining Reclamation and Enforcement, Attention: West Virginia Administrative Record, 603 Morris Street, Charleston, West Virginia 25301.

Copies of the West Virginia program, the modification to the program, a listing of the scheduled public meetings, and all written comments are available for review at the OSM offices and the office of the State regulatory authority listed below, Monday through Friday, 9:00 a.m. to 4:00 p.m., excluding holidays.

Office of Surface Mining Reclamation and Enforcement, 603 Morris Street, Charleston, West Virginia 25301, Telephone: (304) 347-7158.

Office of Surface Mining Reclamation and Enforcement, Room G315, 1100 L Street, N.W., Washington, D.C. 20240, Telephone: (202) 343-7885.

West Virginia Department of Natural Resources, Room 630, Building 3, 1800 Washington Street, East, Charleston, West Virginia 25305, Telephone: (304) 346-9160.

FOR FURTHER INFORMATION CONTACT: David H. Halsey, State Director, Office of Surface Mining, 603 Morris Street, Charleston, West Virginia 25301, Telephone: (304) 347-7158.

SUPPLEMENTARY INFORMATION: On March 17, 1981, the Secretary of the Interior received a proposed regulatory program from the State of West Virginia. On January 21, 1981, following a review of that proposed program as outlined in 30 CFR Part 732, the Secretary of the Interior approved the program conditioned on the correction of minor deficiencies. Information pertinent to the general background of the permanent program submission, as well as the Secretary's findings, the disposition of comments and explanations of the conditions of approval of the West Virginia program can be found in the January 21, 1981 Federal Register (46 FR 5915-5956).

On April 29, 1981, the State provided a copy of proposed coal refuse disposal regulations to OSM for review (Administrative Record No. WV 400). On June 8, 1981, OSM provided an informal listing of deficiencies found in the proposed regulations (Administrative Record No. 401a) and informed the State that the promulgated regulations must be submitted as a program amendment which would be subject to public comment. The regulations were promulgated by West Virginia on October 1, 1981, and submitted as a program amendment on October 28, 1981.

The Director, OSM, determined that the amendment contained minor deficiencies and therefore, conditionally approved the amended regulation on May 11, 1982 (47 FR 20119-20122, Administrative Record No. WV 438). Finding 4 of the Director's approval stated that the State regulations required that water leaving the permit area would not lower the water quality of the river, stream or drainageway into which it is discharged. Since this conflicts with the requirements of 30 CFR 816.41 and 817.41, the Director conditioned the approval of the amended regulations upon compliance with the Federal requirements of June 15, 1982 (See Condition 8 (iii)). On June 17, 1982, the State of West Virginia submitted a copy of an amendment to the Coal Refuse Regulations to satisfy Condition 8 (iii) of the conditional approval. The amendment was filed on an emergency basis with the West Virginia Secretary of State on June 17, 1982. The complete text of the amendment follows. The brackets indicate deleted language and italic indicates the added provision.

"E. 03 Water Quality. a. Water Quality Control—All reasonable measures shall be taken to intercept all surface water by the use of diversions, culverts and drainage ditches or other methods to prevent water from entering the operational area. The water leaving the permit area will not lower the water quality of [meet all applicable federal and state water quality standards for the river, stream or drainageway into which it is discharged. All surface drainage from the disturbed area must pass through a sediment pond or series of sediment ponds or other approved sediment or treatment control structures."

The Director now seeks public comment on the adequacy of this amendment in satisfying Condition 8 (iii) of the conditional program approval. No public hearing will be held concerning this amendment.

Additional Determinations

Pursuant to Section 702(d) of SMCRA, 30 U.S.C. 1282(d), no environmental impact statement need be prepared for this rulemaking.

On August 28, 1981, the Office of Management and Budget (OMB) granted OSM an exemption from Sections 3, 4, 6 and 8 of Executive Order 12291 for all State program actions taken to approve or conditionally approve State regulatory programs, actions or amendments. Therefore, this rule is exempt from a Regulatory Impact Analysis and regulatory review by OMB.

Pursuant to the Regulatory Flexibility Act, Pub. L. 96-354, I have certified that this proposed rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 30 CFR Part 948
Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Dated: July 1, 1982.

William B. Schmidt,
Assistant Director, Program Operations and Inspection.

[FR Doc. 82-18059 Filed 7-8-82; 8:45 am]

BILLING CODE 4310-05-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 712

[OPTS--82004 F; 2039-7]

Chemical Information Rules; Preliminary Assessment Information; Opportunity for Additional Comment

Correction

In FR Doc. 15087 appearing on page 27009 in the issue of Tuesday, June 22, 1982, make the following correction.

On page 27013, second column, paragraph "(f)" third line, in place of the date "September 20, 1982" insert the phrase "(insert date 90 days after date of publication of the final rule in the Federal Register)."

BILLING CODE 1505-01-M
FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA-6355]

Proposed Base Flood Elevation and Zone Designation Determinations for
City of Midwest City, Oklahoma County, Oklahoma, Under National Flood Insurance Program

AGENCY: Federal Emergency Management Agency.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base flood elevations and zone designations as described below.

The proposed base flood elevations and zone designations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to quality or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The period for comment will be ninety (90) days following the second publication of this proposed rule in the newspaper of local circulation in the above-named community.

ADDRESSES: Maps and other information showing the detailed outlines of the floodprone areas and the proposed base flood elevations and zone designations are available for review at the Office of the City Engineer, 100 North Midwest Boulevard, Midwest City, Oklahoma.

Send comments to: Honorable Dave Herbert, Mayor, City of Midwest City, P.O. Box 10570, Midwest City, Oklahoma 73140.


SUPPLEMENTARY INFORMATION:

The Associate Director, State and Local Programs and Support, gives notice of the proposed base flood elevations and zone designations for the City of Midwest City, Oklahoma, in accordance with Section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93–234), 87 Stat. 980, which added Section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director, State and Local Programs and Support.

Issued: June 16, 1982.

Lee M. Thomas,
Associate Director, State and Local Programs and Support.

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[BC Docket No. 82–351; RM–4104]

TV Broadcast Stations (La Salle, and Pontiac, Ill.); Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This action proposes the reallocation of UHF Television Channel 35 from La Salle, Illinois, to Pontiac, Illinois, in response to a petition by Livingston County Broadcasters, Inc. The proposed channel assignment at Pontiac could provide a first local television service to that community.

DATES: Comments must be filed on or before August 9, 1982, and reply comments on or before August 24, 1982.


FOR FURTHER INFORMATION CONTACT: Mark N. Lipp, Broadcast Bureau, (202) 632–7792.

SUPPLEMENTAL INFORMATION:

List of Subjects in 47 CFR Part 73

Television.

In the matter of amendment of § 73.600(b), Table of Assignments, TV Broadcast Stations, (La Salle, and Pontiac, Illinois); BC Docket No. 82–351, RM–4104.

Adopted: June 23, 1982.

Released: July 1, 1982.

1. The Commission herein considers a petition for rule making filed April 19, 1982, by Livingston County Broadcasters, Inc. ("petitioner") seeking the reassignment of UHF television Channel 35 from La Salle, Illinois, to Pontiac, Illinois. Petitioner expressed an interest in applying for the channel, if assigned.
2. Pontiac (population 11,227), the seat of Livingston County (population 41,381), is located 130 kilometers (82 miles) southwest of Chicago, Illinois. La Salle County (population 109,139), is located 65 kilometers (38 miles) southwest of Pontiac. Pontiac has no local television broadcast service.

3. Pontiac is the county seat of Livingston County and is also the largest city in the county. With over 300 businesses in the county, Pontiac was responsible for over $60 million of the county's total retail sales of $184 million in 1981. Even though the population of Livingston County decreased between 1970 and 1980, Pontiac shows an increase in population for that period.

4. Petitioner says that Channel 35 has been assigned to La Salle for ten years without an interest shown. Therefore, a change should be proposed to the TV Table of Assignments.

5. In view of the fact that the proposal could provide a first TV service to Pontiac, it is proposed, That the TV Table of Assignments.

6. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein. NOTE: A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

7. Interested parties may file comments on or before August 9, 1982, and reply comments on or before August 24, 1982, and are advised to read the Appendix for the proper procedures.

8. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules. See, Certification that sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission's Rules, 46 FR 11549, published February 9, 1981.

9. For further information concerning this proceeding, contact Mark N. Lipp, Broadcast Bureau, (202) 632-7792. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all ex parte contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An ex parte contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an ex parte presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment to which the reply is directed constitutes an ex parte presentation and shall not be considered in the proceeding.

Appendix

1. Pursuant to authority found in sections 4(j), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.281(b)(6) and 0.204(b) of the Commission's Rules, it is proposed to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules and Regulations, as set forth in the Notice of Proposed Rule Making to which this Appendix is attached.

2. Showings Required. Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a station promptly. Failure to file may lead to denial of the request.

3. Cut-off Procedures. The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of the Commission's Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. Comments and Reply Comments; Service. Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rule Making to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420(a), (b) and (c) of the Commission's Rules.)

5. Number of Copies. In accordance with the provisions of Section 1.420 of the Commission's Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. Public Inspection of Filings. All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

[FR Doc. 82-1853 Filed 7-8-82; 8:45 am]
BILLING CODE 6712-01-M

1Population figures are taken from the 1980 U.S. Census, Advance Report.
3. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note.—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

4. Interested parties may file comments on or before August 16, 1982, and reply comments on or before August 31, 1982, and are advised to read the Appendix for the proper procedures.

5. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the FM Table of Assignments, § 73.202(b) of the Commission's rules. See, Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission's rules, 46 FR 11549, published February 9, 1981.

6. For further information concerning this proceeding, contact Mark N. Lipp, Broadcast Bureau, (202) 632-7792. However, members of the public should note that from the time a notice of proposed rule making is issued until the matter is no longer subject to Commission consideration or court review, all ex parte contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An ex parte contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the person(s) who filed the comment to which the reply is directed constitutes an ex parte presentation and shall not be considered in the proceeding.

(Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303.)
Federal Communications Commission.

Roderick K. Porter,
Chief, Policy and Rules Division, Broadcast Bureau.

[FR Doc. 82-18827 Filed 7-4-82; 8:45 am]
BILLING CODE 6712-01-M

47 CFR Part 73

[BC Docket No. 82-350; RM-4080]

FM Broadcast Station in Bay Shore, New York; Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This action proposes to assign FM Channel 276A to Bay Shore, New York, in response to a petition filed by Living Communications, Inc. The assignment could provide Bay Shore with a first local aural service.

DATES: Comments must be filed on or before August 9, 1982, and reply comments must be filed on or before August 24, 1982.


FOR FURTHER INFORMATION CONTACT: Nancy V. Joyner, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:
List of Subjects in 47 CFR Part 73
Radio broadcasting.

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations (Bay Shore, New York), BC Docket No. 82-350, RM-4080.

1. Before the Commission is a petition for rule making filed by Living Communications, Inc. ("petitioner"), proposing the assignment of FM Channel 276A to Bay Shore, New York, as that community's first FM assignment. Petitioner stated its intention to apply for the channel, if assigned.

2. Bay Shore (population 11,119) is located in Suffolk County (population 1,284,231), approximately 63 kilometers (39 miles) east of New York, New York. It currently has no local aural service.

3. In support of its proposal, petitioner submits that Bay Shore, a hamlet of Islip Township, is the commercial center for the surrounding portion of Suffolk County. According to petitioner, Bay Shore has numerous retail outlets, schools, health-care facilities, a post office, State and county government facilities, financial institutions, churches, civic and social organizations, as well as local print media. Further,

1Population figure was obtained from the 1970 U.S. Census, since the preliminary 1980 U.S. Census does not provide statistics for unincorporated communities.
2Population figure was derived from the preliminary 1980 U.S. Census.
petitioner indicates that two major highways serve Bay Shore, which is said to be the main access point to Fire Island.

4. In order to accommodate this proposal, the transmitter site is restricted to an area approximately 4 miles south of Bay Shore, New York, to avoid short-spacing to Station WDRC (Channel 275), Hartford, Connecticut, and WNEW (Channel 274), New York, New York. Due to the close proximity to the Atlantic Ocean and the scarcity of land in this area, it is questionable whether an on-shore site can be found.

5. Generally, we are not concerned with site availability at the rule making stage. However, we note that this particular problem was under consideration previously in 1970. At that time, Channel 276A was assigned to Bay Shore as a drop-in, with a 5 mile site restriction. (See, Bay Shore, New York, 20 FCC 2d 898 (1970), 18 RR 2d 1510).

The restricted location required placing the transmitter on a portion of Fire Island, lying within the Fire Island National Seashore. (That area was established pursuant to an Act of Congress in 1964, and placed under the jurisdiction of the Secretary of the Interior or the National Park Service). This very limited area was the only suitable location because of the spacing requirements to the north and west; the Atlantic Ocean to the south and environmental considerations to the east. Furthermore, a Guard tower located less than a mile from the proposed site was not available for joint use since permission by military authorities was not given and, in any event, a tower of 300 feet was required to provide city-grade coverage over all of Bay Shore.

6. At the time the assignment was made, however, the Commission was unaware of the exact provisions of the National Environmental Policy Act of 1969, 42 U.S.C. 4321–4347, which had recently been enacted. That Act directs, inter alia, that all agencies of the Federal Government invoke or implement the environmental impact statement process before deciding on legislative or other major agency actions which would have a significant effect on the quality of the human environment. Further, it requires that, before making an environmental statement, the initiating agency is responsible for consulting with and obtaining the comments of any other Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved.

7. Since the proposed antenna site required to accommodate that Bay Shore proposal would have been located within a national preserve falling within the jurisdiction of the Department of Interior or the National Park Service, those officials should have been contacted to determine whether there would be an impact on the environment from an esthetic viewpoint. Such consultations were never had, and the Department of Interior filed comments opposing the assignment.

8. As a consequence of the opposition, the Commission determined that, although the assignment would have provided Bay Shore residents an opportunity to receive a first local broadcast service, the environmental impact involved outweighed retaining the channel in the Table. Therefore, the Commission rescinded its earlier action and deleted the channel in the Table of Assignments for Bay Shore, New York. See, Bay Shore, New York, 25 FCC 2d 877 (1970), 20 RR 2d 1556.

9. In view of the background circumstances surrounding the lack of a proper site location to accommodate an assignment to Bay Shore, we must require petitioner to provide evidence that the requirements of § 73.208(a)(4) of our Rules can be satisfied. Petitioner should indicate in its comments the extent to which it has investigated Federal, State and local requirements, if any, which must be complied with in order to obtain approval for use of its site, and a technical showing to demonstrate that its proposed site could place the requisite city-grade signal over all of Bay Shore from an acceptable site.

10. In view of the foregoing, the Commission proposes to amend the FM Table of Assignments, § 73.202(b) of the Commission’s Rules with respect to Bay Shore, New York, as follows:

<table>
<thead>
<tr>
<th>City</th>
<th>Channel No.</th>
<th>Present</th>
<th>Proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bay Shore, N.Y.</td>
<td>276A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. The Commission’s authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note.—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

12. Interested parties may file comments on or before August 9, 1982, and reply comments on or before August 24, 1982, and are advised to read the Appendix for the proper procedures.

13. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the FM Table of Assignments, Section 73.202(b) of the Commission’s Rules. See, Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making To Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission’s Rules, 46 FR 11549, published February 9, 1981.

14. For further information concerning this proceeding, contact Nancy V. Joyner, Broadcast Bureau, (202) 632–7792. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all ex parte contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An ex parte contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an ex parte presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment to which the reply is directed constitutes an ex parte presentation and shall not be considered in the proceeding.

(Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.

Roderick K. Porter, Chief Policy and Rules Division, Broadcast Bureau.

Appendix

1. Pursuant to authority found in Sections 4(l), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.281(b)(6) and 0.204(b) of the Commission’s rules, it is proposed to amend the FM Table of Assignments, § 73.202(b) of the Commission’s Rules and Regulations, as set forth in the notice of proposed rule making to which this Appendix is attached.

2. Showings Required. Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if
authorized, to build a station promptly. Failure to file may lead to denial of the request.

3. Cut-off Procedures. The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of the Commission’s Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. Comments and Reply Comments; Service. Pursuant to applicable procedures set out in §§ 1.1415 and 1.420 of the Commission’s Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the notice of proposed rule making to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420(a), (b) and (c) of the Commission’s rules.)

5. Number of Copies. In accordance with the provisions of § 1.420 of the Commission’s Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. Public Inspection of Filings. All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission’s Public Reference Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

7. Cut-off Procedures. The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of the Commission’s Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

47 CFR Part 73
[BC Docket No. 82-352; RM-4096]

TV Broadcast Station Wilmington, North Carolina; Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: Action taken herein proposes to substitute UHF television Channel 26 for Channel 29 at Wilmington, North Carolina, and modify the permit for Channel 26 accordingly in response to a petition filed by Wilmington Telecasters, Inc.

DATES: Comments must be filed on or before August 9, 1982, and reply comments on or before August 24, 1982.


FOR FURTHER INFORMATION CONTACT: Montrose H. Tyree, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73

Television.

Adopted: June 23, 1982.

Released: July 1, 1982.

In the matter of Amendment of § 73.606(b), Table of Assignments, Television Assignments (Wilmington, North Carolina); BC Docket No. 82-352, RM-4096.

1. Wilmington Telecasters, Inc. ("petitioner"), on April 5, 1982, filed a petition for rule making seeking to substitute UHF television Channel 26 for Channel 29 at Wilmington, North Carolina.

2. Petitioner states that the proposal is a result of its search for a suitable transmitter and antenna location for the proposed station on Channel 29.

3. Petitioner is said to be negotiating with Clay Broadcasting Corporation (licensee of Station WWAY-TV), Wilmington, North Carolina, for use of its planned tower. A station operating on Channel 29 at its intended location would be short-spaced to Station WGSE(TV), Myrtle Beach, South Carolina. However, a station operating on Channel 26 at that location could meet the necessary spacing requirements.

4. We believe that the petitioner’s proposal warrants consideration. The channel can be substituted in compliance with the Commission’s minimum distance separation requirements and other technical criteria. In addition, we also propose to modify the permit for Channel 29 to specify Channel 26.

5. The Commission’s authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note.—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

6. Interested parties may file comments on or before August 9, 1982, and reply comments on or before August 24, 1982, and are advised to read the Appendix for the proper procedures.

7. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the FM Table of Assignments, § 73.606(b) of the Commission’s Rules. See, Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend §§ 73.202(b). 73.504 and 73.606(b) of the Commission’s Rules, 46 FR 11549, published February 9, 1981.

8. For further information concerning this proceeding, contact Montrose H. Tyree, Broadcast Bureau, (202) 632-7792. However, members of the public should note that from the time a notice of proposed rule making is issued until the matter is no longer subject to Commission consideration or court review, all ex parte contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An ex parte contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an ex parte presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment to which the reply is directed constitutes

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1 Wilmington Telecasters, Inc. is the permittee for Channel 29 at Wilmington, North Carolina (BC Docket No. 82-352, RM-4096).
an ex parte presentation and shall not be considered in the proceeding.

Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)
Federal Communications Commission.
Roderick K. Porter, Chief, Policy and Rules Division, Broadcast Bureau.

Appendix

1. Pursuant to authority found in Sections 4(f), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.281(b)(6) and 0.204(b) of the Commission's Rules, it is proposed to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules and Regulations, as set forth in the notice of proposed rule making to which this Appendix is attached.

2. Showings Required. Comments are invited on the proposal(s) discussed in the notice of proposed rule making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a station promptly. Failure to file may lead to denial of the request.

3. Cut-off Procedures. The following procedures will govern the consideration of filings in this proceeding.
(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of the Commission's rules.)
(b) With respect to petitions for rule making which conflict with the proposal(s) in this notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.
(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. Comments and Reply Comments: Service. Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the notice of proposed rule making to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420(a), (b) and (c) of the Commission's Rules.)

5. Number of Copies. In accordance with the provisions of § 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleading, briefs, or other documents shall be furnished the Commission.

6. Public Inspection of Filings. All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, NW., Washington, D.C.

[FR Doc. 82-18625 Filed 7-8-82; 8:45 am]
BILLING CODE 7110-01-M

47 CFR Part 73

[BC Docket No. 82-355; RM-4092]

TV Broadcast Station in Farwell, Texas; Proposed Changes in Table of Assignments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This action proposes the assignment of UHF television Channel 18 to Farwell, Texas, as its first television assignment in response to a petition filed by Best Broadcasting Company, Inc.

DATES: Comments must be filed on or before August 13, 1982, and reply comments on or before August 30, 1982.


FOR FURTHER INFORMATION CONTACT: Mark N. Lipp, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73

Television.

Adopted: June 24, 1982.

Released: June 29, 1982.

In the matter of amendment of § 73.606(b); Table of Assignments, Television Broadcast Stations (Farwell, Texas); BC Docket No. 82-355, RM-4092.

1. The Commission herein considers a petition for rule making filed March 23, 1982, by Best Broadcasting Company, Inc. ("petitioner"), which seeks the assignment of UHF television Channel 18 to Farwell, Texas.

2. Farwell (population 1,354) is the seat of Parmer County (population 11,038). It is located approximately 140 kilometers (88 miles) southwest of Amarillo and northwest of Lubbock in the Texas Panhandle. Farwell has no local television service.

3. According to petitioner, Farwell's economy would support a first television assignment. There are no television channels assigned to the community or to Parmer County.

4. The transmitter site is restricted to 1.5 miles north of the city to avoid short spacing to Channel 18 in Midland, Texas.

5. In view of the fact that Farwell could receive a first local television service, the Commission finds that it would be in the public interest to seek comments on the proposal to amend the Television Table of Assignments (§ 73.606(b) of the rules) as follows:

<table>
<thead>
<tr>
<th>City</th>
<th>Channel No.</th>
<th>Present</th>
<th>Proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farwell, Texas</td>
<td>18+</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note.—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

7. Interested parties may file comments on or before August 13, 1982, and reply comments on or before August 30, 1982, and are advised to read the Appendix for the proper procedures.

8. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the Television Table of

1Petitioner is the licensee of AM Station K2OL and an applicant for FM Channel 222 (BH1 811016AQ) in Farwell. Petitioner states that if it is the ultimate permittee of television Channel 18, it will sell its conflicting broadcast interests or seek a waiver of § 73.606 in order to comply with the Commission's multiple ownership rules.

2Population figures were derived from the 1980 U.S. Census Advance Report.
Assignments, § 73.606(b) of the Commission's rules. See, Certification that Section 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission's Rules, 46 FR 11549, published February 9, 1981.

9. For further information concerning this proceeding, contact Mark N. Lipp, Broadcast Bureau, (202) 632-7792. However, members of the public should note that from the time a notice of proposed rule making is issued until the matter is no longer subject to Commission consideration or court review, all ex parte contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An ex parte contact is a message (spoken or written) concerning assignments. An ex parte contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an ex parte presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment to which the reply is directed constitutes an ex parte presentation and shall not be considered in the proceeding.

(See Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)
Federal Communications Commission.
Roderick K. Porter,
Chief, Policy and Rules Division, Broadcast Bureau.

Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.204(b) and 0.28(1)(b)(6) of the Commission's Rules, it is proposed to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules and Regulations, as set forth in the notice of proposed rule making to which this Appendix is attached.

2. Showings Required. Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The petitioner constitutes an ex parte presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment to which the reply is directed constitutes an ex parte presentation and shall not be considered in the proceeding.

(See § 1.415(d) of the Commission's Rules.)

3. Cut-off Procedures. The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of the Commission's Rules.)

(b) With respect to petitions or rule making which conflict with the proposal(s) in this notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given long as they are filed before the date for filing initial comments herein. If any petition is not considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. Comments and Reply Comments; Service. Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the notice of proposed rule making to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420(a), (b) and (c) of the Commission's Rules.)

5. Number of Copies. In accordance with the provisions of § 1.420 of the Commission's rules and regulations, and original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. Public Inspection of Filings. All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

[FR Doc. 82-18624 Filed 7-8-82; 8:45 am]
BILLING CODE 6712-01-M
This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Protection of Historic and Cultural Properties

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of supplementary guidance regarding preparation of Memoranda of Agreement.

SUMMARY: On June 4, 1982, 47 FR 24306, the Advisory Council on Historic Preservation (Council) temporarily suspended its regulations at 36 CFR 800.6(c)(1) which set out directions for preparation of Memoranda of Agreement. The Council now publishes supplementary guidance for the preparation of Memoranda of Agreement to be used in lieu of § 800.6(c)(1).


SUPPLEMENTARY INFORMATION: The Council has prepared this "Supplementary Guidance: Preparation of Memoranda of Agreement" for Federal agencies, State Historic Preservation Officers, and other interested parties to use in lieu of 36 CFR 800.6(c)(1), which was suspended on June 4, 1982, in the preparation of Memoranda of Agreement under the Council's Section 106 process as set forth in 36 CFR Part 800. The purpose of the suspension and these guidelines is to introduce more flexibility into the Memorandum of Agreement process while providing sufficient direction for the adequate preparation of Memoranda of Agreement. The suspension and guidelines do not relieve Federal agencies of any other responsibilities regarding Memoranda of Agreement that are contained in other provisions of 36 CFR Part 800.

Robert R. Garvey,
Executive Director.

Supplementary Guidance: Preparation of Memoranda of Agreement

I. Purpose

This guidance is issued in accordance with 36 CFR 800.14 and provides Federal agencies, State Historic Preservation Officers, and other interested parties with information to assist in the preparation of Memoranda of Agreement (MOA) that are used to meet the requirements of section 106 of the National Historic Preservation Act. This guidance is in lieu of the provisions of 36 CFR 800.6(c)(1), which have been suspended. Suspension of 36 CFR 800.6(c)(1) does not eliminate other provisions of 36 CFR Part 800 regarding Memoranda of Agreement.

II. Policy

A duly executed MOA constitutes the comments of the Council and evidences that a Federal agency has taken into account the effects of its undertaking on historic properties. It is a contractual document setting forth the rights and responsibilities of the signatories. As such, it must be precise in its terms and clearly understandable as to the intent of the parties should a question arise regarding compliance with the MOA. Within this framework, MOAs should be crafted to meet the particular needs of each undertaking and the consulting parties. In reviewing MOAs, the Executive Director will seek to ensure that they accurately and concisely set forth the agreements reached by the parties and that they are then executed with a minimum of paperwork and delay. Objections to a proposed MOA will be based on questions relating only to substantive matters, the clarity of the MOA, or legal sufficiency. Elements strictly of form will not be a basis for rejecting a proposed MOA.

III. Preparation of an MOA

Depending on the circumstances of the particular undertaking, an Agency Official may elect to follow either the normal process of preparing an MOA or an expedited method. An Agency Official is encouraged to assume responsibility for preparing an MOA and should select the method most appropriate to the particular undertaking and its effects. An applicant for Federal assistance or approval may draft the MOA.

A. Normal Process

When the consultation process ([§ 800.6(b)] the SHPO, and the Executive Director have reached agreement on feasible and prudent alternatives to avoid or mitigate the adverse effects of the undertaking and on proposed language for an MOA, the Agency Official should prepare the final MOA, unless the consulting parties determine otherwise. The Agency Official may submit to the Executive Director for review the MOA with the signature of the SHPO and, when appropriate, any other signatory or concurring parties. If the Executive Director determines that it accurately reflects the agreement of the consulting parties, he shall sign it and forward it within 10 days to the Chairman for ratification in accordance with § 800.6(c)[2]. If the Executive Director determines the MOA is deficient, he may return it to the Agency Official for revision or may prepare an alternate MOA.

Alternately, to assist in focusing the consultation, a proposal for an MOA may be developed jointly by the Agency Official and the SHPO prior to formal initiation of the consultation process and submitted for consideration along with the preliminary case report. A draft should not be signed when it is submitted at the beginning of the consultation process. Formalities of preparing the final MOA shall be determined by the consulting parties as the consultation process is concluded.

B. Expedited Process

In the case of noncontroversial undertakings that have effects which are customarily mitigated in a standard manner, following accepted professional practices such as those set out in the Council's Manual of Mitigation Measures, initial discussion between the Agency Official and the SHPO may indicate that a certain course of action is desirable and that further consultation with the Council is likely to reach the same result. In such a case, the Agency Official may prepare an MOA, obtain the signatures of the SHPO and any other appropriate signatories or concurring parties and submit the MOA to the Executive Director concurrent with the request for comments and
substituted language is ambiguous, standard form will not be made unless simply because it deviates from a particular case. Objections to language different language is more appropriate in not be constrained to achieve their objectives. Drafters should incorporate principles are met. Certain standard reflecting the parties' intent. An MOA should be concise and free of MOA. First, an MOA is a legal process.

Two principles guide the form of an MOA. First, an MOA is a legal document evidencing agency compliance with section 106 and must unambiguously state all the terms for taking into account the undertaking's effects on historic properties. Second, an MOA should be concise and free of extraneous language, while accurately reflecting the parties' intent. An MOA may be adapted to the needs of a particular situation as long as these two principles are met. Certain standard language is useful to ensure clarity; drafters are encouraged to employ accepted terms and phrases or incorporate by reference standards and guidelines issued by the Council to achieve their objectives. Drafters should not be constrained by stock terms when different language is more appropriate in a particular case. Objections to language simply because it deviates from a standard form will not be made unless there is a reason to believe the substituted language is ambiguous, misstates the intent of the parties, is legally insufficient or raises problems of substance. An MOA must contain all the substantive elements of the agreement among the parties. These stipulations may be prepared as a separate document, delineating the rights and responsibilities of all signatories; this should be appended to an MOA that conforms to the attached sample. The stipulations may take the form of a letter or memorandum. Alternatively, the MOA may be drafted as a single document, incorporating the stipulations into the body of the MOA.

An MOA is normally executed with all signatures on a single original. Where all parties concur, an MOA may be executed in duplicate originals so that the assembled documents evidence the signatures of all parties, though not on a single document. An MOA executed this way will be submitted to the Chairman for ratification when all signed originals have been received by the Executive Director.

V. Parties to an MOA

The Council's regulations require that an MOA be signed by the Agency Official, the Executive Director, and the SHPO, unless the latter has declined to participate pursuant to § 800.5(c). As a general rule, any other party who assumes a responsibility for action under the terms of an MOA should also be a signatory. Other parties who have an interest in the undertaking and its effects on historic properties may be invited by the consulting parties to indicate their concurrence with the MOA. This can be indicated by a concurring signature on the MOA or a letter of concurrence.

VI. Additional Information

Agency Officials, SHPOs and others who have specific questions regarding the preparation of an MOA are encouraged to contact the Executive Director for assistance in meeting the objectives of this guidance.

Sample—Memorandum of Agreement

Whereas, the (agency) has determined that (undertaking) will have an effect upon properties included in or eligible for inclusion in the National Register of Historic Places and has requested the comments of the Advisory Council of Historic Preservation pursuant to section 106 (and section 110f) of the National Historic Preservation Act (16 U.S.C. 470) and its implementing regulations, "Protection on Historic and Cultural Properties (36 CFR Part 800). Now, Therefore, the (agency), the (State) Historic Preservation Officer, and the Advisory Council on Historic Preservation agree that the undertaking shall be implemented in accordance with the following or attached stipulations in order to take into account the affect of the undertaking on historic properties.

(Insert stipulations or attach to document)

Execution of this Memorandum of Agreement evidences that the (agency) has afforded the Council a reasonable opportunity to comment on the (undertaking) and its effects on historic properties and that the (agency) has taken into account the effects of its undertaking on historic properties.

Agency Official Date

State Historic Date

Preservation Officer

Executive Director, ACHP Date

Chairman, ACHP Date

[FR Doc. 82-18706 Filed 7-6-82; 8:45 am]
BILLING CODE 4310-10-M

DEPARTMENT OF AGRICULTURE

Forest Service

Nezperce National Forest Grazing Advisory Board; Meeting

The Nezperce National Forest Grazing Advisory Board will meet at 8:00 a.m., August 10, 1982, at Hoot's Cafe near White Bird, Idaho. The purpose of the meeting will be to make a guided field survey of noxious weeds, wildlife and local livestock grazing allotments.

Public participation is welcome; however, participants will be responsible for their own transportation.

David M. Spores,
Acting Forest Supervisor.
June 30, 1982.

[FR Doc. 82-18065 Filed 7-6-82; 8:45 am]
BILLING CODE 0410-11-M

South Kaibab Grazing Advisory Board; Meeting

July 1, 1982.

The South Kaibab Grazing Advisory Board will meet at 10:00 A.M., Friday, August 6, 1982, at the Supervisor's Office, 800 South 6th Street, Williams, Arizona.

The purpose of this meeting is:

1. Election of Officers.
2. Adoption of By-Laws.
3. Elk Management (Tom Britt—Arizona Game and Fish Department).
5. Utilization of Range Betterment Funds.

The meeting will be open to the public. Persons who wish to attend should notify: Forest Supervisor, Kaibab National Forest, 800 South 6th Street, Williams, Arizona 86046, Telephone: (602) 835–2681.

Those attending may express their views when recognized by the Chairman.

Dated: June 30, 1982.
Leonard A. Lindquist,
Forest Supervisor.

[FR Doc. 82-18663 Filed 7-8-82; 8:45 am]
BILLING CODE 3410-11-M

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Rural Electrification Administration

Tri-State Generation and Transmission Association, Inc. and Colorado-Ute Electric Association, Inc.; Final Environmental Impact Statement

AGENCY: Rural Electrification Administration, USDA.

ACTION: Availability of Final Environmental Impact Statement.

SUMMARY: Notice is hereby given that REA has prepared a Final Environmental Impact Statement (FEIS) in connection with the proposed construction of an approximately 145 km (90 mi) 345 kV transmission line and associated facilities by the Tri-State generation and Transmission Association, Inc., (Tri-State) and Colorado-Ute Electric Association, Inc., (Colorado-Ute). The proposed line would connect the existing Hayden Substation in Routt County, Colorado, with the proposed Blue River Substation, to be located northwest of Dillon in Summit County, Colorado. REA has been requested to provide assistance with financing for the proposed construction.

DATE: Public comments must be received by REA no later than August 9, 1982.

ADDRESS: Submit written comments to Mr. Frank W. Bennett, Director, Power Supply Division, Rural Electrification Administration, Room Number 0230, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Mr. Frank W. Bennett, Director, Power Supply Division, above address, telephone number (202) 382–1400 or FTS 382–1400.

SUPPLEMENTARY INFORMATION: In connection with the anticipated request for financing assistance from Tri-State and Colorado-Ute, REA has prepared a FEIS on the proposed construction of an approximately 145 km (90 mi) 345 kV transmission line and associated facilities in Grand, Routt and Summit Counties, Colorado.

The FEIS may be examined during regular business hours at the following locations, and also at the public libraries of Northglenn (Adams County), Kremmling (Grand County), Steamboat Springs (Routt County) and Breckenridge (Summit County), Colorado.

Rural Electrification Administration, 14th and Independence Avenue SW., Washington, D.C. 20250
Tri-State Generation and Transmission Association, Inc., 12076 Grant Street, Thornton, Colorado 80241
Colorado-Ute Electric Association, Inc., 845 South Townsend Avenue, Montrose, Colorado 81401.

Alternatives considered in the FEIS are no action, alternative voltages, upgrading of existing facilities, alternative sources, energy conservation, and alternative routes and construction methods.

The preferred alternative, which is construction of the 345 kV transmission line, will not affect threatened or endangered species, prime farmland, archaeological or historic sites. The project is anticipated to affect some floodplain and wetland areas associated with the Colorado and Yampa Rivers. To cross the Colorado River, a maximum of 5 km (3 mi) of designated 100-year floodplain will be crossed. For the Yampa River, a maximum of 2 km (1.6 mi) of designated 100-year floodplain will be crossed. REA has tentatively concluded that there is no practicable alternative to crossing these areas.

Further information concerning this matter can be found in the FEIS.

Copies of the FEIS have been sent to various Federal, State and local agencies and individuals outlined in the Council on Environmental Quality guidelines (40 CFR Part 1500). Limited copies of the FEIS are available upon request to: Mr. Frank W. Bennett, Director, Power Supply Division, address above.

Final REA action concerning the project, including any release of funds for construction, will be taken only after REA has reached satisfactory conclusions with respect to its environmental effects and compliance with the National Environmental Policy Act of 1969 and with other environmentally related statutes, regulations, Executive Orders and Secretary’s Memoranda.

This program is listed in the Catalog of Federal Domestic Assistance as 10.850—Rural Electrification Loans and Loan Guarantees.

Dated: July 2, 1982.
Jack Van Mark,
Acting Administrator.

[FR Doc. 82-18663 Filed 7-8-82; 8:45 am]
BILLING CODE 3410-15-M

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United Power Association; Elk River, Minn.; Proposed Loan Guarantee

Under the authority of Pub. L. 93–32 (87 Stat. 65), and in conformance with the applicable agency policies and procedures as set forth in REA Bulletin 20–22 (Guarantee of Loans for Bulk Power Supply Facilities), notice is hereby given that the Administrator of REA will consider providing a guarantee supported by the full faith and credit of the United States of America for a loan in the approximate amount of $5,748,000 to United Power Association (UPA) of Elk River, Minnesota. This loan guarantee will be used to finance UPA’s 44 percent share of system improvements at the existing Coal Creek 1000 MW power plant and associated transmission facilities.

Legally organized lending agencies capable of making, holding and servicing the loan proposed to be guaranteed may obtain information on the proposed project, including the engineering and economic feasibility studies and the proposed schedule for the advances to the borrower of the guaranteed loan funds from Mr. Phillip O. Martin, Manager, United Power Association, Elk River, Minnesota 55330.

In order to be considered, proposals must be submitted on or before August 9, 1982, to Mr. Martin. The right is reserved to give such consideration and to make such evaluation or other disposition of all proposals received as UPA and REA deem appropriate.

Prospective lenders are advised that the guaranteed financing for this project is available from the Federal Financing Bank under a standing agreement with the Rural Electrification Administration.


This program is listed in the Catalog of Federal Domestic Assistance as 10.850—Rural Electrification Loans and Loan Guarantees.
Dated at Washington, D.C., this 1st day of July, 1982.
Jack Van Marck,
Acting Administrator, Rural Electrification Administration.

[FR Doc. 82-18662 Filed 7-8-82; 8:45 am]
BILLING CODE 3410-15-M

Soil Conservation Service
Calapooya Creek Watershed, Oregon; Availability of a Record of Decision

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of availability of a record of decision.

SUMMARY: Jack P. Kanalz, the Responsible Federal Official for projects administered under the provisions of the State of Oregon, is hereby providing notification that a Record of Decision to proceed with the installation of the Calapooya Creek Watershed Project is available. Single copies of the Record of Decision may be obtained from Jack P. Kanalz at the address shown below.

FOR FURTHER INFORMATION CONTACT: Jack P. Kanalz, State Conservationist, Soil Conservation Service, 1220 S.W. Third Avenue, 16th Floor, Portland, Oregon 97204, telephone (503) 221-2751.

[Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention. Office of Management and Budget Circular A-99 regarding State and local clearinghouse review of Federal and federally-assisted programs and projects is applicable]

Dated: June 29, 1982.
Graham T. Munkttrick,
State Conservationist.

[FR Doc. 82-18417 Filed 7-6-82; 8:45 am]
BILLING CODE 3410-16-M

OFFICE OF THE FEDERAL INSPECTOR
FOR THE ALASKAN NATURAL GAS TRANSPORTATION SYSTEM

Final Design Cost Estimate

AGENCY: Office of the Federal Inspector for the Alaska Natural Gas Transportation System.

ACTION: Notice of tentative decision and request for public comments, on the final design cost estimate for Compressor Station No. 8 on Phase I of the Eastern Leg of the Alaska Natural Gas Transportation System.

Take notice that on July 2, 1982, the Office of the Federal Inspector (OFI) made a tentative decision on the Final Design Cost Estimate (FDCE) submitted by the Northern Border Pipeline Company for Compressor Station No. 8 being constructed in Phase I of the Eastern Leg of the Alaska Natural Gas Transportation System. Copies of this tentative decision are available by writing or telephoning: Mr. Richard Berman, Director, Audit and Cost Analysis, Office of the Federal Inspector, ANGTS, Room 2319, Post Office Building, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20044; (202) 275-1153.

Public comments on this tentative decision should be submitted in writing to the OFI, at the same address by August 2, 1982.

As a first step to implement the Incentive Rate of Return (IROR) for Phase I of the Eastern Leg, the Federal Energy Regulatory Commission (FERC) on April 28, 1980, set the Certification Cost and Schedule Estimate (CCSE) at $1,061,581,000 (1979 dollars).

On April 15, 1981, the OFI approved a FDCE of $1,229,452,100, incorporating certain changes to the certified design. Subsequently, Northern Border applied for and was granted by the FERC (Docket Nos. CP78-123, et al., April 24, 1981) a Certificate of Public Convenience and Necessity for a Second Compressor Station as part of the Phase I facilities, including a CCSE for the station of $10,743,000.

Northern Border then applied to the OFI for approval of changes to its compressor station design. These engineering and schedule matters have been analyzed and approved, where appropriate, by OFI. As a related matter, Northern Border seeks OFI approval of an increase of about $964,000 from its CCSE to yield its FDCE upon which the IROR will operate.

It is solely this $964,000 portion of the FDCE for Compressor Station No. 8 to which the OFI’s tentative decision is, and public comments should be, addressed. Commenters may also address whether these design changes comport with Condition 9 of the FERC’s Order Nos. 31 and 31-B.

Dated: July 2, 1982.
Peter L. Cook,
Acting Federal Inspector.

[FR Doc. 82-18577 Filed 7-6-82; 8:45 am]
BILLING CODE 6119-01-M

CIVIL AERONAUTICS BOARD

[Docket 40658]

Hawaii Express, Inc., Fitness Investigation; Reopened Hearing

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that the hearing in the above-titled proceeding will be reopened on July 9, 1982, at 10:00 a.m. (local time), in Room 1012, Universal Building, 1825 Connecticut Avenue, N.W., Washington, D.C., before Administrative Law Judge William A. Kane, Jr.

For information concerning the issues involved and other details of this proceeding, interested persons are referred to Board Order 82-5-128 adopted May 24, 1982, the order by the undersigned dated June 30, 1982, and other documents which are in the docket of this proceeding on file in the Docket Section of the Civil Aeronautics Board.

Dated at Washington, D.C., July 1, 1982.
William A. Kane, Jr.,
Administrative Law Judge.

[FR Doc. 82-18657 Filed 7-8-82; 8:45 am]
BILLING CODE 6119-01-M
Administrative Review of Antidumping

BILLING CODE 6320-01-M

Administrative Law Judge.

animal glue and inedible gelatin from West Germany. The review covered

November 20230

November 1977,


SUPPLEMENTARY INFORMATION:

Background

On December 22, 1977, an antidumping finding with respect to animal glue and inedible gelatin from West Germany was published in the Federal Register as Treasury Decision 78-1 (42 FR 64118). On December 29, 1981, the Department of Commerce ("the Department") published in the Federal Register (46 FR 62887-9) the preliminary results of its administrative review of the finding. The Department has now completed that administrative review.

Scope of the Review

Imports covered by the review are shipments of animal glue and inedible gelatin, of which there are two principal types, hide glue and bone glue. They are organic colloids of protein derivation. There is no significant difference between animal glue and inedible gelatin. Animal Glue and inedible gelatin are currently classifiable under items 455.4000 and 455.4200 of the Tariff Schedules of the United States.

Analysis of Comments Received

Interested parties were given an opportunity to submit comments on the preliminary results of review, and we determined that the following weighted-average margins exist:

<table>
<thead>
<tr>
<th>Manufacturer/exporter</th>
<th>Time period</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rendsberg</td>
<td>05/05/79-11/30/80</td>
<td>158.00</td>
</tr>
<tr>
<td>Mariner</td>
<td>07/01/78-12/31/78</td>
<td>0</td>
</tr>
<tr>
<td>Conrad</td>
<td>01/01/78-11/30/80</td>
<td>10.00</td>
</tr>
<tr>
<td>Stoes/Goud</td>
<td>01/01/78-11/30/80</td>
<td>67.00</td>
</tr>
<tr>
<td>Hacke</td>
<td>01/01/78-11/30/80</td>
<td>158.00</td>
</tr>
<tr>
<td>Weiss</td>
<td>05/01/78-12/31/78</td>
<td>22.64</td>
</tr>
<tr>
<td>Animal Produkten</td>
<td>01/01/78-12/31/78</td>
<td>8.25</td>
</tr>
<tr>
<td></td>
<td>01/01/80-11/30/80</td>
<td>16.34</td>
</tr>
<tr>
<td></td>
<td>09/01/79-11/30/80</td>
<td>100.00</td>
</tr>
</tbody>
</table>

No shipments during the period.

The Department shall determine, and the U.S. Customs Service shall assess, antidumping duties on all appropriate shipments made by these firms with purchase dates during the periods involved. Individual differences between United States price and foreign market value may vary from the percentages stated above. The Department will issue appraisement instructions on each exporter directly to the Customs Service.

Further, as provided for by section 353.48(b) of the Commerce Regulations, a cash deposit of estimated antidumping duties based on the margins calculated above shall be required on all shipments by these firms of animal glue and inedible gelatin from West Germany entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice. For any shipment from a non-exporter not covered in this review, unrelated to any covered firm, a cash
deposit shall be required at the highest rate for responding firms with shipments during the most recent period in which shipments occurred. These deposit requirements shall remain in effect until publication of the final results of the next administrative review. The Department intends to conduct the next administrative review by the end of December 1982.

The Department encourages interested parties to review the public record and submit applications for protective orders, if desired, as early as possible during the next administrative review.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1675(a)(1)) and §353.53 of the Commerce Regulations (19 CFR 353.53).

Gary N. Horlick,
Deputy Assistant Secretary for Import Administration.

July 2, 1982.

[FR Doc. 82-18653 Filed 7-8-82; 8:45 am]
BILLING CODE 3510-25-M

[A-580-073]

Bicycle Tires and Tubes From Korea; Preliminary Results of Administrative Review of Antidumping Finding

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of Preliminary Results of Administrative Review of Antidumping Finding.

SUMMARY: The Department of Commerce has conducted an administrative review of the antidumping finding on bicycle tires and tubes from Korea. This review covers the six known manufacturers and exporters of this merchandise to the United States and generally the period from April 1, 1980 through March 31, 1981. The review indicates the existence of de minimis dumping margins in the period for two exporters and margins in an earlier period for a third firm. As a result of the review, the Department has preliminarily determined to assess dumping duties for the three exporters equal to the calculated differences between foreign market value and United States price on each of their shipments occurring during the covered period. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: July 9, 1982.


SUPPLEMENTARY INFORMATION:

Background

On April 13, 1979, a dumping finding with respect to bicycle tires and tubes from Korea was published in the Federal Register as Treasury Decision 79-115 (44 FR 22051–2). The Department of Commerce published in the Federal Register of March 18, 1981 (46 FR 16821) a notice of intent to conduct administrative reviews of outstanding dumping findings. As required by section 751 of the Tariff Act of 1930 ("the Tariff Act"), the Department has conducted an administrative review of the finding on bicycle tires and tubes from Korea. The substantive provisions of the Antidumping Act of 1921 ("the 1921 Act") apply to all unliquidated entries made prior to January 1, 1980.

Scope of the Review

Imports covered by this review are shipments of bicycle tires and tubes from Korea. The term "bicycle tires and tubes" means pneumatic bicycle tires and tubes of rubber or plastics, whether such tires and tubes are sold together as units or separately. Bicycle tires and tubes are currently classifiable under items 772.4800 and 772.5700 respectively of the Tariff Schedules of the United States Annotated (TSUSA). The Department knows of six exporters to the United States of Korean bicycle tires and tubes. This review covers those firms generally for the period from April 1, 1980 through March 31, 1981.

The Department discovered the existence of one firm, Dae Woo Industrial Co., Ltd., too late for inclusion in the last administrative review. This present review therefore covers the period from April 1, 1978 through March 31, 1981 for Dae Woo. Daw Woo did not export bicycle tires and tubes during the latter period covered by this review. The estimated cash deposit rate for this firm shall be its margin for the earlier period since this is the most recent information available.

United States Price

In calculating United States price, the Department used purchase price, as defined in section 772 of the Tariff Act or section 203 of the 1921 Act as appropriate, for five companies since sufficient quantities of such or similar merchandise were sold in the home market by them to provide a basis for comparison during the periods covered. The Department used third-country price (Canada), as defined in section 773(b) of the 1921 Act, for the sixth company since such or similar merchandise was not sold by it in the home market. The home market prices and third-country prices are based on either delivered or F.O.B. prices to unrelated purchasers in the home market or third country, with adjustments for inland freight, rebates, bonuses, commissions to unrelated parties, credit costs incurred on delayed payment on home market sales, advertising costs incurred on behalf of customers and directly related to bicycle tires and tubes sold in the home market in accordance with section 353.15 of the Commerce Regulations, and packing differences where applicable. Also, where appropriate we made adjustments based on cost for differences in similar merchandise in accordance with section 353.16 of the Commerce Regulations. Claims made for insurance, advertising, bad debts, entertainment expenses and interest costs were not allowed because the firms did not show that such costs were directly attributable to sales of bicycle tires and tubes. No other adjustments were claimed or allowed.

Foreign Market Value

In calculating foreign market value, the Department used home market price, as defined in section 773(a) of the Tariff Act or section 203 of the 1921 Act as appropriate, for five companies since sufficient quantities of such or similar merchandise were sold in the home market by them to provide a basis for comparison during the periods covered. The Department used third-country price (Canada), as defined in section 773(b) of the Tariff Act, for the sixth company since such or similar merchandise was not sold by it in the home market. The home market prices and third-country prices are based on either delivered or F.O.B. prices to unrelated purchasers in the home market or third country, with adjustments for inland freight, rebates, bonuses, commissions to unrelated parties, credit costs incurred on delayed payment on home market sales, advertising costs incurred on behalf of customers and directly related to bicycle tires and tubes sold in the home market in accordance with section 353.15 of the Commerce Regulations, and packing differences where applicable. Also, where appropriate we made adjustments based on cost for differences in similar merchandise in accordance with section 353.16 of the Commerce Regulations. Claims made for insurance, advertising, bad debts, entertainment expenses and interest costs were not allowed because the firms did not show that such costs were directly attributable to sales of bicycle tires and tubes. No other adjustments were claimed or allowed.

Preliminary Results of the Review

As a result of our comparison of United States price to foreign market value, we preliminarily determined that the following margins exist:

<table>
<thead>
<tr>
<th>Korean exporter</th>
<th>Time period</th>
<th>Margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dae Yung Commercial Co., Ltd.</td>
<td>4/1/80-3/31/81</td>
<td>0.00</td>
</tr>
<tr>
<td>Hung-A Industrial Co., Ltd.</td>
<td>4/1/80-3/31/81</td>
<td>0.00</td>
</tr>
<tr>
<td>Korea Inoue Kasvi Co., Ltd.</td>
<td>4/1/80-3/31/81</td>
<td>0.15</td>
</tr>
<tr>
<td>Shin Hung Rubber Co., Ltd.</td>
<td>4/1/80-3/31/81</td>
<td>0.37</td>
</tr>
<tr>
<td>Dae woo Industrial Co., Ltd.</td>
<td>4/1/78-3/31/81</td>
<td>2.32</td>
</tr>
<tr>
<td>Kulje (ICC) Corporation</td>
<td>4/1/80-3/31/81</td>
<td>0.00</td>
</tr>
</tbody>
</table>

No shipments during this period.

Interested parties may submit written comments on these preliminary results on or before August 9, 1982, and may
SUMMARY: On May 6, 1982, the Department of Commerce published the preliminary results of its administrative review of the antidumping finding on stainless steel plate from Sweden. The review covered one of the two known exporters of this merchandise to the United States, Avesta Jernverk Aktiebolag, and the period October 1, 1976 through May 31, 1980.

Interested parties were given an opportunity to submit oral or written comments on these preliminary results. We received no comments.

EFFECTIVE DATE: July 9, 1982.


SUPPLEMENTARY INFORMATION:

Background

On June 8, 1973, an antidumping finding with respect to stainless steel plate from Sweden was published in the Federal Register as Treasury Decision 73-157 (38 FR 15079). On May 6, 1982, the Department of Commerce ("the Department") published in the Federal Register (47 FR 19307-72) the preliminary results of its administrative review of the finding. The Department has now completed that administrative review.

Scope of the Review

Imports covered by the review are shipments of stainless steel plate, which is commonly used in scientific and industrial equipment because of its resistance to staining, rusting, and pitting. Stainless steel plate is currently classifiable under item 607.9005 of the Tariff Schedules of the United States Annotated (TSUSA).

The Department knows of two exporters of stainless steel plate from Sweden to the United States, Avesta Jernverk Aktiebolag ("Avesta") and Uddeholm/Nyby Uddeholm AB ("Uddeholm"). This review covers Avesta for the period October 1, 1976 through May 31, 1980. The Department separately reviewed Uddeholm for the period January 1, 1980 through May 31, 1980 (47 FR 16066-7). The Department will cover shipments by both firms in earlier periods, unreviewed by the Treasury Department, in a subsequent review.

Final Results of the Review

Interested parties were invited to comment on the preliminary results. The Department received no written comments or requests for a hearing.

Therefore, the final results of our review are the same as those presented in the preliminary results of review, and we determine that a margin of 5.22 percent exists for the period.

The Department shall determine, and the U.S. Customs Service shall assess, dumping duties on all appropriate entries with purchase dates during the period involved. The Department will issue assessment instructions directly to the Customs Service.

Further, as provided for in § 353.48(b) of the Commerce Regulations, a cash deposit of estimated antidumping duties based on the above margin shall be required on all shipments of stainless steel plate manufactured by Avesta entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice. This deposit requirement shall remain in effect until publication of the final results of the next administrative review. The Department intends to conduct the next administrative review by the end of June 1983. The Department encourages interested parties to review the public record and submit applications for protective orders, if desired, as early as possible after the Department’s receipt of the information during the next administrative review.

This administrative review and notice are in accordance with section 775(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1675(a)(1)) and § 353.53 of the Commerce Regulations (19 CFR 353.53).

Gary N. Horlick,
Deputy Assistant Secretary for Import Administration.
July 2, 1982.

[FR Doc. 82-18685 Filed 7-8-82; 8:45 am]
BILLING CODE 3510-25-M

Initiation of Countervailing Duty Investigation; Steel Wire Rope From South Africa

AGENCY: International Trade Administration, Commerce.

ACTION: Initiation of Countervailing Duty Investigation.

SUMMARY: On the basis of a petition filed with the U.S. Department of Commerce, we are initiating a countervailing duty investigation to determine whether producers, manufacturers, or exporters in South Africa of steel wire rope receive benefits which constitute bounties or grants within the meaning of the countervailing duty law. If our investigation proceeds normally, we will make our preliminary determination on or before September 7, 1982.
EFFICIENT DATE: July 9, 1982.


SUPPLEMENTARY INFORMATION:

Petition

On June 14, 1982, we received a petition from counsel for the Committee of Domestic Steel Wire Rope and Specialty Cable Manufacturers, on behalf of the U.S. industry producing steel wire rope. In compliance with the filing requirements of section 355.26 of the Commerce Regulations (19 CFR 355.26), the petition alleges that manufacturers, producers, or exporters in South Africa of steel wire rope receive, directly or indirectly, bounties or grants within the meaning of section 303 of the Tariff Act of 1930, as amended (the "Act").

Since South Africa is not a "country under the Agreement" within the meaning of section 701(b) of the Act, and the steel wire rope at issue here is dutiable, the domestic industry is not required to allege that, and the U.S. International Trade Commission ("ITC") is not required to determine whether, imports of these products cause or threaten material injury to the U.S. industry in question.

Initiation of Investigation

Under section 702(c) of the Act, we must determine, within 20 days after a petition is filed, whether a petition sets forth the allegations necessary for the initiation of a countervailing duty investigation and whether it contains information reasonably available to the petitioner supporting the allegations. We have examined the petition on steel wire rope, and we have found that the petition meets these requirements.

Therefore, we are initiating a countervailing duty investigation to determine whether manufacturers, producers, or exporters in South Africa of steel wire rope as described in the "Scope of the Investigation" section of this notice receive bounties or grants. If our investigation proceeds normally, we will make our preliminary determination by September 7, 1982.

Scope of the Investigation

For the purpose of this investigation, the term "steel wire rope" covers ropes, cables, and cordage, other than wire strand, made of steel wire, other than brass plated wire, whether or not cut to length and not fitted with hooks, swivels, clamps, clips, thimbles, sockets or other fittings, or made up into slings, cargo nets, or similar articles and not covered with textile or other nonmetallic material, currently provided for in items 642.1200, 642.1400, 642.1600, and 642.1800 of the Tariff Schedules of the United States Annotated.

Allegations of Bounties or Grants

The petition alleges that manufacturers, producers, or exporters of steel wire rope in South Africa receive the following benefits that constitute bounties or grants: reduced transportation rates; preferential pre- and post-shipment financing for exports; tax deductions and investment allowances for doing business in certain development areas and in the beneficiation of base minerals; rebates provided through the Iron and Steel Export Promotion Scheme; and tax deductions and rebates provided through the Export Incentive Program.

Gary N. Horlick,
Deputy Assistant Secretary for Import Administration.
July 2, 1982.

IMPORTERS AND RETAILERS AND MANAGEMENT-LABOR TEXTILE ADVISORY COMMITTEES; PUBLIC MEETINGS

July 1, 1982.

AGENCY: International Trade Administration, Commerce.

SUMMARY: The Importers and Retailers Textile Advisory Committee was established by the Secretary of Commerce on August 13, 1983 to advise U.S. Government officials of the effects on imports markets of cotton, wool, and man-made fiber textile agreements.

The Management-Labor Textile Advisory Committee was established by the Secretary of Commerce on October 18, 1961 to advise U.S. Government officials on problems and conditions in the textile and apparel industry and furnish information on world trade in textiles and apparel.

TIME AND PLACE: September 8, 1982 at 10:30 a.m. for the Importers and Retailers and 1:00 p.m. for the Management-Labor Textile Advisory Committee. The meetings will take place at the Main Commerce Building, Room 6802, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

PUBLIC PARTICIPATION: The meetings will be open to public participation to the extent time is available. The public may file written statements with the Committees before or after the meetings. Approximately 30 seats will be available for the public on a first-come, first-served basis.


Paul T. O'Day,
Deputy Assistant Secretary for Textiles and Apparel.

BILLING CODE 3510–25–M

TELECOMMUNICATIONS EQUIPMENT TECHNICAL ADVISORY COMMITTEE; CLOSED MEETING

Agency holding the meeting: International Trade Administration.

Federal Register citation of previous announcement: 47 FR 25175.

Previously announced time and date of the meeting: 10:00 a.m., July 13, 1982. Changes in the meeting: 10:00 a.m., July 20, 1982, at the Main Commerce Building, Room 8641, 14th Street and Constitution Avenue, N.W., Washington, D.C.

DATED: July 8, 1982.

Vincent F. DeCain,
Acting Director, Office of Export Administration.

BILLING CODE 3510–25–M

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

NATIONAL MARINE FISHERIES SERVICE; ISSUANCE OF PERMIT

On May 26, 1982, Notice was published in the Federal Register (47 FR 23000), that an application had been filed with the National Marine Fisheries Service by Tel Aviv Dolphinarium, Ltd., Charles Clore Park, Herbert Samuel Boulevard, P.O. Box 29131, Tel Aviv 61290, Israel, for a Permit to take six (6) Atlantic bottlenose dolphins (Tursiops truncatus) for the purpose of public display.

Notice is hereby given that on July 2, 1982, and as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407), the National Marine Fisheries Service issued a Permit for the above
taking to Tel Aviv Dolphinarium subject to certain conditions set forth therein.

The Permit is available for review in the following offices:


Dated: July 2, 1982.

Richard B. Roe,
Acting Director, Office of Marine Mammals and Endangered Species, National Marine Fisheries Service.

[FR Doc. 82-18639 Filed 7-9-82; 8:45 am]

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Increasing Import Restraint Levels for Certain Cotton and Man-Made Fiber Textile Products From the Republic of Singapore

AGENCY: Committee for the Implementation of Textile Agreements.

ACTION: Increasing the consultation levels for women's, girls', and infants' cotton and man-made fiber blouses in Categories 341 and 641, produced or manufactured in the Republic of Singapore and exported during the agreement year which began on January 1, 1982, to respective levels of 58,276 dozen from 48,276 dozen and to 69,276 dozen from 48,276 dozen.


SUMMARY: Pursuant to the terms of the Bilateral Cotton, Wool, and Man-Made Fiber Textile Agreement of September 21 and 22, 1978, as amended, between the Governments of the United States and the Republic of Singapore, the consultation levels established for cotton and man-made fiber textile products in Categories 341 and 641 are being increased for the agreement year which began on January 1, 1982 and extends through December 31, 1982.

EFFECTIVE DATE: July 12, 1982.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: On December 15, 1981, there was published in the Federal Register (46 FR 5926) a letter dated December 15, 1981 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs, which established levels of restraint for certain specified categories of cotton, wool, and man-made fiber textile products, produced or manufactured in Singapore, which may be entered into the United States for consumption, or withdrawn from warehouse for consumption, during the twelve-month period which began on January 1, 1982 and extends through December 31, 1982.

The Chairman of the Committee for the Implementation of Textile Agreements which directs the Commissioner of Customs to adjust the twelve-month levels previously established for Categories 341 and 641 to the designated amounts.

Paul T. O'Day,
Chairman, Committee for the Implementation of Textile Agreements.

July 2, 1982.

Committee for the Implementation of Textile Agreements

Chairman of the Committee for the Implementation of Textile Agreements which directs you to prohibit entry for consumption, or withdrawal from warehouse for consumption, during the twelve-month period which began on January 1, 1982 and extends through December 31, 1982.

The Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs, which established levels of restraint for certain specified categories of cotton, wool, and man-made fiber textile products, produced or manufactured in Singapore, which may be entered into the United States for consumption, or withdrawn from warehouse for consumption, during the twelve-month period which began on January 1, 1982 and extends through December 31, 1982.

Chairman of the Committee for the Implementation of Textile Agreements which directs the Commissioner of Customs to adjust the twelve-month levels previously established for Categories 341 and 641 to the designated amounts.

Paul T. O'Day,
Chairman, Committee for the Implementation of Textile Agreements.

July 2, 1982.

Committee for the Implementation of Textile Agreements

Chairman of the Committee for the Implementation of Textile Agreements which directs you to prohibit entry for consumption, or withdrawal from warehouse for consumption, during the twelve-month period which began on January 1, 1982 and extends through December 31, 1982.

1. The levels of restraint have not been adjusted to reflect any imports after December 31, 1981.

The actions taken with respect to the Government of the Republic of Singapore and with respect to imports of cotton and man-made fiber textile products from Singapore have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, these directions to the Commissioners of Customs, which are necessary for the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the Federal Register.

Sincerely,

Paul T. O'Day,
Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 82-18639 Filed 7-9-82; 8:45 am]

BILLING CODE 3510-25-M

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List 1982; Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Additions to procurement list.

SUMMARY: This action adds to Procurement List 1982 commodities to be produced by workshops for the blind and other severely handicapped.

EFFECTIVE DATE: July 9, 1982.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT: W. Fletcher, (703) 557-1145.

SUPPLEMENTARY INFORMATION: On March 18, 1982 and April 30, 1982, the Committee for Purchase from the Blind and Other Severely Handicapped published notices (47 FR 11918 and 47 FR 18639) of proposed additions to Procurement List 1982, November 12, 1981 (49 FR 55740).

After consideration of the relevant matter presented, the Committee has determined that the commodities and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 48-48c, 88 Stat. 77.

Accordingly, the following commodities and services are hereby added to Procurement List 1982:

Class 1130

Filter, Air Conditioning

4130-00-670-8796

4130-00-274-7800

4130-00-541-3220

4130-00-756-1840

4130-00-720-4143

4130-00-870-8796

4130-00-249-0968
Procurement List 1982; Proposed Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to Procurement List 1982 commodities to be produced by and services to be provided by workshops for the blind and other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: August 11, 1982.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 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. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government will be required to procure the commodities and services listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodities and services to Procurement List 1982, November 12, 1981 (46 FR 55740):

**SIC 7349**

Janitorial Service
Federal Building, Moultrie, Georgia
Federal Building, U.S. Post Office and U.S. Courthouse, Thomasville, Georgia
Janitorial/Custodial, Federal Building, 6th and State Streets, Erie, Pennsylvania

**SIC 6411**

Metal Furniture Rehabilitation, Naval Ordance Station, Louisville, Kentucky
C. W. Fletcher, Executive Director.

[FR Doc. 82-18045 Filed 7-6-82; 8:45 am]
BILLING CODE 6820-35-M

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

Intent To Prepare Draft Environmental Impact Statement (DEIS) for Flood Control Project at Oneida Creek in Oneida, Madison County, NY

AGENCY: U.S. Army Engineer District, Buffalo, DOD.

ACTION: Notice of intent to prepare a draft environmental impact statement (DEIS).

PROPOSED ACTION: The proposed action would involve various structural and nonstructural measures to provide a 500-year level of flood protection for Oneida Creek, to the occupants of the floodplain in the city of Oneida, Madison County, and the towns of Vernon and Verona, Oneida County, NY. Structural measures would include levee and training dike construction, an overflow channel, and construction of a holiday pond. In addition, a series of nonstructural measures such as floodproofing and relocations are proposed.

ALTERNATIVES CONSIDERED: A total of four alternatives were considered in detail. Each of these alternatives are briefly described below:

1. No Action—This alternative plan implies that the Federal Government acting through the Corps of Engineers, without any action, would not take any structural or nonstructural action to reduce flood damage under the existing study authority.

2. Plan C-1—This plan entails the removal of approximately 27,000 cubic yards of an abandoned New York Central Railroad (NYCRR) bridge embankment (right bank) to reduce the flow constriction in the creek, thus creating a dry overflow diversion channel. In addition to the structural measure, nonstructural measures such as small ring levees, floodwalls, flood shields, and relocations would be provided.

3. Plan D—This plan would remove a portion of the NYCRR bridge (ref. Plan C-1), and would rebuild the existing levee to Federal standards. A training dike would be constructed in the underpass of the railroad embankment (left bank) to prevent overbank flooding from flowing back behind the levee. Interior drainage behind the levee would be handled by a system consisting of drainage ditches, storm sewers with flap gates, and a constructed 5.6-acre grass-
DEPARTMENT OF ENERGY

**Energy Emergencies Telephone Contact Number**

June 30, 1982.

**AGENCY:** Assistant Secretary for Environmental Protection, Safety, and Emergency Preparedness, DOE.

**ACTION:** Energy Emergency Contact Telephone Number.

**SUMMARY:** DOE hereby gives notice of the establishment of a new energy emergency contact telephone number, (202) 252-5161, for use by utilities, energy concerns, Government agencies, and the general public, who wish to report energy emergencies to the DOE. This replaces the telephone number formerly used for electricity emergency reporting: (202) 653-3832. Such emergency energy reports should not be considered as satisfying the mandatory reporting requirements established by the Federal Energy Regulatory Commission (FERC) or other Federal agencies.

**DATE:** July 9, 1982.

**FOR FURTHER INFORMATION CONTACT:** Ronald L. Winkler, Deputy Assistant Secretary for Energy Emergencies, Department of Energy, Room 3G-072, Forrestal Building (EP-40), 1000 Independence Avenue, S.W., Washington, D.C. 20585, (202) 252-2443.

**SUPPLEMENTARY INFORMATION:** Pursuant to the recent DOE reorganization, the Office of Energy Emergencies of DOE is responsible for receiving timely reports of energy emergency situations from electric utilities, petroleum refinery and/ or operating organizations, natural gas production and transmission utilities, Federal agencies, State and local governments and the general public when Federal response action may be appropriate. Certain types of electric power outages, major electric system disturbances and other similar events must be reported to DOE pursuant to 10 CFR 205.355 et seq., while reports of any other energy emergencies are voluntary. To assure the timely receipt of this information, the Office of Energy Emergencies has established an Alert Coordination Officer (ACO) system and a single telephone number, (202) 252-5161, to which reports may be made. This telephone number will be answered 24 hours per day, seven days per week, and replaces the telephone number formerly used for electric power outages and disturbance reporting, (202) 653-3832, which has been disconnected. Written reports regarding energy emergencies should be sent to: Alert Coordination Officer, Office of Energy Emergencies, Department of Energy, Room 3G-072, Forrestal Building (EP-40), 1000 Independence Avenue, S.W., Washington, D.C. 20585.

Recently, the FERC issued a Notice of Proposed Rulemaking indicating certain proposed reporting procedures and a telephone number for use by natural gas pipeline companies during service interruptions or emergencies. 47 FR 18944 (April 19, 1982). The Office of Energy Emergencies of DOE currently is discussing with FERC the possibility of coordinating these emergency alert procedures. If that proves feasible, we may need to adopt changes in one or both alert systems. However, as noted above, for the present, the telephone contact number and alert system established by this notice are separate and distinct from the FERC procedures proposed in the April 15, 1982 Notice.


William A. Vaughan,
Assistant Secretary for Environmental Protection, Safety, and Emergency Preparedness.
substance is any chemical substance that is not on the Inventory of existing substances compiled by EPA under section 8(b) of TSCA. Section 5(a)(1) requires each premanufacture notice (PMN) to be submitted in accordance with section 5(d) and any applicable requirements of section 5(b). Section 5(d)(1) defines the contents of a PMN and section 5(b) contains additional reporting requirements for certain new chemical substances.

Section 5(h), "Exemptions", contains several provisions for exemptions from some or all of the requirements of section 5. In particular, section 5(h)(1) authorizes EPA, upon application, to exempt persons from any requirements of section 5(a) or 5(b), and to permit them to manufacture or process chemical substances for test marketing purposes. To grant an exemption, the Agency must find that the test marketing activities will not present any unreasonable risk of injury to health or the environment. EPA must either approve or deny the application within 45 days of its receipt, and under section 5(h)(6) the Agency must publish a notice of this disposition in the Federal Register. If EPA grants a test marketing exemption, it may impose restrictions on the test marketing activities.

On May 20, 1982, EPA received an application from the Quaker Oats Company for an exemption from the requirements of sections 5(a) and 5(b) of TSCA to manufacture a new chemical substance for test marketing purposes. The application was assigned test marketing exemption number TM-82-20. The submission is for a formaldehyde polymer with 2-furanmethanol and 2-methylxirane, to be used as a component polyol for rigid urethane foam. The submitter claimed the production volume of the new substance and process substance as confidential business information. The test marketing application is for a period not to exceed 12 months. During manufacture, the test market chemical will be produced in a closed process. Protective equipment and clothing will be provided during the sampling, mixing and processing operations. Up to eight processors will test the new chemical and as many as 35 workers could be exposed to the test market chemical at processing sites.

A notice published in the Federal Register of May 28, 1982 (47 FR 23554) announced receipt of this application and requested comment on the appropriateness of granting the exemption. The Agency did not receive any comments concerning the application.

EPA has established that the test marketing of the new chemical substance described in TM-82-20, under the specific conditions set out in the application, will not present any unreasonable risk of injury to health or the environment. Although there were health concerns for the test market substance, exposure to workers during manufacture will be minimal since it is manufactured in a closed process and test processing will be limited to workers experienced in the art of foam operations. Processing procedures will be performed under ventilated hooded areas and the workers will be provided with equipment and clothing. Overall release to the environment should be negligible.

This test marketing exemption is granted based on the facts and information obtained and reviewed, but is subject to all conditions set out in the exemption application and, in particular, those enumerated below.

1. This exemption is granted solely to this manufacturer.
2. The applicant must maintain records of the date(s) of shipment(s) to the customers specified in the application, and the quantities shipped in each shipment, and must make these records available to EPA upon request.
3. Each bill of lading that accompanies a shipment of the substance during the test marketing period must state that the use of the substance is restricted to that described to EPA in the test marketing exemption application.
4. The production volume of the new substance may not exceed the quantity described in the test marketing exemption application.
5. The test marketing activity approved in this notice is limited to a 12-month period commencing on the date of signature of this notice by the Assistant Administrator for Pesticides and Toxic Substances.
6. The number of workers exposed to the new chemical should not exceed that specified in the application, and the exposure levels and duration of exposure should not exceed those specified in the application.

The Agency reserves the right to rescind its decision to grant this exemption should any new information come to its attention which casts significant doubt on the Agency's conclusions that the test marketing of this substance under the conditions specified in the application will not present an unreasonable risk of injury to human health or the environment.

Dated: July 2, 1982.
John A. Todhunter, Assistant Administrator for Pesticides and Toxic Substances.
[FR Doc. 82-15809 Filed 7-12-82; 8:45 am]
BILLING CODE 6560-50-M

[WH-FRL-2167-3]

Management Advisory Group to the Construction Grants Program; Open Meeting

Under Public Law 92-463, notice is hereby given that a meeting of the Management Advisory Group (MAG) to the Construction Grants Program will be held at EPA Headquarters, Waterside Mall, Room S353, 401 M Street, S.W., Washington, D.C. 20460, on July 26–27, 1982. This meeting will begin at 9:00 a.m. on July 26, 1982.

The purpose of the meeting is to discuss and review the following: the status of the construction grants program, regulations reform, management of sludge, and proposed Clean Water Act Amendments. There will also be MAG Sub-Committee Task Force Meetings on various aspects of the construction grants program.

The meeting will be open to the public. Any member of the public wishing to attend the meeting should contact the Acting Executive Secretary, Mr. Alan Hais, Acting Director, Municipal Construction Division, EPA, Washington, D.C. 20460. The telephone number is area code 202–426–8986.

Frederick A. Eidsness, Assistant Administrator for Water, July 2, 1982.
[FR Doc. 82-15811 Filed 7-10-82; 8:45 am]
BILLING CODE 6560-50-M

[ER-FRL-2166-8]

Availability of Environmental Impact Statements Filed June 28 Through July 2, 1982 Pursuant to 40 CFR Part 1506.9

RESPONSIBLE AGENCY: Office of Federal Activities, General Information, 382–5075 or 382–5706.

Corps of Engineers:
EIS #820441, FS supp, COE, LA, Barataria Bay Waterway/GIWW to Gulf of Mexico, Maintenance Dredging, Due: Aug. 8, 1982.
EIS #820434, Report, COE, NJ, Report—NJ Coastal Inlets/Reach, Barnegat Inlet, Ocean County.
Department of Energy:


Department of Interior:


Department of Transportation:

EIS #820432, Draft, FHWA, NJ, County Route 522, Realignment, US 1 to US 130, Middlesex County, Due: Aug. 23, 1982.

EIS #820437, Final, FHWA, IN, Hamilton Co. Bridge No. 218 over Stoney Creek, Greenfield Pike, Replace, Due: Aug. 9, 1982.

EIS #820435, Final, FHWA, NJ-152 Reconstruction, Bay Avenue to JFK Bridge, Atlantic County, Due: Aug. 9, 1982.

Department of Housing and Urban Development:

EIS #820438, Final, HUD, TX, Mission Glen Subdivision, Mortgage Insurance, Fort Bend County, Due: Aug. 6, 1982.


EIS #820442, Draft, CDB, MA, North Station Urban Renewal Area, CDBG, Suffolk County, Due: Aug. 23, 1982.

EIS #820439, Final, CDBG, CA, Valley Boulevard Redevelopment Project, CDBG, Los Angeles County, Due: Aug. 9, 1982.

EIS #820439, Final, CDB, NY, City of Yonkers Waterfront Development, UDAF, Westchester County, Due: Aug. 9, 1982.

Nuclear Regulatory Commission:

EIS #820445, Draft, NRC, WY, Teton Solution Mining Project, Operating License, Converse County, Due: Aug. 23, 1982.

Department of Defense, Army:

EIS #820433, Final, USA, WI, Fort McCoy Ongoing Mission, Sparta, Monroe County, Due: Aug. 9, 1982.

Dated: July 6, 1982.

Paul C. Cahill,
Office of Federal Activities.

Federal Register / Vol. 47, No. 132 / Friday, July 9, 1982 / Notices

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 82-353, File No. 21572-CD-P(1)-82; CC Docket No. 82-354, File No. 22568-CD-P(1)-82]

Autophone of San Antonio, Inc. and Luling Mobilphone, Inc., Designating Applications for Consolidated Hearing on Stated Issues

In the matter of applications of Autophone of San Antonio, Inc., for a construction permit to establish an additional transmitter location for Station KR5651 to operate on frequency 152.24 MHz in the Domestic Public Land Mobile Radio Service at New Braunfels, Texas, CC Docket No. 82-353, File No. 21572-CD-P(1)-82 and Luling Mobilphone, Inc., for a construction permit for a new one-way station to operate on frequency 152.24 MHz in the Domestic Public Land Mobile Radio Service at Luling, Texas, CC Docket No. 82-354, File No. 22568-CD-P(1)-82.

Order Designating Applications for Hearing

Adopted: June 23, 1982.
Released: June 26, 1982.

1. Presently before the Commission, pursuant to delegated authority, are the captioned applications of Autophone of San Antonio, Inc. (Autophone) and Luling Mobilphone, Inc. (Luling). These applications are mutually exclusive; therefore, a comparative hearing will be held to determine which applicant would better serve the public interest. We find the applicants to be otherwise qualified.

2. Accordingly, it is ordered, pursuant to Section 308 of the Communications Act of 1934, as amended, that the applications of Autophone of San Antonio, Inc. and Luling Mobilphone, Inc. are designated for hearing in a consolidated proceeding upon the following issues:

(a) To determine on a comparative basis, the nature and extent of service proposed by each applicant, including the rates, charges, maintenance, personnel, practices, classifications, regulations, and facilities pertaining thereto;

(b) To determine on a comparative basis, the areas and populations that each applicant will serve within the prospective interference-free area within the 43 dBi contours, based upon the standards set forth in Section 22.504(a) of the Commission's Rules, and to determine the relative demand for the proposed service in said areas; and

(c) To determine, in light of the evidence adduced pursuant to the foregoing issues, what disposition of the referenced applications would best serve the public interest, convenience, and necessity.

3. It is further ordered, That the hearing shall be held at a time and place and before an Administrative Law Judge to be specified in a subsequent Order.

4. It is further ordered, That the Chief, Common Carrier Bureau, is made a party to the proceeding.

5. It is further ordered, That the applicants shall file written notices of appearances under § 1.221(c) of the Commission's Rules within 20 days of the release date of this Order.

6. The Secretary shall cause a copy of this Order to be published in the Federal Register.

William F. Alder,
Chief, Mobile Services Division, Common Carrier Bureau.

[FR Doc. 82-18552 Filed 7-8-82; 8:45 am]
BILLING CODE 6712-01-M

[BC Docket No. 82-371, File No. BRH-8102022G7; BC Docket No. 82-372, File No. BPH-810501AD]

GAF Broadcasting Co., Inc. and Classical Radio, Inc., Designating Applications for Consolidated Hearing on Stated Issues

In the matter of applications of GAF Broadcasting Company, Inc. Has: 104.3 MHz, Channel 282, Channel 39, broadcast in 1220 Feet, for renewal of license of station WGCN(FM) New York, New York.

For the purpose of this proceeding, the interference-free area is defined as the area within the 43 dBi contour as calculated from § 22.504, in which the ratio of desired-to-unwanted signal is equal to or greater than R in FCC Report No. R-400, equation 8.

Section 22.504(a) of the Commission's Rules and Regulations describes a field strength contour of 43 decibels above one microvolt per meter as the limits of the reliable service area for base stations engaged in one-way communications service on frequencies in the 120 MHz band. Propagation data set forth in § 22.504(a) are the proper bases for establishing the location of service contours of the facilities involved in this proceeding. (The applicants should consult with the Bureau counsel with the goal of reaching joint technical exhibits.)
York, BC Docket No. 82-371, File No. BPH-810501AD; Classical Radio, Inc., New York, New York. Req: 104.3 MHz, Channel 292 5.4 kW(H)-3.8 kW(V), 1220 Feet, BC Docket No. 82-372, File No. BPH-810501AD, for construction permit.

Memorandum Opinion and Order
Adopted: June 30, 1982.
Released: July 2, 1982.

1. The Commission, by the Chief, Broadcast Bureau, acting pursuant to delegated authority, has before it for consideration the 1981 license renewal application of GAF Broadcasting Company, Inc. ("GAF Broadcasting") for FM Station WCNCG in New York, New York, and a mutually exclusive construction permit application filed by Classical Radio, Inc. ("Classical").

2. GAF Broadcasting filed a petition to deny against Classical's construction permit application. Since the pleading is, in essence, a predesignation petition to specify issues and such petitions are no longer permitted, it will be dismissed.

Processing of Contested Broadcasting Applications, 72 FCC 2d 202 (1979); GAF Broadcasting, however, will have an opportunity to raise the issues contained in the petition post designation, pursuant to § 1.229 of the Commission's Rules. In addition, GAF Broadcasting filed requests for expedited action on December 17, 1981 and April 12, 1982, which are rendered moot by our action today and will be dismissed. To the extent that GAF Broadcasting attempted to raise issues against Classical therein, those matters may be raised post designation.

3. Construction permit applicant Classical Radio, Inc. and renewal applicant GAF Broadcasting Company, Inc. appear qualified to be Commission licensees. However, since the proposals are mutually exclusive, they must be designated for hearing in a consolidated proceeding.

4. Accordingly, it is ordered, That, pursuant to section 309(e) of the Communications Act of 1934, as amended, the application of GAF Broadcasting Company, Inc., for renewal of license of Station WCNCG(FM), New York, New York, and the construction permit application of Classical Radio, Inc. are designated for consolidated hearing, at a time and place to be specified in a subsequent Order, upon the following issues:
   1. To determine which of the proposals would, on a comparative basis, better serve the public interest.
   2. To determine, in light of the evidence adduced pursuant to the foregoing issue, which of the applications should be granted.

5. It is further ordered, That the petition to deny and requests for expedited action filed by GAF Broadcasting Company, Inc., are dismissed.

6. It is further ordered, That, to avail themselves of the opportunity to be heard, the applicants herein shall, pursuant to § 1.221(c) of the Commission's rules, in person or by attorney, within 20 days of the mailing of this Order, file with the Commission in triplicate a written appearance stating an intention to appear on the date fixed for the hearing and to present evidence on the issues specified in this Order.

7. It is further ordered, That the applicants herein shall, pursuant to section 311(a)(2) of the Communications Act of 1934, as amended, and § 73.3594 of the Commission's rules, give local notice of the hearing (either individually or, if feasible and consistent with the rules, jointly) within the time and in the manner prescribed in such rule, and shall advise the Commission of the publication of such notice as required by § 73.3594(g) of the rules.

8. It is further ordered, That the Secretary shall send, by Certified Mail—Return Receipt Requested, a copy of this Memorandum Opinion and Order to each of the parties named herein.

Roy J. Stewart,
Chief, Renewal and Transfer Division.

Radio Technical Commission for Marine Services; Meetings
In accordance with Pub. L. 92-463, "Federal Advisory Committee Act," the schedule of future Radio Technical Commission for Marine Services (RTCM) meetings is as follows:

Special Committee No. 78
"Federal Radionavigation Plan Review" Notice of 9th Meeting Tuesday, July 27, 1982—9:30 a.m.
Conference Room 9236/9232
Nassif (DOT) Building
400 Seventh Street, S.W. at D Street
Washington, DC

Agenda
1. Cell to order and administrative matters.
3. Decision regarding scope of review to be recommended to RTCM Executive Committee.
4. Discussion concerning a proposed civil alternative to NAVSTAR-GPS.

John C. Fuechsel, Chairman SC-78,
National Ocean Industries Assoc.,
1100 17th Street NW., Washington, DC, Phone: (202) 765-5116

The RTCM has acted as a coordinator for maritime telecommunications since its establishment in 1947. All RTCM meetings are open to the public. Written statements are preferred, but by previous arrangement, oral presentations will be permitted within time and space limitations.

Those desiring additional information concerning the above meeting(s) may contact either the designated chairman or the RTCM Secretariat (phone: (202) 632-8400).

William J. Tricarico,
Secretary, Federal Communications Commission.

[FR Doc. 82-18551 Filed 7-2-82; 8:45 am]
BILLING CODE 6712-01-M

FEDERAL RESERVE SYSTEM

Acquisition of Bank Shares by Bank Holding Companies
The companies listed in this notice have applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire voting shares or assets of a bank. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

A. Federal Reserve Bank of Atlanta (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:
   1. NCNB Corporation, Charlotte, North Carolina; to acquire 100 percent of the voting shares or assets of the successor by merger of Gulfstream Banks, Inc., Boca Raton, Florida and thereby indirectly acquire 100 percent of Gulfstream Bank, Tamarac, Florida and Gulfstream Bank, N.A., Boca Raton, Florida. Comments on this application must be received not later than July 31, 1982.
   2. SouthTrust Corporation, Birmingham, Alabama; to acquire 80
percent of the voting shares or assets of Citizens Bank of Northport, Northport, Alabama. Comments on this application must be received not later than July 31, 1982.

B. Federal Reserve Bank of San Francisco [(Harry W. Green, Vice President) 400 Sansome Street, San Francisco, California 94110]

1. Seafirst Corporation, Seattle, Washington; to acquire 100 percent of the voting shares or assets of Western National Bank, Bothell, Washington, a de novo bank. Comments on this application must be received not later than July 31, 1982.

Board of Governors of the Federal Reserve System, July 1, 1982.

Dolores S. Smith, Assistant Secretary of the Board.

[FR Doc. 82-16543 Filed 7-8-82; 8:45 am]
BILLING CODE 6210-01-M

Bank Holding Companies; Proposed de Novo Nonbank Activities

The bank holding companies listed in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and §225.4(b)(1) of the Board’s Regulation Y (12 CFR 225.4(b)(1)), for permission to engage de novo (or continue to engage in an activity earlier commenced de novo), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to each application, interested persons may express their views on the question whether consummation 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 interest, or unsound banking practices.” Any comment on an application that requests a hearing must include a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearings should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than August 1, 1982.

A. Federal Reserve Bank of New York (A. Marshall Puckett, Vice President) 33 Liberty Street, New York, New York:

1. Barclays Bank PLC and its subsidiary, Barclays Bank International Limited, each a bank holding company whose principal office is in London, England (consumer finance, Plano, Texas): To engage through their subsidiary, Barclays American/Financial, Inc., a Texas corporation in making direct consumer loans, including loans secured by real estate, and purchasing sales finance contracts representing extensions of credit such as would be made or acquired by a consumer finance company, and wholesale financing (floor planning); and acting as agent for the sale of related credit life, credit accident and health and credit property insurance. Credit life and credit accident and health insurance sold as agent may be underwritten or reinsured by BAC’s insurance underwriting subsidiaries.

This activity would be conducted from an office of BAC located at 230 W. Park Rd., Plano, Texas, serving customers in Plano and surrounding areas in Texas. This notification is for the relocation of an existing office located at 201 W. Louisiana St., McKinney, Texas.

B. Federal Reserve Bank of Chicago (Marshall Puckett, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. NBD Bancorp, Inc., Detroit, Michigan (insurance agency activities; Michigan, Virginia, California, Florida, Maryland, and the District of Columbia): To act indirectly through a de novo subsidiary, NBD Insurance Agency, Inc., as an agent for the sale of life, accident and health and accidental death and dismemberment insurance that is directly related to extensions of mortgage credit and/or the provision of other financial services by its bank and bank-related firms. These activities would be conducted from offices in Detroit, Michigan, serving Michigan, Virginia, California, Florida, Maryland, and the District of Columbia.

2. Bank of New York Company, Inc., New York, New York (mortgage banking; California). This notice corrects a previous published document (FR Doc. 82-17367) published at page 27965 of the issue for Monday, June 28, 1982. The proposed service area is the California counties of Los Angeles, Shasta, and Yolo.

B. Federal Reserve Bank of Chicago (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60604:

1. Manufacturers Hanover Corporation, New York, New York (reinsurance activities; Nex Mexico): To engage, through its indirect subsidiary, Tempco Life Insurance Company (“Tempco”), in the activity of reinsuring single and joint credit life insurance directly related to extensions of credit made in the State of New Mexico by
subsidiaries of Manufacturers Hanover Corporation. These activities would be conducted from offices in Phoenix, Arizona, serving the State of New Mexico.

2. Northeast Bancorp Incorporated, New Haven, Connecticut (issuance and sale of travelers checks; United States): To engage, through its subsidiary, Union Financial Services Corporation, in the business of issuing and selling travelers checks. These activities would be conducted from an office in Norwalk, Connecticut, serving the United States.

B. Federal Reserve Bank of Cleveland (Harry W. Huning, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Mellon National Corporation, Pittsburgh, Pennsylvania (leasing activities; throughout the United States and overseas): To engage, through its indirect subsidiary, Mellon Leasing and Management Company, in the leasing of real or personal property or acting as agent, broker or adviser in leasing such property so that the lease will serve as the functional equivalent of an extension of credit in accordance with § 225.4(a)(6) (a) and (b) of Regulation Y. These activities will be conducted from offices in Dallas, Texas; Cleveland, Ohio: Atlanta, Georgia; Chicago, Illinois; and Boston, Massachusetts, serving the United States and overseas.

C. Federal Reserve Bank of Kansas City (Thomas M. Hoening, Assistant Vice President) 923 Grand Avenue, Kansas City, Missouri 64119:

1. Royal Dominion Ltd., Denver, Colorado (data processing and related financial and administrative activities; Denver, Colorado): To engage, through its wholly-owned subsidiary, Royal Dominion Service Center Ltd., in activities limited to provision of bookkeeping, accounting and data processing services, business record keeping, storage and retrieval services and related financial and administrative services to affiliated banks and bank subsidiaries. These activities will be conducted from an office in Denver, Colorado, serving subsidiary banks and affiliated banks located within the Denver, Colorado metropolitan area.

D. Federal Reserve Bank of Dallas (Anthony J. Montelaro, Assistant Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. Allied Bancshares, Inc., Houston, Texas, (trust Company; Texas): To engage through a proposed subsidiary to be known as Allied Trust Company, in activities that may be carried on by a trust company, including activities of a fiduciary, investment advisory, agency or custodial nature. These activities will be conducted at offices located in Houston, Texas, serving the State of Texas.

Board of Governors of the Federal Reserve System, July 1, 1982.

Dolores S. Smith,
Assistant Secretary of the Board.

[FR Doc. 82-18545 Filed 7-8-82; 8:45 am]
BILLING CODE 6210-01-M

Formation of Bank Holding Companies

The company listed in this notice has applied for the Board’s approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become bank holding companies by acquiring voting shares and/or assets of a bank. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the Federal Reserve Bank of New York. Comments on this application must be received not later than August 1, 1982.

D. Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551:

1. Em Kay Financing Corp., Panama, Panama; and Em Kay Holdng Corp., New York, New York; to become bank holding companies by acquiring at least 66 percent of the voting shares of Village Bank of New Jersey, South Orange, New Jersey. This application may be reviewed at the Federal Reserve Bank of New York. Comments on this application must be received not later than August 1, 1982.

Dolores S. Smith,
Assistant Secretary of the Board.

[FR Doc. 82-18543 Filed 7-8-82; 8:45 am]
BILLING CODE 6210-01-M

Formation of Bank Holding Company

The company listed in this notice has applied for the Board’s approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring voting shares and/or assets of a bank. The factors that are considered in acting on the applications are set forth in section 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 indicated. With respect to the application, interested persons may express their views in writing to the address indicated. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

A. Federal Reserve Bank of Cleveland (Harry W. Huning, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. State National Bancorp Inc., Maysville, Kentucky; to become a bank holding company by acquiring 100 percent of the voting shares of The State National Bank of Maysville, Maysville, Kentucky. Comments on this application must be received not later than August 1, 1982.

2. Union Bancshares Corp., Bellevue, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of The Union Bank & Savings Company, Bellevue, Ohio. Comments on this application must be received not later than August 1, 1982.

B. Federal Reserve Bank of Atlanta (Robert R. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. LaPlace Bancshares, Inc., LaPlace, Louisiana; to become a bank holding company by acquiring 100 percent of the voting shares of Bank of LaPlace of St. John the Baptist Parish, LaPlace, Louisiana. Comments on this application must be received not later than August 1, 1982.

C. Federal Reserve Bank of St. Louis (Delmer P. Weisz, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Clark County Bancshares, Inc., Wyaconda, Missouri; to become a bank holding company by acquiring 82 percent of the voting shares of Peoples Bank of Wyaconda, Wyaconda, Missouri. Comments on this application must be received not later than August 1, 1982.

D. Secretary, Board of Governors of the Federal Reserve System, Kansas City, Missouri 64101:

1. Kansas State Investments, Inc., Manhattan, Kansas; to become a bank holding company by acquiring 90.61 percent of the voting shares of Kansas State Bancshares, Inc., Manhattan,
Formation of Bank Holding Companies

The companies listed in this notice have applied for the Board’s approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become bank holding companies by acquiring voting shares and/or assets of a bank. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing.

Federal Reserve Bank of Atlanta (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. BOS Bancshares, Inc., Metairie, Louisiana; to become a bank holding company by acquiring at least 80 percent of the voting shares of Bank of the South, Metairie, Louisiana. Comments on this application must be received not later than July 31, 1982.

2. FBT Bancshares, Inc., Slidell, Louisiana; to become a bank holding company by acquiring 80 percent of the voting shares of Fidelity Bank and Trust Company, Slidell, Louisiana. Comments on this application must be received not later than July 31, 1982.

First Hogansville Bankshares, Inc., Hogansville, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of The Citizens Bank, Hogansville, Georgia. Comments on this application must be received not later than July 31, 1982.

United Bancorporation of Alabama, Inc., Atmore, Alabama; to become a bank holding company by acquiring at least 80 percent of the voting shares of the successor by merger to The Bank of Atmore, Atmore, Alabama, and the successor by merger to Peoples Bank of Frisco City, Frisco City, Alabama. Comments on this application must be received not later than July 31, 1982.

B. Federal Reserve Bank of St. Louis (Delmer P. Weisz, Vice President) 411 Locust Street, St. Louis, Missouri 63169:

1. Kentucky Southern Bancorp, Inc., Bowling Green, Kentucky; to become a bank holding company by acquiring 100 percent of the voting shares of The Citizens National Bank of Bowling Green, Bowling Green, Kentucky. Comments on this application must be received not later than July 31, 1982.

Board of Governors of the Federal Reserve System, July 1, 1982.

Dolores S. Smith, Assistant Secretary of the Board.

FEDERAL TRADE COMMISSION

Early Termination of the Waiting Period of the Premerger Notification Rules; Coast Federal Savings and Loan Association

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: Coast Federal Savings and Loan Association is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of all the voting securities of Gakopa BV. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by both parties. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: June 24, 1982.


SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the Federal Register.

By direction of the Commission.

Carol M. Thomas, Secretary.

Early Termination of the Waiting Period of the Premerger Notification Rules; European Ferries Plc

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: European Ferries Plc is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of all the voting securities of Gakopa BV. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by both parties. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: June 24, 1982.


SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the Federal Register.

By direction of the Commission.

Carol M. Thomas, Secretary.
GENERAL SERVICES ADMINISTRATION
National Archives and Records Service
Advisory Committee on Preservation; Meeting

Notice is hereby given that the Subcommittee on Long Range Planning of the National Archives and Records Service Advisory Committee on Preservation will meet on July 28, 1982 from 10 a.m. to 4 p.m., in the Conference Room, 1221 Avenue of the Americas, New York, N.Y.

The meeting will be devoted to the identification of issues likely to arise during the next three years.

The meeting will be open to the public. For further information call Alan Calmes, 202-523-3159.

Dated: June 23, 1982.

Edward Weldon,
Acting Archivist of the United States.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Consumer participation; Open Meetings

Correction

In FR Doc. 82-11749 appearing at page 18667 in the issue of Friday, April 30, 1982, on page 18667, first column, under “FOR FURTHER INFORMATION CONTACT:”, fourth line, the telephone number “589-2400” should read “589-2420”.

BILLING CODE 4520-01-M

<table>
<thead>
<tr>
<th>Docket No. 82-0149</th>
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Thyroid Hormone Human Prescription Drug Products; Availability of Class Labeling Guideline

AGENCY: Food and Drug Administration.

DATE: Effective July 9, 1982, a person may adopt the class labeling guideline for thyroid hormone human prescription drug products and rely on it to meet FDA’s professional labeling requirements for prescription drugs.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Persons interested in obtaining copies of the guideline should contact Benjamin P. Lewis, Jr., at the address below.

FOR FURTHER INFORMATION CONTACT: Benjamin P. Lewis, Jr., National Center for Drugs and Biologics (HFD-177), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6004.

SUPPLEMENTARY INFORMATION: FDA has prepared a guideline for the professional labeling of thyroid hormone human prescription drug products. The guideline labeling can be used for each product within the drug class because all drugs in the class are closely related in chemical structure, pharmacology, therapeutic activity, and adverse reactions. Use of the guideline constitutes compliance with §§ 201.56, 201.57, and 201.100 (21 CFR 201.56, 201.57, and 201.100) of the agency’s regulations for the content and format of professional labeling for human prescription drugs.

The professional labeling of prescription drugs is required to contain the information and be in the format specified by §§ 201.56 and 201.57. The application of these regulations to drug products is proceeding under the schedule established in § 201.59 (21 CFR 201.59). As described more fully in § 201.59, the regulations apply to thyroid hormone drug products as follows: (1) On April 10, 1981, to thyroid drug products that are not subject to section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355); (2) on February 1, 1984, to thyroid drug products that on December 26, 1979, were subject to an approved new drug application under section 505 of the act, and duplicates of those products; and (3) as of December 26, 1979, to other thyroid drug products for which marketing approval under section 505 of the act is sought from FDA. The agency recognizes that some manufacturers and distributors of drugs in the first category may have already revised their drug labeling to comply with the regulations. The agency nonetheless encourages those persons to adopt the agency’s guideline class labeling for thyroid hormone drug products when practicable.

Class labeling guidelines should enhance the agency’s regulatory program for prescription drugs. The guidelines will promote consistency in labeling among various drugs of the same drug class and help the agency review proposed labeling for new drugs and antibiotics. They will also help drug manufacturers prepare labeling for drugs they propose to market that is in compliance with legal requirements. Finally, class labeling will be most helpful to health care professionals who prescribe and dispense prescription drug products. Prescribers and dispensers must now compare the labeling for members of a drug class to determine the similarities and differences among the products in the class. Class labeling, which contains information about each member of the drug class, will eliminate the need for such comparisons.

The guideline that is the subject of this notice is intended to provide class labeling for the thyroid drug class. The thyroid guideline has been developed by FDA, with the assistance of the agency’s Endocrinologic and Metabolic Drugs Advisory Committee and two consultants. At the time the guideline was being developed, the advisory committee consisted of the following members: Chairman, Mortimer B. Lipsett, M.D.; Executive Secretary, A. T. Gregoire, Ph. D., FDA; Richard Brand, Ph. D., Department of Biomedical and Environmental Sciences, School of Public Health, University of California, Berkeley, CA; Walter Henry, M.D., Howard University College of Medicine, Washington, DC; Margaret MacGillivray, M.D., Professor of Pediatrics, SUNYAB School of Medicine, Children’s Hospital of Buffalo, NY; Robert Neer, M.D., Associate Professor, Massachusetts General Hospital, Boston, MA; Lillian Recant, M.D., Professor of Medicine, Veterans Administration Hospital, Washington, DC; Simeon Margolis, M.D., Professor of Medicine, Johns Hopkins School of Medicine, Baltimore, MD; William H. Daughaday, M.D., Director, Metabolism Division, Department of Medicine, Washington University, St. Louis, MO; Seymour Reichlin, M.D., Ph. D., Professor of Medicine, New England Medical Center Hospital, 171 Harrison Ave., Boston, MA. The two consultants to the committee were Dr. Jack Robbins, Chief, Clinical Endocrinology Branch, NIH, and Dr. Tom Foley, Director, Clinical Research Center, Children’s Hospital of Pittsburgh. This guideline is appropriate as the basis for labeling for the following drugs in the thyroid hormone drug class in the route of administration identified in parenthesis:

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Liothyronine (T₃) Sodium (oral) Levothyroxine (T₄) Sodium (oral) These two drugs constitute the principal ingredient of five official preparations listed in the United States Pharmacopeia (USP): Thyroid Tablets (oral) Thyroglobulin Tablets (oral) Levothyroxine Sodium Tablets (oral) Lithothyronine Sodium Tablets (oral) Liotrix Tablets (oral) This is the fourth guideline FDA has made available as part of an effort to develop guideline professional labeling for 32 classes of prescription drug products. The first to be published as part of this effort was the class labeling guideline for single-entity barbiturates, which appeared in the Federal Register of November 18, 1980 (46 FR 76356). That guideline was followed by the guideline for androgen drug products, for which a notice of availability was published in the November 18, 1980 notice. In the future, FDA intends to develop and make available a class labeling guideline for the following drug classes: Aminoglycosides Anesthetics—local Anorectics—nonamphetamine Anticoagulants—oral Anticholinergic—centrally active Anticholinergic—synthetic Antidepressants Antihistamines Antipsychotics Benzodiazepines Cardiac glycosides Cephalosporins Diagnostic intravenous radiopaques Diagnostic oral radiopaques Erythromycins Glucocorticoids Insulins Narcotic analgesics Neuromuscular blocking drugs Penicillins—G & V Penicillins—semisynthetic Potassium preparations Quinidine salts Rauwolfia alkaloids Sulfonylamides Tetracyclines Thiourea Thiocyanates—volatile This notice is issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidelines to establish procedures of general applicability that are not legal requirements, but are acceptable to the agency. A person who follows this guideline is assured that his or her conduct is acceptable to the agency. The agency advises that the class labeling guideline for thyroid drug products complies with the prescription drug labeling regulations in §§ 201.50, 201.57, and 201.100 and can be relied upon by any person to meet these requirements. Under § 314.8 (21 CFR 314.8), manufacturers are required to submit supplemental new drug applications (NDA’s) advising the agency that the labeling is being revised. However, under § 314.8(d) the guideline labeling may be used before approval of a supplement to an NDA. A person may choose to use alternative labeling statements that are not provided for in the guideline. If a person chooses to depart from the guideline, he or she may discuss the matter further with the agency to prevent expenditure of money and effort for labeling that the agency may later determine to be unacceptable. Effective July 9, 1982, a person may adopt the class labeling guideline for thyroid prescription drug labeling requirements. Interested persons may submit written comments on the guideline to the Dockets Management Branch (address above). Comments will be considered in determining whether future amendments to the guideline are warranted. Comments should be in two copies except that individuals may submit single copies, identified with the docket number found in brackets in the heading of this document. The guideline received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Persons interested in obtaining copies of the guideline should contact Benjamin P. Lewis, Jr. (address above).

Dated: June 30, 1982.
William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

Office of Human Development Services [Program Announcement No. 13600–821]
Discretionary Funds Programs AGENCY: Office of Human Development Services, HHS. SUBJECT: Correction notice. SUMMARY: The Administration for Children, Youth and Families (ACYF) in the Office of Human Development Services (OHDS) announced in the Federal Register FR Doc. 82–13197 Monday, May 17, 1982, the Head Start Training and Technical Assistance Program: Availability of FY 1982 Funds. There are three errors in the announcement which we are correcting this notice.

On page 21194, in Appendix II, the line on which “Trust Territory” appears should have read “Guam, Trust Territories of the Pacific and Commonwealth of the Northern Mariana Islands” in order to comply with legislative changes in the Head Start Act of 1981. The revised deadline for the grant application from these areas is August 16, 1982.

On the same page in Appendix II, with respect to Arizona, the reference to footnote “3” should have been omitted, and the word “and” which appears immediately after Arizona should have read “and”.

DATE: July 9, 1982.
Dated: July 1, 1982
Dorcas R. Hardy,
Assistant Secretary for Human Development Services.
FR Doc. 82–13197 Filed 7–8–82; 8:45 am
BILLING CODE 4130–01–M

Office of the Secretary
Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on July 2.

Public Health Service
Food and Drug Administration
Subject: Recordkeeping Requirements for Low-Acid Canned Food Processors (0910–0036)—Extension Respondents: Processors of low-acid canned foods
Subject: American Society of Hospital Pharmacists/Food and Drug Administration Drug Shortage Monitoring Program (0910–0054)— Extension Respondents: Designated hospital pharmacies
OMB Desk Officer: Fay S. Judicello
Social Security Administration

Subject: Placement and Progress Report for Refugee Unaccompanied Minors (ORR-3/ORR-4)—New
Respondents: State or local governments/businesses or other institutions

Subject: Monthly Statistical Report on Recipients and Payments Under State Administered Assistance Programs for Aged, Blind, and Disabled Recipients (SSA-9741)—Extension
Respondents: State or local governments
OMB Desk Officer: Mile Sanderhauf

Health Care Financing Administration

Subject: Monthly Statistical Report on Medical Care: Medicaid Program (HCFA-120)—Extension no change
Respondents: States

Subject: Medicaid Quality Control Review Schedule (HCFA-301)—Revision
Respondents: States

Subject: Medicaid Quality Control Third Party Liability Resource Worksheet (HCFA-301C)—Extension no change
Respondents: States

Subject: Medicaid Quality Control Claims Processing Review Schedule and Documentation Source Sheet (HCFA-331)—New
Respondents: States
OMB Desk Officer: Fay S. Iudicello

Copies of the above information collection clearance packages can be obtained by calling the HHS Reports Clearance Officer on 202-245-6611. Written comments and recommendations for the proposed information collections should be sent directly to both the HHS Reports Clearance Officer and the appropriate OMB Desk Officer designated above at the following addresses:

J. J. Storm, HHS Reports Clearance Officer, Hubert H. Humphrey Building, Room 524F, Washington, D.C. 20201
OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, D.C. 20503, Attn. [name of OMB Desk Officer]

Dated: July 2, 1982.
Dale W. Soppe, Assistant Secretary for Management and Budget

[FR Doc. 82-18977 Filed 7-8-82; 8:45 am]
BILLING CODE 4150-04-M

Public Health Service

National Toxicology Program Board of Scientific Counselors; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the National Toxicology Program Board of Scientific Counselors, U.S. Public Health Service, in Conference Room 703-727A, Hubert H. Humphrey Building, Department of Health and Human Services, 200 Independence Avenue, SW, Washington, DC, on August 11, 1982.

The meeting will be open to the public from 9:00 a.m. until adjournment for the purpose of providing peer review of the data from the chronic carcinogenesis bioassay of FD&C Blue No. 2 in Charles River albino rats and Charles River CD-1, OBS (ICR-derived) mice of both sexes. The bioassay was sponsored by the Certified Color Manufacturers Association, conducted by Bio/Dynamics Inc., and submitted to the Food and Drug Administration (FDA) in support of permanent listing of FD&C Blue No. 2.

The meeting will commence with a brief overview of the study. This will be followed with presentations by scientific staff from the Bureau of Foods, FDA, concerning the pathology findings and statistical analyses of the bioassay. Sufficient time will be allowed for public comment.

The Executive Secretary, Dr. Larry G. Hart, Office of the Director, National Toxicology Program, P.O. Box 12233, Research Triangle Park, North Carolina 27709, telephone [919] 541-3971, FTS 629-3971, will furnish summary minutes of the meeting and other meeting information.

Dated: June 28, 1982.
David P. Rall, Director, National Toxicology Program.

Indian Fishing—Hoopa Valley Reservation

Bureau Form Number: BIA-5601
Frequency: On occasion
Description of Respondents: Indians fishing in the Hoopa Valley Indian Reservation
Annual Responses: 200
Annual Burden Hours: 10

Bureau clearance officer: Ronald D. Eden, 202-343-7894
Dated: June 23, 1982.
Kenneth Smith, Assistant Secretary—Indian Affairs.

[FR Doc. 82-18981 Filed 7-8-82; 8:45 am]
BILLING CODE 4150-02-M

Bureau of Land Management

[I-18593]

RECEIPT ACTION: Competitive Sale of Public Lands; Gooding County, Idaho


ACTION: Notice.

SUMMARY: The following-described land has been examined and identified as suitable for disposal by sale under Section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713) at no less than the fair market value of $8,600.00.

Boise Meridian, Idaho

T. 6 N., Range 13 East, Sec. 12, NW1/4.

Comprising 40.00 acres.

The land, which will be sold at public auction by competitive bidding, is no longer required for any Federal purpose. It does not complement BLM programs and the location and physical characteristics of the tract, along with the private ownership of adjoining lands, make it uneconomical to manage as public land. Disposal would not have any significant effect on resource values and would best serve the public interest.

A patent for the land, when issued, shall be subject to the following conditions:


2. All minerals including Gas and Oil shall be reserved to the United States as required by Section 209(a) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1719.

3. All valid existing rights and reservations of record; specifically the highway right-of-way I-80-03, 200 ft. in

[FR Doc. 82-18987 Filed 7-8-82; 8:45 am]
BILLING CODE 4310-02-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Information Collection Submitted for Review

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made directly to the Bureau's clearance officer and the Office of Management and Budget reviewing official, Mr. William T. Adams, at 202-395-7340.

- Title: 25 CFR Part 250 (Proposed).
width, and county road right-of-way established under R.S. 2477 prior to October 21, 1976, on the west side of the tract, 50 ft. in width.

The sale will be held at the Shoshone District Office, Bureau of Land Management, 400 West F Street, Shoshone, Idaho 83352 at 1:00 p.m., on Wednesday, October 6, 1982.

Bidding Information and Instructions

Bidder Qualifications: The Federal Land Policy and Management Act requires that bidders must be citizens of the United States, 18 years of age or over, or, in the case of a corporation, be subject to the laws of any State or the United States. Bids may be made by a principal (the one desiring to purchase the land) or his duly qualified agent.

Bid Standards: No bid will be accepted for less than the appraised fair market value of $8,600. Bids must be for all the land.

Method of Bidding: Bids may be made either by mail or personally at the sale. Bids sent by mail shall only be considered if received at the Shoshone District Office, 400 West F Street, Shoshone, Idaho 83352 prior to 1:00 p.m., on October 6, 1982. Bids sent by mail must be in sealed envelopes accompanied by a certified check, postal money order, or cashier's check made payable to the Bureau of Land Management for not less than one-fifth of the amount of the bid. The sealed envelope must be marked in the lower left-hand corner, “Sealed Bid, Public Land Sale I-18593, Sale to be October 6, 1982.” If two or more valid sealed bids in the same amount are received and they are the high bid, the determination of which is to be considered the highest bid shall be by a drawing. The drawing, if required, shall be held immediately following the opening of the bids. The highest qualifying sealed bid shall be announced.

Oral bids will be received immediately after all sealed bids have been opened and the highest sealed bid is announced. The highest sealed bid shall be the base for oral bids. All oral bids must be in increments of not less than $20.00. Sealed bidders present at the sale may also make oral bids. The highest bid price, either sealed or oral, shall establish the sale price. If the highest bid is an oral bid, the successful bidder shall be required to pay immediately one-fifth of the high bid price by cash, personal check, money order, or any combination of these.

Final Details

The successful higher bidder, whether it is by sealed or oral bid, shall be required to submit full payment for the balance of the bid within 30 days from the date of the sale. Failure to submit such payment within the 30 day period shall result in cancellation of the sale and the bid deposit shall be forfeited. All unsuccessful sealed bids will be returned within 30 days from the sale date. If no bids for the land, either sealed or oral, are received on the sale date, the sale will be adjourned until the next Wednesday at the same hour and place and continued on each succeeding Wednesday, until the lands are sold as specified in this notice or the sale is otherwise terminated.

Further Information/Inquiries:

Detailed information concerning this sale, including the planning documents and Environmental Assessment, is available for review in the Shoshone District Office at the address indicated above. For a period of 45 days from the date of this notice, interested parties may submit comments to the Shoshone District Manager. Any adverse comments will be evaluated by the Idaho State Director, Bureau of Land Management, who may vacate or modify this sale action and issue a final determination. In the absence of any action by the State Director, this sale action will become the final determination of the Department of the Interior.

Dated: June 29, 1982.

Charles J. Haszier, Shoshone District Manager.

California; Order Providing for Partial Revocation of Interpretations of Public Water Reserve 107

1. The Secretarial Orders of Interpretation Nos. 140 and 212, dated November 11, 1930, and January 18, 1935, respectively, of Public Water Reserve 107, are hereby revoked as to the following described lands which do not meet the criteria of the Executive Order of April 17, 1926:

Parcel A, San Bernardino Meridian
T. 5 N., R. 18 W., Sec. 14, 20 acres, SW1/4, SW1/4, NE1/4.

Parcel B, Mount Diablo Meridian
T. 21 S., R. 39 E., Sec. 20, 20 acres, NE1/4.

2. The land in Parcel A is located in the Los Padres National Forest and is withdrawn for Power Site Classification No. 414.

3. At 10 a.m. on July 9, 1982, the land in Parcel A will be open to non-metalliferous mineral location under the United States mining laws, subject to Public Law 359 (69 Stat. 661). The land has been and continues to be open to metalliferous mineral location under the mining laws and to applications and offers under the mineral leasing laws.

4. The land described in Parcel B is withdrawn for a Naval Ordnance Testing Center and Proving Range and will remain closed to operation of the public land laws, including the mining and mineral leasing laws pursuant to Public Land Order 431, dated December 19, 1947.

Inquiries concerning the land should be addressed to the State Director, Bureau of Land Management, 2800 Cottage Way, Sacramento, CA 95825.

Ron Hofman,
Acting State Director.

BILLING CODE 4310-84-M

California; Termination of Suspension From all Forms of Filing and Entry

June 29, 1982.

1. Pursuant to the authority delegated by Bureau Order No. 701 of July 23, 1964 (29 FR 10526), the General Land Office Order dated May 31, 1927, which suspended the following land from all forms of filing and entry, is hereby terminated:

Mount Diablo Meridian
T. 13 N., R. 10 E., Sec. 14, lots 2, 3, 4, 5, SW1/4, NE1/4, SW1/4, 1.76 acres, NE1/4.

2. All the lands described remain in existing withdrawals or are in private ownership and will not be opened to operation of the general land laws or to operation of the mining laws. The purpose of this action is to clear the records of an obsolete encumbrance.

The lands described in sections 14 and 22 remain open to offers and applications under the mineral leasing laws.

Ed Hastey,
State Director.

BILLING CODE 4310-84-M
Utah; Order Providing for Opening of Public Lands; Correction

In the Federal Register Document 82-10294, published on Thursday, April 15, 1982, Pages 16218, 16219, the lands listed as "U-50790" are hereby delineated and the following inserted:

Salt Lake Meridian, Utah

U-50790

T. 13 N., R. 9 W., Sec. 32, SE%.
T. 13 N., R. 10 W., Sec. 25, W%.
T. 14 N., R. 10 W., Sec. 7, lots 3, 4, E%EWSW, SE%.

Aggregating 2,880.58 acres in Box Elder County.

DATED: June 30, 1982.

Darrell Barnes,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 82-18587 Filed 7-8-82; 8:45 am]
BILLING CODE 4310-84-M

Michigan, Filing of Plat of Survey

1. On November 19, 1981, the plat representing the survey of 3 islands in Lake Huron, which were omitted from the original survey, was accepted. It will be officially filed in the Eastern States Office, Alexandria, Virginia, at 7:30 a.m. on October 7, 1982.

The tracts shown below describe the islands omitted from the original survey.

Michigan Meridian, Michigan

T. 42 N., R. 3 E., Tract Nos. 37 and 38.

2. The islands described above are separate and distinct yet similar in all respects to that of the adjacent surveyed lands.

a. The island Tract No. 37 rises approximately 6 feet above the ordinary high water mark of Lake Huron and has a soil composition of organic matter over glacial-till. Timber consists of cedar, spruce, tamarack, and birch. Boring revealed trees to be up to 70 years old. Large boulders were found on the island.

b. The island Tract No. 38 rises approximately 6 feet above the ordinary high water mark of Lake Huron and has a soil composition of organic matter over glacial-till. Timber consists of cedar, spruce, tamarack, and birch. Boring showed trees to be up to 70 years old. Decomposed stumps and large boulders were found on the island.

c. The island Tract No. 39 rises approximately 3 feet above the ordinary high water mark of Lake Huron and has a soil composition of organic matter over glacial-till. Timber consists of spruce, aspen, and birch. Boring showed trees to be up to 60 years old. Decomposed stumps and large boulders were found on the island.

3. The islands described above were found to be over 50 percent upland in character within the purview of the Swamp Lands Act of September 28, 1850 (9 Stat. 519). They are, therefore, held to be public land.

4. Except for valid existing rights, the islands will not be subject to application, petition, location, or selection under any public law until a further order is issued.

All inquiries relating to these islands should be sent to the Chief, Division of Lands and Minerals Operations, Eastern States Office, Bureau of Land Management, 350 South Pickett Street, Alexandria, Virginia 22304 on or before October 7, 1982.

Jeff O. Holdren,
Chief, Division of Lands and Minerals Operations.

[FR Doc. 82-18587 Filed 7-8-82; 8:45 am]
BILLING CODE 4310-84-M

Jeff O. Holden,
Chief, Division of Lands and Minerals Operations.

(FR Doc. 82-18588 Filed 7-8-82; 8:45 am)
BILLING CODE 4310-04-M

[ES 30505, Survey Group 78]

Michigan; Filing of Plat of Survey

1. On November 19, 1981, the plats representing the survey of 5 islands in Potagannissing Bay, which were omitted from the original survey, was accepted. It will be officially filed in the Eastern States Office, Alexandria, Virginia, at 7:30 a.m. on October 7, 1982. The tracts shown below describe the islands omitted from the original survey.

Michigan Meridian, Michigan
T. 42 N., R. 5 E.,
Tract Nos. 37, 38, 39, 40, and 41.

2. The tracts described above are separate and distinct yet similar in all respects to that of the adjacent surveyed lands.

a. The island Tract No. 37 rises approximately 3 feet above the ordinary high water mark of Potagannissing Bay (Lake Huron) and has a soil composition of stony loam over glacial-till. Timber consists of cedar, spruce, balsam fir, and birch. Borings showed trees to be up to 70 years old. Large boulders were found on the island.

b. Tract No. 38 rises approximately 6 feet above the ordinary high water mark of Potagannissing Bay (Lake Huron) and has a soil composition of stony loam over glacial-till. Tree species consist of cedar, spruce, balsam fir, and birch. Borings showed trees to be up to 70 years old. Large boulders were found on the island.

c. The island Tract No. 39 rises approximately 5 feet above the high water mark of Potagannissing Bay (Lake Huron) and has a soil composition of stony loam over glacial-till. Tree species consist of cedar, spruce, balsam fir, and birch. Borings showed trees to be up to 70 years old. Large boulders were found on the island.

d. Tract No. 40 rises approximately 3 feet above the ordinary high water mark of Potagannissing Bay (Lake Huron) and has a soil composition of stony loam over glacial-till. Tree species consist of cedar, spruce, balsam fir, and birch. Borings showed trees to be up to 70 years old. Large boulders were found on the island.

e. The island Tract No. 41 rises approximately 5 feet above the ordinary high water mark of Potagannissing Bay (Lake Huron) and has a soil composition of stony loam over glacial-till. Timber consists of cedar, spruce, tamarack, balsam fir, and birch. Borings showed trees to be up to 70 years old. Large boulders were found on the island.

3. The islands described above were found to be over 50 percent upland in character within the purview of the Swamp Lands Act of September 28, 1850 (9 Stat. 519). They are, therefore, held to be public land.

4. Except for valid existing rights, the islands will not be subject to application, petition, location, or selection under any public law until a further order is issued.

5. All inquiries relating to these islands should be sent to the Chief, Division of Lands and Minerals Operations, Eastern States Office, Bureau of Land Management, 350 South Pickett Street, Alexandria, Virginia 22304 on or before (90 days from date of publication).

Jeff O. Holden,
Chief, Division of Lands and Minerals Operations.

(FR Doc. 82-16691 Filed 7-8-82; 8:45 am)
BILLING CODE 4310-04-M

New Mexico; Proposed Land Exchange Between City of Albuquerque and Bureau of Land Management and USDA Forest Service

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action of proposed land exchange.

SUMMARY: This notice is to advise the public that the Albuquerque District of the Bureau of Land Management (BLM) is proposing to include an additional 2,928.61 acres of public land in a land exchange with the Region 3 Office of the U.S. Forest Service and the City of Albuquerque.

SUPPLEMENTARY INFORMATION: A notice of Realty Action (NORA) was published in the Federal Register on May 14, 1982, advising the public that 15,759 acres of public land in the vicinity of Las Cruces, Albuquerque and Farmington and 3,930.31 acres in the Sedillo Unit of the Cibola National Forest were identified as being suitable for exchange out of federal ownership. On June 23, 1982, an initial decision was published in the Federal Register amending the San Juan Management Framework Plan (MFP), to identify and additional 2,928.61 acres of public land in Farmington area as being suitable for exchange. When this decision becomes final, the BLM will include the 2,928.61 acres described below in the same land exchange with the U.S. Forest Service and the City of Albuquerque under authority of Section 206 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2743).

Amendment Lands Found Suitable for Exchange

T. 29 N., R. 12 W., NMPM

Section 7—Lot 4

| W1/2 NW1/2 | S1/2 SE1/2 | N1/2 W1/2 | SE1/2 | 4.00
| NW1/2 SW1/2 | 80.00 | 10.00 | 20.00 | E1/2 | NE1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |

Section 9—E1/2 SW1/2

| NE1/2 NW1/2 | 80.00 | 10.00 | 20.00 | E1/2 | NE1/2 | 5.00 | 6.00 |
| NW1/2 SW1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |

Section 17—E1/2

| NE1/2 NW1/2 | 80.00 | 10.00 | 20.00 | E1/2 | NE1/2 | 5.00 | 6.00 |
| NW1/2 SW1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |

Section 20—N1/2

| NW1/2 SW1/2 | 80.00 | 10.00 | 20.00 | E1/2 | NE1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |
| NW1/2 SE1/2 | 80.00 | 10.00 | 20.00 | W1/2 SW1/2 | 5.00 | 6.00 |

When these lands are combined with the 15,759 acres of other public land and 3,930 acres of Forest Service land, they should approximate the value of 7,941.21 acres that are located in the Sandia Mountains adjacent to the city of Albuquerque. When these private lands are conveyed to the United States, they
Las Vegas District Grazing Advisory Board; Meeting

June 30, 1982.

AGENCY: Bureau of Land Management, Las Cruces District, Interior.

ACTION: Notice of meeting.

SUMMARY: Agenda.

DATE: July 9, 1982 9:30 AM.

ADDRESS: Elephant Butte Inn, Highway 52, 5 miles north of Truth or Consequences, New Mexico.

FOR FURTHER INFORMATION CONTACT:
Daniel C. B. Rathbun, District Manager, Las Cruces District, Bureau of Land Management, P.O. Box 1420, Las Cruces, New Mexico 88004, Telephone (505) 524-8551 FTS 572-0257.

SUPPLEMENTARY INFORMATION:

Agenda

1. Approval of Minutes.
2. Fiscal Year '83 Range Improvement Projects.
3. Actual Use Records Keeping.
4. Utilization Studies.
5. Update on Las Cruces-Lordsburg MFP Amendment and Wilderness Analysis Reports.

At 2:00 PM, Comments from the public will be received.

Daniel C. B. Rathbun, District Manager.

Las Vegas District Grazing Advisory Board; Meeting

Notice is hereby given in accordance with Public Law 92-463 that a meeting of the Las Vegas District Grazing Advisory Board will be held on August 9, 1982, at 10:00 a.m. in the Caliente Resources Area conference room of the Bureau of Land Management Office, Caliente, Nevada.

The agenda for the meeting will include: (1) Setting priorities for the FY83 range improvement projects; (2) public comment.

The meeting is open to the public. Interested persons may make oral statements to the board between 1:00 p.m. and 2:00 p.m. on the date of the meeting or file written statements for the Board's consideration before or during the meeting. Anyone wishing to make an oral statement must notify the District Manager, Bureau of Land Management, 4705 West Vegas Drive, Las Vegas, Nevada 89126 (P.O. Box 26569) by August 9, 1982. Depending on the number of persons wishing to make an oral statement, the District Manager may establish a per person time limit.

Summary minutes of the Board meeting will be maintained at the District Office. They will be available for public inspection and reproduction (during regular business hours) within thirty days after the meeting.

Dated: June 30, 1982.

Kemp Conn, District Manager.
available to the public for information only.

4. This survey was executed to meet certain administrative needs of this Bureau and the U.S. Department of Agriculture Forest Service.

5. All inquiries relating to this land should be sent to the California State Office, Bureau of Land Management, Federal Office Building, Room E-2204, Cottage Way, Sacramento, California 95825.

Herman J. Lyttge, Chief, Section of Records and Data Management.

[FR Doc. 82-18595 Filed 7-8-82; 8:45 am]
BILLING CODE 4310-44-M

[ES 30510, Survey Group 78]

Michigan; Filing of Plat of Survey

1. On November 19, 1981, the plat representing the survey of 1 island in Raber Bay, which was omitted from the original survey, was accepted. It will be officially filed in the Eastern States Office, Alexandria, Virginia, at 7:30 a.m. on October 7, 1982.

The tract shown below describes the island omitted from the original survey.

Michigan Meridian, Michigan

T. 43 N., R. 7 E., Tract Nos. 37, 38, 39, and 40.

2. The islands described above are separate and distinct yet similar in all respects to that of the adjacent surveyed lands.

a. The island Tract No. 37 rises approximately 4 feet above the ordinary high water mark of Dickenson Lake and has a soil composition of stony loam over a rocky base. Tree species consist of cedar, balsam fir, spruce, and birch. Borings showed trees to be up to 60 years old.

b. Tract No. 38 rises approximately 3 feet above the ordinary high water mark of Bass Lake and has a thin layer of soil over a rocky base. Timber consists of balsam fir, spruce, birch, and cedar. Undergrowth consists primarily of alder.

c. The island Tract No. 39 rises approximately 4 feet above the ordinary high water mark of Lake Huron and has a soil composition of stony loam. Tree species consist of birch, aspen, spruce, tamarack, balsam fir, and cedar with undergrowth of alder, willow, sumac, and alder comprising most of the undergrowth.

d. Tract No. 40 rises approximately 2 feet above the ordinary high water mark of Lake Huron and is composed of bedrock. Vegetation consists of a lone birch tree and a small bunch of alder.

3. The islands described above were found to be over 50 percent upland in character within the purview of the Swamp Land Act of September 28, 1850 (9 Stat. 519). They are, therefore, held to be public land.

4. Except for valid existing rights, the islands will not be subject to application, petition, location, or selection under any public law until a further order is issued.

5. All inquiries relating to these islands should be sent to the Chief, Division of Lands and Minerals Operations, Eastern States Office, Bureau of Land Management, 350 South Pickett Street, Alexandria, Virginia 22304 on or before October 7, 1982.

Jeff O. Holdren, Chief, Division of Lands and Minerals Operations.

[FR Doc. 82-18595 Filed 7-8-82; 8:45 am]
BILLING CODE 4310-44-M

[ES 30509, Survey Group 78]

Michigan; Filing of Plat of Survey

1. On November 19, 1981, the plat representing the survey of 2 islands in Munuscong Lake, which were omitted from the original survey, was accepted. It will be officially filed in the Eastern States Office, Alexandria, Virginia, at 7:30 a.m. on October 7, 1982.

The tracts shown below describe the islands omitted from the original survey.

Michigan Meridian, Michigan

T. 44 N., R. 3 E., Tract Nos. 37 and 38.

2. The islands are separate and distinct yet similar in all respects to that of the adjacent surveyed lands.

a. Tract No. 37 rises approximately 5 feet above the ordinary high water mark of Munuscong Lake and has a thin layer of soil. Many boulders were found on the island. Timber consists of ash and elm with willow, sumac and alder comprising most of the undergrowth.

b. Tract No. 38 rises approximately 1 foot above the ordinary high water mark of Munuscong Lake and has a thin layer of soil over a rocky base. Boulders were found on the island. Timber consists of birch, aspen, balsam fir, and cedar.

3. The islands described above were found to be over 50 percent upland in character within the purview of the Swamp Land Act of September 28, 1850 (9 Stat. 519). They are, therefore, held to be public land.

4. Except for valid existing rights, the islands will not be subject to application, petition, location, or selection under any public law until a further order is issued.

5. All inquiries relating to these islands should be sent to the Chief, Division of Lands and Minerals Operations, Eastern States Office, Bureau of Land Management, 350 South Pickett Street, Alexandria, Virginia 22304 on or before October 7, 1982.

Jeff O. Holdren, Chief, Division of Lands and Minerals Operations.

[FR Doc. 82-18596 Filed 7-8-82; 8:46 am]
BILLING CODE 4310-44-M
FOR FURTHER INFORMATION CONTACT:
William G. Leavell, State Director,
Bureau of Land Management, Oregon
State Office, P.O. Box 2995, 825 NE
Multnomah, Portland, Oregon 97208,
503-6251.

SUPPLEMENTARY INFORMATION: The new Vale District will include the following resource areas and public lands:

<table>
<thead>
<tr>
<th>Resource area</th>
<th>Acres of SLM Administered</th>
<th>Acres of public lands</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baker Resource Area:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baker County</td>
<td>368,522</td>
<td></td>
</tr>
<tr>
<td>Malheur County</td>
<td>10,046</td>
<td></td>
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<tr>
<td>Morrow County</td>
<td>2,347</td>
<td></td>
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<tr>
<td>Umatilla County</td>
<td>12,600</td>
<td></td>
</tr>
<tr>
<td>Union County</td>
<td>2,265</td>
<td></td>
</tr>
<tr>
<td>Wallowa County</td>
<td>22,165</td>
<td></td>
</tr>
<tr>
<td>Aa Chin County, WA</td>
<td>6,758</td>
<td></td>
</tr>
<tr>
<td>Garfield County, WA</td>
<td>70</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>431,073</td>
<td></td>
</tr>
<tr>
<td>Northern Malheur Resource Area:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malheur County</td>
<td>1,870,717</td>
<td></td>
</tr>
<tr>
<td>Grant County</td>
<td>8,383</td>
<td></td>
</tr>
<tr>
<td>Harney County</td>
<td>8,180</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1,989,270</td>
<td></td>
</tr>
<tr>
<td>Southern Malheur Resource Area:</td>
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<td></td>
</tr>
<tr>
<td>Malheur County</td>
<td>2,492,022</td>
<td></td>
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<tr>
<td>Harney County</td>
<td>162,904</td>
<td></td>
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<tr>
<td>Humboldt County, NV</td>
<td>31,666</td>
<td></td>
</tr>
<tr>
<td>Elko County, NV</td>
<td>995</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2,688,531</td>
<td></td>
</tr>
</tbody>
</table>

William G. Leavell,
State Director.
July 2, 1982.

[FR Doc. 82-18599 Filed 7-8-82; 8:45 am]
BILLING CODE 4310-84-M

[OR-9041-D]
Oregon; Order Providing for the Opening of Public Lands

1. The following identified Secretarial Orders of Interpretation of Public Water Reserve No. 107 are hereby revoked insofar as they affect the following described lands which do not meet the criteria of the Executive Order of April 17, 1934:

Williamette Meridian

Interpretation No. 62 of April 7, 1928
T. 12 S., R. 42 E.,
Sec. 35, NW\NW and NE\NW.

Interpretation No. 83 of April 12, 1929
T. 5 N., R. 37 E.,
Sec. 35, SE\SE.

Interpretation No. 108 of October 23, 1929
T. 4 N., R. 37 E.,
Sec. 1, SE\SE.

Interpretation No. 198 of February 3, 1934
T. 8 S., R. 42 E.,
Sec. 15, SE\SE.

[FR Doc. 82-18591 Filed 7-8-82; 8:15 am]
BILLING CODE 4310-84-M

Idaho Falls District; Grazing Advisory Board; Meeting

Notice is hereby given in accordance with Pub. L. 92-463 that the Idaho Falls District Grazing Advisory Board will meet August 25, 1982.

The meeting will begin at 9 a.m. in the conference room of the Bureau of Land Management Office, 940 Lincoln Road, Idaho Falls, Idaho 83401. The meeting is open to the public. The Board will take statements from the public between 11:30 a.m. and 12 noon. Anyone wishing to make an oral statement must notify
the Idaho Falls BLM District Manager at the above address by August 20, 1982. Written statements will be accepted anytime prior to the Board meeting.

The agenda for the meeting will include:

1. Review of minutes.
2. Recommendations on Range Betterment Funds.
4. Update on District's progress on maintenance plans for range projects.
5. Effects that the asset management program may have on grazing privileges.
6. Discussion on effects that Egin Lake Recharge outlet is having on Egin Lake Grazing Allotment.

Summary minutes of the Board meeting will be kept in the District Office and be available for public inspection and reproduction during regular business hours within 30 days of the Board meeting.

Dated: July 1, 1982.
O'dell A. Frandsen,
District Manager.

[FR Doc. 82-18603 Filed 7-9-82; 8:45 am]
BILLING CODE 4310-84-M

[AA-6670-A through AA-6670-K]

Alaska Native Claims Selection

The purpose of this decision is to modify the Decision to Issue Conveyance (DIC) dated January 23, 1980, and published in the Federal Register on page 5402 through 5405. The DIC contained final determinations as to navigability and easements in accordance with the Alaska State Director (SD) Bureau of Land Management, memorandum dated November 16, 1979.

On May 20, 1982, an amendment to the SD Memorandum of November 16, 1979, was issued in accordance with a stipulation filed on May 18, 1982, with the Alaska Native Claims Appeal Board (ANCAB)(VLS 80-13). This amendment contained an administrative redetermination declaring Slopocket Lake and Alexcy Lake as major waterways and identified three additional easements to be reserved.

On May 28, 1982, ANCAB directed the Bureau of Land Management to comply with the aforementioned stipulation. Therefore, the DIC, dated January 23, 1980, is modified to include the following.

Page 5405

Add the following easements:

n. [EIN 11a C5] A site easement

upland of the ordinary high water mark in Sec. 27, T. 3 S, R. 32 W, Seward Meridian, on the north shore of Alexcy Lake. The site is one (1) acre in size with an additional 25-foot easement on the bed of the lake along the entire waterfront of the site. The allowable uses are those listed above for a one (1) acre site easement.

o. [EIN 11e C5] An easement for an existing access trail twenty-five (25) feet in width from site EIN 11a C5 on the north shore of Alexcy Lake northerly to site EIN 12a C5 on the Tazimina River. The allowable uses are those listed above for a twenty-five (25) foot trail easement.

p. [EIN 12a C5] a one-half (1/2) acre site easement upland of the ordinary high water mark in Sec. 22, T. 3 S., R. 32 W., Seward Meridian, on the left bank of the Tazimina River. The allowable uses are those listed above for a one (1) acre site easement.

In accordance with Departmental regulation 43 CFR 2050.7(d), notice of this modified decision is being published once in the Federal Register and once a week, for four (4) consecutive weeks, in the ANCHORAGE TIMES.

Any party claiming a property interest in lands affected by this modified decision, an agency of the Federal government, or regional corporation may appeal the decision to the Alaska Native Claims Appeal Board before June 30, 1982, or to the Interior Board of Land Appeals after June 30, 1982; provided, however, pursuant to Public Law 96-487, this modified decision constitutes the final administrative determination of the Bureau of Land Management concerning navigability of water bodies.

If an appeal is taken before June 30, 1982, the notice of appeal must be filed with the Alaska Native Claims Appeal Board, P.O. Box 2433, Anchorage, Alaska 99510, with a copy served upon both the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513, and the Regional Solicitor, Office of the Solicitor, 510 L Street, Suite 100, Anchorage, Alaska 99501.

If an appeal is taken after June 30, 1982, the notice of appeal must be filed in the Bureau of Land Management, Alaska State Office, Division of ANCSA and State Conveyances (960), address given above. Do not send the appeal directly to the Interior Board of Land Appeals. The appeal and copies of pertinent case files will be sent to the Board from this office. A copy of the appeal must be served upon the Regional Solicitor, address given above. The time limits for filing an appeal are:

1. Parties receiving service of this modified decision shall have 30 days from the receipt of this modified decision to file an appeal.
2. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, and parties who failed or refused to sign the return receipt shall have until August 9, 1982 to file an appeal.

Any party known or unknown who is adversely affected by this modified decision shall be deemed to have waived those rights which were adversely affected unless an appeal is timely filed with the Alaska Native Claims Appeal Board or the Bureau of Land Management, Alaska State Office, Division of ANCSA and State Conveyances.

To avoid summary dismissal of the appeal, there must be strict compliance with the regulations governing such appeals. Further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, 701 C Street, Box 13, Anchorage, Alaska 99513.

If an appeal is taken, the parties to be served with a copy of the notice of appeal are:

State of Alaska, Department of Natural Resources, Division of Technical Services, Pouch 7-005, Anchorage, Alaska 99510.
Iliamna Natives Limited, Iliamna, Alaska 99806.
Brattle Bay Native Corporation, P.O. Box 198, Dillingham, Alaska 99576.

Except as modified by this decision, the decision of January 23, 1980, stands as written.

Ann Johnson,
Chief, Branch of NACSA Adjudication.

[FR Doc. 81-18639 Filed 7-9-82; 8:45 am]
BILLING CODE 4310-84-M

F-14951-A

Alaska Native Claims Selections

Correction

In FR Doc. 82-17892 appearing on page 28822 in the issue of July 1, 1982 please make following change.

On page 28824, column 3 paragraph 8 should read as follows:

To avoid summary dismissal of the appeal, there must be strict compliance with the regulations governing such appeal. Further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, Alaska State
Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Texaco U.S.A.

AGENCY: Minerals Management Service, Interior.


SUMMARY: Notice is hereby given that Texaco U.S.A. has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS-G 1606, Block 54, South Pass Area, offshore Louisiana.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the Plan and that it is available for public review at the Office of the Minerals Manager, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: Minerals Management Service, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone (504) 637-4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised § 250.34 of Title 30 of the Code of Federal Regulations.

DATED: July 2, 1982.

John L. Rankin,
Acting Minerals Manager, Gulf of Mexico OCS Region.


Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Tenneco U.S.A.

AGENCY: Minerals Management Service, Interior.


SUMMARY: Notice is hereby given that Tenneco Oil Exploration and Production has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS-G 3959, Block 13, Sabine Pass Area, offshore Louisiana.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the Plan and that it is available for public review at the Office of the Minerals Manager, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: Minerals Management Service, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone (504) 637-4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised
§ 250.34 of Title 30 of the Code of Federal Regulations.  
Dated: July 2, 1982.
John L. Rankin,
Acting Minerals Manager, Gulf of Mexico OCS Region.

[FR Doc. 82-16000 Filed 7-8-82; 8:45 am]  
BILLING CODE 4310-31-M
INTERSTATE COMMERCE COMMISSION
Permalink Authority Decisions; Decision-Notice
The following applications, filed on or after February 9, 1982, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the Federal Register on December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the Federal Register issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 C.F.R. 1100.252. Applications may be protested only on the grounds that applicant is not fit, willing, and able to provide the transportation service or to comply with the appropriate statutes and Commission regulations. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings
With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication (or, if the application later become unopposed), appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after the publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to the Ombudsman's Office, (202) 273-7326.

Volume No. OP1-114
Decided: June 29, 1982.
By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier.

MC 141051 (Sub-2), filed June 24, 1982. Applicant: GROVE TRANSPORT, INC., 215 14th St., Jersey City, NJ 07302. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07834, (201) 234-0301. As a broker of general commodities (except household goods), between points in the U.S. (except AK and HI).


MC 162820, filed June 22, 1982. Applicant: SHORELINE EXPRESS, INC., 611 Old Toll Rd., Madison, CT 06443. Representative: William Campbell (same address as applicant), (203) 421-3178. (1) As a broker of general commodities (except household goods), between points in the U.S. (except AK and HI); and (2) transporting (a) for or on behalf of the U.S. Government, general commodities (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S. (except AK and HI); (b) food and other edible products and byproducts intended for human consumption (except alcoholic beverages and drugs), agricultural limestone and fertilizer, and other soil conditioners by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI); and (c) used household goods for the account of the U.S. Government incident to the performance of a pack-and-crate service on behalf of the Department of Defense, between points in the U.S. (except AK and HI).

MC 162640, filed June 24, 1982. Applicant: JOHN M. REIMER, Box 1244, Carman, Manitoba, Canada, ROG-OJO. Representative: John M. Reimer (same address as applicant), (203) 745-2567. Transporting food and other edible products and byproducts intended for human consumption (except alcoholic beverages and drugs), agricultural limestone and fertilizers, and other soil conditioners, by the owner of the vehicle in such vehicle, between points in the U.S. (except AK and HI).

MC 162641, filed June 24, 1982. Applicant: T.W.A. TRUCK LINE, INCORPORATED, 725 North Springfield Avenue, Chicago, IL 60624. Representative: Abraham A. Diamond, 29 South La Salle Street, Chicago, IL 60603, (312) 220-0540. Transporting, for or on behalf of the United States Government, general commodities (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S. (except AK and HI).

Volume No. OP3-102
Decided: June 30, 1982.
By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.
Box 357, Gladstone, NJ 07934, (201) 234-0301. Transporting shipments weighing 100 pounds or less, if transported in a motor vehicle in which no one package exceeds 100 pounds, between points in the U.S. (except AK and HI).

MC 152175 (Sub-3), filed June 21, 1982. Applicant: GRIFFIN DISTRIBUTING CO., INC., Rocky Ford Rd., P.O. Box 18471, Valdosta, GA 31601. Representative: Ken Combs (same address as applicant), [912] 242-8635. Transporting, for or on behalf of the U.S. Government, general commodities (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S. (except AK and HI).

Volume No. OP4-242

Decided: July 2, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams. (Member Williams not participating.)


Volume No. OP4-244

Decided: June 30, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 150947 (Sub-2), filed June 24, 1982. Applicant: ELDON L. ANNIS, d.b.a. ANNIS TRUCKING, Route 1, Glenwood City, WI 54013. Representative: Richard A. Westley, 4506 Regent St., Suite 100, P.O. Box 5066, Madison, WI 53705-0086, (608) 238-3119. Transporting food and other edible products and byproducts intended for human consumption (except alcoholic beverages and drugs), agricultural limestone and fertilizers, and other soil conditioners by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI).

Volume No. OP4-248

Decided: July 2, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 162716, filed June 29, 1982. Applicant: JRX TRUCKING, INC., 9121 Capital Beach Blvd., Lincoln, NE 68528. Representative: Michael J. Ogborn, P.O. Box 62028, Lincoln, NE 68501, (402) 475-6761. Transporting food and other edible products and byproducts intended for human consumption (except alcoholic beverages and drugs) agricultural limestone and fertilizers, and other soil conditioners by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI).

MC 162468, filed June 14, 1982. Applicant: CHARLES TAGUE & BRUCE TAGUE, RR 1, Gorin, MO 63543. Representative: Charles Tague (same address as applicant), [618] 479-5691. Transporting food and other edible products and byproducts intended for human consumption (except alcoholic beverages and drugs), agricultural limestone and fertilizer, and other soil conditioners by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI).
Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission’s Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the Federal Register of December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the Federal Register issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission’s policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission’s regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is not a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication, (or, if the application later becomes unopposed) appropriate authoritative documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued. Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper “under contract”.

Please direct status inquiries to the Ombudsman’s Office, (202) 275-7326.

Volume No. OP-102

Decided: July 1, 1982.

By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.

MC 81933 (Sub-11), filed June 21, 1982. Applicant: MONIOWCZAK TRANSIT COMPANY, Pineridge—U.S. 2 & 41, Escanaba, MI 49829. Representative: William B. Elmer, P.O. Box 801, Traverse City, MI 49684. (619) 941-5313. Transporting malt beverages, between Milwaukee, WI, on the one hand, and, on the other, points in the upper peninsula of MI.

MC 107744 (Sub-7), filed June 24, 1982. Applicant: B & G TRUCKING, INC., 10907 So. Painter Ave., Santa Fe Springs, CA 90670. Representative: Raymond P. Keigher, Suite 102, 401 E. Jefferson St., Rockville, MD 20850. (301) 424-2420. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in AZ, AR, CA, CO, ID, KS, LA, MT, NV, NM, OK, OR, TX, UT, WA and WY.

MC 115554 (Sub-47), filed June 25, 1982. Applicant: HEARTLAND EXPRESS, INC. OF IOWA, P.O. Box 88B, R.R. #6, Iowa City, IA 52240. Representative: Michael J. Ogboom, P.O. Box 62026, Lincoln, NE 68501. (402) 475-6761. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI).

MC 133194 (Sub-27), filed June 21, 1982. Applicant: WOODLINE MOTOR FREIGHT, INC., Airport Rd., P.O. Box 1047, Russellville, AR 72801. Representative: Scotty D. Douthit, Sr. (same address as applicant), (601) 968-2240. Transporting general commodities (except classes A and B explosives, household goods and commodities in bulk), between points in AR, KS, MO, OK, TX, LA, MS, KY, TN, AL, GA, NC, SC, and FL.

Note.—Applicant intends to tack this authority to its existing regular route authority.

MC 133735 (Sub-17), filed May 13, 1982. Applicant: AUDUBON-BROOKHISER TRANSPORT, INC., P.O. Box 186, Wever, IA 52658. Representative: Larry D. Knox, 600 Hubbell Bldg., Des Moines, IA 50309. (515) 244-2529. Transporting (1) food and related products and (2) chemicals and related products, between points in Lake County, IN, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 143394 (Sub-28), filed June 21, 1982. Applicant: GENIE TRUCKING LINE, INC., P.O. Box 840, 401 East Louther St., Carlisle, PA 17013. Representative: C. Kenneth Bishop (same address as applicant), (717) 249-2425. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI).

MC 147494 (Sub-13), filed June 18, 1982. Applicant: BOBBY KITCHENS, INC., P.O. Drawer 5690, Jackson, MS 39208. Representative: Fred W. Johnson, Jr., P.O. Box 1291, Jackson, MS 39205. (601) 355-3543. Transporting (1) scrap industrial batteries, between points in the U.S. (except AK and HI), under continuing contract(s) with MPN Corporation, D/B/A Dallas Scrap Baling Co., of Dallas, TX, (2) (a) building and construction materials, (b) machinery, (c) transportation equipment, and (d) metal products, between points in the U.S. (except AK and HI), under continuing contract(s) with Irby Construction Company, of Jackson, MS, (3) (a) electrical equipment, (b) metal products, and (c) machinery, between points in the U.S. (except AK and HI), under continuing contract(s) with Electric Wire and Cable Company, of Houston, TX, and (4) (a) pipe fittings, (b) iron and steel articles, and (c) machinery, between points in the U.S. (except AK and HI), under continuing contract(s) with G & W—Taylor Forge Division, of Ackerman, MS.

MC 149195 (Sub-20), filed June 21, 1982. Applicant: ARCADIAN MOTOR CARRIERS, 1100 Sierra St., Kingsburg, CA 93631. Representative: James F. Hauenstein (same address as applicant), (209) 897-4122. Transporting electrical appliances and equipment, lamps, lanterns, and lighting fixtures, between
points in NM, MS, TN, WI, CA, UT, and CT, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 151375 (Sub-2), filed June 21, 1982.
Applicant: COMPUTER TRANSPORT OF GEORGIA, INC., 6105 Purdue Dr., S.W., Atlanta, GA 30336.
Representative: Bruce E. Mitchell, 3390 Peachtree Rd. N.E., Suite 520, Atlanta, GA 30326, (404) 262-7855. Transporting (1) duplicating machines, (2) computers, (3) typewriters, (4) instruments, and (5) photographic goods, between Baltimore, MD, on the one hand, and, on the other, points in MD and VA.

MC 157544, filed June 24, 1982.
Applicant: DEVON PUNNEO, d.b.a. PUNNEO'S SERVICE, P.O. Box 156, Lone Grove, OK 73443. Representative: William P. Parker, P.O. Box 54857, Oklahoma City, OK 73154, (405) 424-3301. Transporting (1) scrap metal, (2) feed and feed ingredients, and (3) farm supplies, between points in OK, on the one hand, and, on the other, points in AR, KS, MO, TN, and TX.

Applicant: LAR-CO EXPRESS, A DIVISION OF EXE-CAL TRANSPORTATION SALES, INC., 16083 Los Alamos, Fountain Valley, CA 92708. Representative: Lawrence J. Exe (same address as applicant), (714) 963-7706. Transporting general commodities (except classes A and B explosives, household goods, and hazardous waste materials), between points in the U.S., under continuing contract(s) with Lawi/Csa Consolidator, Inc., of Huntington Park, CA.

MC 161925, filed June 21, 1982.
Applicant: KEENENDY LEASING, INC., P.O. Box 68, Birdsboro, PA 19508. Representative: Lynd E. Zampella (same address as applicant), (215) 582-2222. Transporting (1) pulp and paper, and (2) plastic and related articles, between points in Berks, Lycoming, and Allegheny Counties, PA, and Tuscarawas County, OH, on the one hand, and, on the other, points in MD, NY, PA, NJ, MA, DE, RI, CT, NH, and VA.

MC 161974, filed June 23, 1982.
Applicant: TRIDENT TRUCK LINE, INC., 23724 Saklen Rd., Hayward, CA 94544. Representative: Eugene Q. Carmody, 15523 Sedgeman St., San Leandro, CA 94579, (415) 357-6236. Transporting general commodities (except classes A and B explosives, household goods and commodities in bulk), between points in CA.

MC 162035, filed June 23, 1982.
Applicant: RON ABRAMS, d.b.a. ABRAMS TRUCKING, 743 West 11th St., Rushville, IN 46173. Representative: (same as above), (317) 932-4790. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in Rush County, IN, on the one hand, and, on the other, points in the U.S. (except AK and HI).

Volume No. OP4-241

Decided: July 2, 1982.
By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.
MC 162508, filed June 22, 1982.
Applicant: RITE TRUCK LINES, INC., 3779 Sparks Dr. SE, Suite 224, Grand Rapids, MI 49506. Representative: Edward Malinzak, 900 Old Kent Bldg., Grand Rapids, MI 49503, (616) 459-8121. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), (1) between points in IL, IN, MI, OH, and (2) between points in MI.

Volume No. OP4-243

Decided: July 2, 1982.
By the Commission, Review Board No. 2, Members Carleton, Fisher, and Williams.
MC 149406 (Sub-16), filed June 25, 1982.
Applicant: JOSEPH MOVING & STORAGE CO. d.b.a. ST. JOSEPH MOTOR LINES, 5724 New Peachtree Rd., Chamblee, GA 30341. Representative: Edward J. Kiley, 1730 M St., N.W., Washington, DC 20036, (202) 296-2900. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between Atlanta, GA, and points in Fulton, DeKalb, and Gwinnett Counties, GA, on the one hand, and, on the other, points in AL, AR, FL, GA, LA, TX, NC, SC, and TN. Notice: Issuance of a certificate in this proceeding is conditioned upon a request in writing by applicant for coincidental cancellation of its permits Nos. MC-146490 (Sub-Nos. 2, 5, 7, 13, 14, and 18).

MC 148286 (Sub-2), filed June 24, 1982.
Applicant: RALPH QPPERMAN, 1017 Valley View Dr., Fortuna, CA 95540. Representative: Milton, W. Flack, 8484 Wilshire Blvd., #840, Beverly Hills, CA 90211. (213) 655-3573. Transporting lumber and wood products, and building materials, between points in AZ, CA, CO, ID, KS, MN, MT, NE, NV, ND, NM, OK, OR, SD, TX, UT, WA and WY.

MC 156336 (Sub-1), filed June 25, 1982.
Applicant: OSCEOLA WASTE MATERIALS, INC., P.O. Box 752, Industrial Dr., Osceola, AR 72370. Representative: Thomas B. Staley, 3390 Peachtree Rd., N.E., Suite 224, Atlanta, GA 30326. (415) 357-6236. Transporting general commodities (except classes A and B explosives, household goods and commodities in bulk), between points in Salt Lake County, UT, on the one hand, and, on the other, points in CT, MA, NJ, NY, and PA.

MC 160397, filed May 17, 1982, and previously noticed in the Federal Register issue of June 4, 1982. Applicant: C.R. COPE ENTERPRISES-LCM, Route 4, Box 120, Seminole, TX 75360. Representative: Timothy Mashburn, P.O. Box 2207, Austin, TX 78766, (512) 476-6391. Transporting general commodities, between points in KY, MI, NC, SC, and VA, and points in the U.S. in and west of LA, AR, MO, IA and MN.

MC 161507, filed June 25, 1982.
Applicant: SUNCOOK TAXI & BUS

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MC 152637, filed June 24, 1982.
Applicant: CESCO TRANSPORT, INC., 490 Park Ridge Dr., Munroe Falls, OH 44262.
Representative: Lewis S. Witherspoon, 2455 North Star Rd., Columbus, OH 43221. (614) 486-9448.
Transporting general commodities, between points in the U.S. and their baggage, in special and charter operations, (1) between points in MI, MA, and ME, and (2) between points in NH, MA, and ME, on the one hand, and, on the other, points in the U.S. (except HI).

MC 152638, filed June 24, 1982.
Applicant: MIDWEST OIL TRANSIT, INC., P.O. Box 1277, Goldsboro, NC 27530.
Representative: Ralph McDonald, P.O. Box 2240, Raleigh, NC 27602. (919) 628-0731.
MC 156570, filed June 26, 1982.
Applicant: COASTAL TRANSPORT, INC., P.O. Box 1277, Goldsboro, NC 27530.
Representative: Tom B. Kretzinger, P.O. Box 238, Liberty, MO 64068. (816) 781-6000.
MC 151896, filed June 25, 1982.
Applicant: R. L. JONES & SONS, INC., 4900 E 12th St., Kansas City, MO 64127.
Representative: Tom B. Kretzinger, P.O. Box 238, Liberty, MO 64068. (816) 781-6000.
MC 152056, filed June 25, 1982.
Applicant: RHETT BUTLER TRUCKING, INC., Route 6, Box 83, Andalusia, AL 36420.
Representative: Gerald D. Colvin, Jr., 601-09 Frank Nelson Blvd., Birmingham, AL 35203. (205) 251-2881.
MC 150464, filed June 28, 1982.
Applicant: HABIT MOTOR LINES, INC., 90 N Broad St., Salem, NH 03079.
Representative: Wesley S. Chused, 15 Court Square, Boston, MA 02106. (617) 742-3530.
Transporting general commodities (except classes A and B explosives, household goods and commodities in bulk), between points in CT, ME, MA, NH, NJ, NY, PA, RI, and VT, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 152656, filed June 25, 1982.
Applicant: CHARLES G. UNSER, d.b.a. TRAVEL LAND TOURS, 117 E. 8th St., Suite 200C, Long Beach, CA 90813.
Representative: Charles G. Unser (same address as applicant), (213) 435-4401.
To operate as a broker, at Long Beach, CA, in arranging for the transportation, by motor vehicle, in interstate or foreign commerce, of passengers and their baggage, in special and charter operations, between points in the U.S. (except HI).

MC 152676, filed June 25, 1982.
Representative: Antonietta Bellucci (same address as applicant), (207) 775-1560.
To operate as a broker, at Portland, ME, in interstate or foreign commerce, in arranging for the transportation of passengers and their baggage, in special and charter operations, beginning and ending at points in Cumberland County, ME, and extending to points in the U.S. (except AK and HI).

MC 152066, filed June 26, 1982.
Applicant: EMMBASSY LIMO. SERVICE, 10944 Hayford St., Norwalk, CA 90650.
Representative: Phil Constable (same address as applicant), (213) 694-1113.
Transporting passengers and their baggage, in special or charter operations, in round-trip sightseeing and pleasure tours, between points in CA, UT, AZ, and NV, under continuing contract(s) with All American Tours, of Los Angeles, CA.

MC 150563, filed June 29, 1982.
Applicant: ARMELLINI EXPRESS LINES, INC., P.O. Box 2394, Stuart, FL 33494.
Transporting such commodities as are dealt in or used by the horticultural industry, between points in the U.S. (except AK and HI).

MC 154563, filed June 18, 1982.
Applicant: BOB BRINK, INC., 165 Steuben St., Winona, MN 55987.
Representative: Edward H. Instenes, P.O. Box 076, 128% Plaza E., Winona, MN 55987, (507) 454-3914.
Transporting general commodities (except classes A and B explosives, household goods and commodities in bulk), between points in MN, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 152576, filed June 28, 1982.
Applicant: TERMINAL & TRANSPORT SYSTEMS, INC., 130 Freight St., Waterbury, CT 06723.
Representative: Edward M. Taber, 64 Nottingham Terr., Waterbury, CT 06704. (203) 753-6839.
Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI).

MC 152700, filed June 28, 1982.
Applicant: MIDWEST OIL TRANSIT, INC., P.O. Box 68063, Indianapolis, IN 46288.
Representative: Robert B. Herbert, 777 Chamber of Commerce Bldg., Indianapolis, IN 46204. (317) 639-4511.
Transporting petroleum and coal products, between Toledo, OH, on the one hand, and, on the other, Indianapolis, IN.

MC 157420, filed June 28, 1982.
Transporting general commodities (except classes A and B explosives, household goods and commodities in bulk), between points in WA, OR, CA and AK, under continuing contract(s) with Hathaway Meats, Inc., of Spokane, WA.

MC 161236, filed June 29, 1982.
Applicant: BARBARA KRAKJIO, d.b.a. K & K TRUCKING, R.R. #1, Box 106, Eldridge, IA 52748.
Representative: Richard D. Howe, 600 Hubbell Bldg., Des Moines, IA 50309. (515) 244-2329.
Transporting coal and coal products, (1) between Davenport and Dubuque, IA, and points in La Salle County, IL, on the one hand, and, on the other, Madison,
transporting
distilled spirits and wines, between points in the U.S. (except AK and HI), under continuing contract(s) with Metro Banks, Inc., of Traverse City, MI, and Capital Hauling Company of Milwaukee, WI.

MC 138569 (Sub-6), filed June 21, 1982. Applicant: BRAITHWAITE TRUCKING, INC., 3819 Sunset Dr., Rapid City, SD 57701. Representative: Thomas J. Simmons, P.O. Box 480, Sioux Falls, SD 57101, 605–339–3629. Transporting cement and concrete products, between points in the U.S. under continuing contract(s) with U-Cart Concrete and Precast Products of Gillette, WY.

MC 139069 (Sub-1), filed June 14, 1982. Applicant: GIBRUS’ EXPRESS, INC., 10 Rex Dr., Braintree, MA 02184. Representative: L. J. O’Donnell, 60 Adams St., P.O. Box 238, Milton, PA 15217, 617–669–7610. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in CT, MA, ME, NH, RI, and VT.

MC 140288 (Sub-1), filed June 21, 1982. Applicant: J-CEM TRANSPORTATION, INC., 1418 17th St., Long Beach, CA 90813. Representative: Ensley Weimer (same address as applicant), (213) 263–6851. Transporting air conditioning equipment, between points in the U.S. (except AK and HI), under continuing contract(s) with Frigidaire Co./Frig, Inc., of Santa Fe Springs, CA.

MC 140288 (Sub-2), filed June 18, 1982. Applicant: J-CEM TRANSPORTATION, INC., 1418 17th St., Long Beach, CA 90813. Representative: Ensley Weimer (same address as applicant), (213) 263–6851. Transporting piping and tubing, between points in the U.S. (except AK and HI), under continuing contract(s) with Hughes Offshore (Division of Hughes Tool Corporation), of Torrance, CA.

MC 140288 (Sub-3), filed June 14, 1982. Applicant: J-CEM TRANSPORTATION, INC., 1418 17th St., Long Beach, CA 90813. Representative: Ensley Weimer (same address as applicant), (213) 263–6851. Transporting mercer commodities between points in the U.S. (except AK and HI), under continuing contract(s) with Ogden Company of Ogden, UT.

MC 144118 (Sub-2), filed June 21, 1982. Applicant: COMPUTER TRANSPORT OF OHIO, INC., 3669 Interchange Rd., Columbus, OH 43201. Representative: Bruce E. Mitchell, 3390 Peachtree Rd., NE, Suite 520, Atlanta, GA 30326, 404–262–7855. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in OH, IL, IN, KY, MI, NY, PA, VA, and WV.

MC 150798 (Sub-8), filed June 21, 1982. Applicant: CKR TRANSPORT, LTD., P.O. Box 599, Elmhurst, IL 60126. Representative: D. R. Beeler, P.O. Box 482, Franklin, TN 37064, (815) 790–2510. (1) transporting chemicals and related products, food and drug health care items, and food and related products, between points in CA, IL, IN, NJ, NC, DE, PA, WI, MN, MI, and TX, on the one hand, and, on the other, points in the U.S. (except AK and HI), and (2) chemicals and related products between Omaha, NE, Oklahoma City, OK, Vancouver, WA and West Memphis, AR, on the one hand, and, on the other, points in the U.S. (except AK and HI).


MC 162479, filed June 14, 1982. Applicant: LEACH MANUFACTURING COMPANY, INC., P.O. Box 1010, Gadsden, AL 35902. Representative: John W. Cooper, P.O. Box 162, Mentone, AL 35904, (205) 634–4883. Transporting metal products between Birmingham, AL, New Orleans, LA, Memphis, TN, and points in Calhoun and Etowah Counties, AL, on the one hand, and, on the other, points in NJ, PA, OH, MD, DE, WV, VA, NC, SC, IN, IL, KY, TN, MO, GA, FL, AL, AR, MS, IA, KS, OK, TX, and DC.

MC 162488, filed June 15, 1982. Applicant: CHRISTOPHER J. STESKAL, d.b.a. C.J. STESKAL TRUCKING, 417 Township Line Road, Chalfont, PA 18914. Representative: Mary C. Eberle, One South Fifth St., Perkasie, PA 18944. Transporting (1) construction materials and construction equipment between points in PA, ME, VT, NH, MA, CT, RI,
NY, OH, NJ, MD, DE, VA, WV, NC, SC, and DC, and [2] garden supplies between points in Bucks and Montgomery Counties, PA, on the one hand, and, on the other, points in (1) above.

MC 162908, filed June 16, 1982.
Applicant: BROUGHTON FOODS COMPANY, 114 Virginia St., W., Washington, D.C. 20004. Representative: Philip H. Smith (same address as applicant), (304) 342-2176. Transporting bananas, between Charleston, SC and points in Hillsborough County, FL, on the one hand, and, on the other points in the U.S., under continuing contract(s) with Surface Banana Co., Inc., of Bluefield, WV.

MC 162906, filed June 21, 1982.
Applicant: MARLIN C. BORTNER d.b.a. M.C.B. TRUCKING, 415 Hanover Rd., York, PA 17404. Representative: Norman T. Petow, 43 North Duke St., York, PA 17401. (717) 843-8004. Transporting (1) bakerie waste, (2) poultry feed supplement, and (3) grains and seeds, between those points in the U.S. on and east of a line beginning at the mouth of the Mississippi River, and extending along the Mississippi River to its junction with the western boundary of Itasca County, MN, then northward along the western boundaries of Itasca and Koochiching Counties, MN, to the international boundary line between the U.S. and Canada.

Applicant: MAXON & SON'S TOWING, INC., 48 Main St., Norfolk, MA 02056. Representative: Robert C. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181. (617) 235-5571. Transporting motor vehicles and automotive parts, and supplies, between points in RI and MA, on the one hand, and, on the other, points in CT, ME, MA, NH, RI, and VT.

Volume No. OPS-140
Decided: June 24, 1982.
By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC 79658 (Sub-23), filed June 18, 1982.
Applicant: ATLAS VAN LINES INC., 207 Mill St., Leominster, MA 01453. Representative: Steve L. Weinman, Suite 200, 444 N. Frederick Ave., Calthersburg, MD 20877, (301) 860-8656. Transporting general commodities (except classes A and B explosives, commodities in bulk and household goods), between points in the U.S. (except AK and HI), under continuing contract(s) with Digital Equipment Corporation, of Northborough, MA.

MC 131118 (Sub-2), filed June 17, 1982.
Applicant: TRI-WEST TRANSPORTATION CO., 8045 S. 179th Ave., Beaverton, OR 97007. Representative: Earl V. White, 2400 S. W. Fourth Ave., Portland, OR 97201, (503) 226-6491. Transporting (1) greases, motor and lubricating oils, and (2) tires, batteries and auto accessories, between points in Multnomah County, OR, on the one hand, and, on the other points in WA, under continuing contract(s) with Tri-City Oil Co., of Kennewick, WA, Christensen Oil Co., of Enumclaw, WA, Inland Oil Co., of Ephrata, WA, Carey & Son, of Issaquah, WA, and Mercer Oil Ltd., of Sunnydale, WA.

MC 138589 (Sub-5), filed June 18, 1982.
Applicant: BRAITHWAITE TRUCKING, INC., 3819 Sunset Dr., Rapid City, SD 57701. Representative: Thomas J. Simmons, P.O. Box 480, Sioux Falls, SD 57101, 605-339-3629. Transporting general commodities (except classes A and B explosives, and household goods), between points in the U.S. under continuing contract(s) with The Great Western Sugar Company of Denver, CO.

MC 141318 (Sub-23), filed June 18, 1982.
Applicant: WEATHER SHIELD TRANSPORTATION, LTD., P.O. Box 4614, Medford, WI 54451. Representative: Robert S. Lee, 1600 TCF Tower, 121 So. 8th St., Minneapolis, MN 55402, 612-333-1341. Transporting food and related products, between points in Cache, Davis, Morgan, Salt Lake and Weber Counties, UT and Taylor County, WI, on the one hand, and, on the other, points in the U.S.(except AK and HI).

MC 142539 (Sub-13), filed June 17, 1982.

MC 147978 (Sub-10), filed June 14, 1982.
Applicant: SYSTEM REEFER SERVICE, INC., 4014 Lincoln Ave., Cypress, CA 90630. Representative: Dixie C. Newhouse, 1329 Pennsylvania Ave., P.O. Box 1417, Hagerstown, MD 21740, (301) 797-6800. Transporting toilet articles and tobacco products, between points in Baltimore County, MD, on the one hand, and, on the other, points in OR, WA, ID, AZ and MT.

MC 150339 (Sub-48), filed June 14, 1982.
Applicant: PIONEER TRANSPORTATION SYSTEMS, INC., 151 Easton Boulevard, Federalburg, MD 21632. Representative: Ronald D. Endzel (same address as applicant), (301) 754-5084. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk) between points in the U.S. (except AK and HI), under continuing contract(s) with Exxon Corporation, of Houston, TX.

MC 156428, filed June 18, 1982.

MC 156238 (Sub-1), filed June 17, 1982.
Applicant: CLARENCE A. MILLER TRUCKING CO., INC., P.O. Box 628, Jackson, OH 45640. Representative: James M. Burch, 100 E. Broad St., Columbus, OH 43215, 614-228-1541. Transporting cool, clay and limestone, between points in Gallia, Jackson, Meigs, Lawrence and Vinton Counties, OH, on the one hand, and, on the other, points in IN, IL, MI, PA, and VA.

MC 156859 (Sub-1), filed June 14, 1982.
Applicant: O. DEAN TRANSPORTATION, INC., 406 West Williamsburg Road, Sandston, VA 23150. Representative: P. Owen Dean (same address as applicant), (804) 737-7938. Transporting (1) pulp, paper and related products, (2) rubber and plastic products, and (3) machinery parts between Richmond, VA, Chicago, IL, Minerva, OH and points in Wood County, OH, Middlesex, Worcester, Berkshire, and Hampshire Counties, MA, Washtenaw, Oakland, and Kalamazoo Counties, MI, New Castle County, DE, Hunterdon County, NJ, Franklin County, ME, Bucks County, PA, and Coos County, NH, on the one hand, and, on the other, points in the U.S., under continuing contract(s) with James...
River Corporation of Virginia, of Richmond, VA.

MC 159006 (Sub 3), filed June 14, 1982. Applicant: NORTHERN CARRIERS, INC., 3814 11th St., Rockford, IL 61110. Representative: William D. Brejcha, 180 North Michigan Ave., Suite 1700, Chicago, IL 60601, (312) 263-1600. Transporting such commodities as are dealt in or used by manufacturers of wheels, brake drums, and hubs, between points in the U.S. (except AK and HI), under continuing contract(s) with the Gunite Division of Kelsey Hayes Company of Rockford, IL.

MC 161979, filed May 14, 1982. Published initially in the Federal Register on June 15, 1982. Applicant: BEN C. WILLIAMS BAKERY SERVICE, INC., 6000 Denton Dr., Dallas, TX 75235. Representative: D. Paul Stafford, P.O. Box 45538, Dallas, TX 75245, 214-358-3341. Transporting such commodities as are dealt in or used by wholesale and retail bakeries, between points in TX, TN, NM, AL, AR, AZ, CO, GA, KS, KY, LA, MS, MO, OK, and IL.

Note—This application is republished to include AZ as sought by applicant.


MC 162520, filed June 16, 1982. Applicant: ROBERT E. BENNETT, P.O. Box 462, Jamestown, NY 14701. Representative: Kent S. Pope, 10 Grant St., Clarion, PA 16214, 814-226-5700. Transporting (1) cool, between points in Armstrong, Butler, Clarion, and Elk Counties, PA, on the one hand, and, on the other, Buffalo, NY, and (2) scrap metal, (a) between points in Chautauqua County, NY, on the one hand, and, on the other, points in PA, and (b) between Pittsburgh, PA, on the one hand, and, on the other, Syracuse, NY.

MC 162538, filed June 18, 1982. Applicant: LINDELL MAY, d.b.a. LINDELL MAY TRUCKING SERVICE, Rt. 1. Metropolitan, IL 62960. Representative: Lindell May (same address as applicant), (618) 524-9762. Transporting general commodities (except classes A and B explosives and household goods), between points in Massac County, IL and McCracken County, KY, on the one hand, and, on the other, points in AL, AR, IN, IA, KS, KY, MO, OH, PA, TN, and WV.

MC 162549, filed June 18, 1982. Applicant: RIVER CITY FOREST PRODUCTS, INC., Indiana Hwy 60, P.O. Box 52, Borden, IN 47106. Representative: Robert L. Kinser, 314 West Main St., P.O. Box 464, Frankfort, KY 40602, 502-223-8244. Transporting furniture and fixtures, between points in Washington County, IN, on the one hand, and, on the other, points in the U.S. (except AK and HI).

Volume No. OP 5–141

Decided: June 29, 1982.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC 109618 (Sub-101), filed June 23, 1982. Applicant: WENGER TRUCK LINE INC., P.O. Box 3427, 8909 West Rushmore, Davenport, IA 52808. Representative: Larry D. Knox, 600 Hubbell Bldg., Des Moines, IA 50309, (515) 244-2329. Transporting (1) such commodities as are dealt in or used by food business houses and (2) hides and skins, between points in the U.S. (except AK and HI).

MC 143639 (Sub-6), filed June 24, 1982. Applicant: SMITH AND SMITH, INC., 4361 Headquarters Road, P.O. Box 71355, Charleston Heights, SC 29405. Representative: Frank A. Graham, Jr., P.O. Box 11864, Columbia, SC 29211, (803) 799-0122. Transporting fertilizer and fertilizer materials, between points in GA and SC.

MC 144298 (Sub-11), filed June 21, 1982. Applicant: MASTER TRANSPORT SERVICES, INC., 6000 Wyoming Ave., Suite 203, Dearborn, MI 48128. Representative: William B. Elmer, P.O. Box 801, Traverse City, MI 49684, (616) 941-5313. Transporting general commodities (except classes A and B explosives and household goods), between points in Wyandotte County, MI, Monroe County, PA, De Kalb County, GA, and Los Angeles County, CA, on the one hand, and, on the other, points in the U.S.

MC 152439 (Sub-6), filed June 23, 1982. Applicant: WILLETT INTERSTATE SYSTEM, INC., 3901 S. Ashland Ave., Chicago, IL 60609. Representative: Donald S. Mullins, 1003 Graceland Ave., Des Plaines, IL 60016, 312-298-1094. Transporting general commodities (except classes A and B explosives and household goods), between points in the U.S. (except AK and HI), under continuing contract(s) with ITOFCA, Inc., of Downers Grove, IL.

MC 157459 (Sub-1), filed June 21, 1982. Applicant: LEWIS C. HOWARD, INC., 760 E. Vine St., Kalamazoo, MI 49001. Representative: Edward Malinuzak, 600 Old Kent Blvd., Grand Rapids, MI 49503, 616-458-6121. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in Kalamazoo County, MI, on the one hand, and, on the other, points in IN, IL, and OH.

MC 161139, filed June 24, 1982. Applicant: REDER, LTD., 1817 Winter Street, Superior, WI 54880. Representative: Richard A. Westley, 4508 Regent St., Suite 100, P.O. Box 5086, Madison, WI 53703-0086, (608) 238-3119. Transporting food and related products, between points in MN and WI, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 162249, filed May 28, 1982. Applicant: DAVID E. SHEEHAN, d.b.a. AIR-RIDE EXPRESS, 14339 So. California, Posen, IL 60469. Representative: David E. Sheehan (same address as applicant), (312) 835-5307. Transporting metal products, between points in AR, IA, IL, IN, KS, KY, MN, MO, MS, NE, OK, PA, TN, TX, VA, and WI.

MC 162578, filed June 21, 1982. Applicant: SRA RAIL CARTAGE, INC., P.O. Box 17480, Portland, OR 97217. Representative: Michael D. Crew, 1618 S.W. First Ave., Suite 205, Portland, OR 97201, 503-221-1529. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in OR and WA, on the one hand, and, on the other, points in the U.S. (except HI).

MC 162639, filed June 24, 1982. Applicant: McMILLIAN TRANSPORT, INC., 300 Chauncey Ave., Manchester, NH 03104. Representative: Hughan R. H. Smith, 28 Kenwood Place, Lawrence, MA 01841, (617) 657-6071. Transporting building materials and supplies between points in the U.S., under continuing contract(s) with Kalwall Corp., Inc., of Manchester, NH.

Volume No. OP 5–142

Decided: July 1, 1982.

By the Commission, Review Board No. 3, Members Krock, Joyce, and Dowell.

MC 134009 (Sub-4), filed June 21, 1982. Applicant: SECURITY ARMORED CAR SERVICE, INC., 1022 So. 9th St., St. Louis, MO 63104. Representative: B. W. LaTourette, Jr., 11 So. Meramec, Suite 1400, St. Louis, MO 63105, (314) 727–0777. Transporting coin, currency, bullion, stamps, negotiable instruments, and articles of unusual value, between points in the U.S. (except AK and HI), under continuing contract(s) with Federal Reserve Bank of St. Louis, of St. Louis, MO.
MC 146108 (Sub-7), filed June 14, 1982. Applicant: BIO T TRANSFER, INC., P.O. Box 287, New Albany, IN 47150. Representative: Harold C. Jolliff, 3242 Beech Drive, Columbus, IN 47201, (812) 379-2556. Transporting drums between Little Rock and Fort Smith, AR. Indianapolis and Evansville, IN, Bayonne, NJ, Pittsburgh, PA, and points in IL, OH, TN, and KY, on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 150209 (Sub-2), filed June 18, 1982. Applicant: E. & G. MOTOR EXPRESS, INC., U.S. Highway 42, Carrollton, KY 41008. Representative: Robert H. Kinker, 314 West Main St., P.O. Box 464, Franklin, KY 40602, 502-223-8244. Transporting general commodities (except classes A and B explosives, household goods, and commodities in bulk), between points in IN, OH, TN, WV, and that part of KY in and north of Bracken County, Industry. Between points in Lackawanna County, PA, on the one hand, and, on the other, New York, NY, and Elizabeth and Newark, NJ, (2) waste or scrap materials not identified by subcategory, (1) coal, and (2) used motor vehicles, between points in NY, NJ, and CT, and (3) used motor vehicles, between points in NY, PA, OH, MD, DE, CT, RH, and MA.

MC 150658 (Sub-1), filed March 10, 1982 (previously filed in Federal Register [republication] on March 30, 1982). Applicant: FEDDERLY MARION FREIGHT LINES, INC., P.O. Box 228, Issaquah, WA 98027. Representative: Jack R. Davis, 1100 IBM Bldg., Seattle, WA 98101, (206) 624-7973. Transporting (1) nonmetallic metals, (2) chemicals and related products, (3) clay, concrete, glass or stone products, and (4) construction materials, between points in WA, OR, CA, ID, MT, NV, and UT. Note.—Purpose of republication is to include OR in territorial description.

MC 151878 (Sub-2), filed June 25, 1982. Applicant: THREE WAY CORPORATION, 1120 Karlstad Drive, Sunnyvale, CA 94086. Representative: Charles H. White, Jr., 1018 19th St. NW, Suite 800, Washington, DC 20006, (202) 785-3420. Transporting general commodities (except classes A and B explosives and commodities in bulk), between points in the U.S., under continuing contract(s) with Memorex Corporation, of Santa Clara, CA.

MC 154488 (Sub-4), filed June 25, 1982. Applicant: LASLEY TRUCKING COMPANY, INC., Highway 94 East, P.O.Box 1368, Conway, AR 72032. Representative: John B. Fowles, Jr. (same address as applicant). (501) 327-4477. Transporting such commodities as are dealt in or used by a manufacturer of sucker rods, between points in the U.S., under continuing contract(s) with J. A. Patton Corporation, of Little Rock, AR.

MC 157608 (Sub-1), filed June 21, 1982. Applicant: DANIEL W. LANG d.b.a., DANDY INTERMODAL SERVICE, 11444 Perry Hwy., Wexford, PA 15090. Representative: David W. Donley, 610 Smithfield St., Suite 400, Pittsburgh, PA 15222, 412-471-6272. Transporting general commodities (except classes A and B explosives, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with General Nutrition Corporation of Pittsburgh, PA.

MC 157809, filed June 18, 1982. Applicant: JOHN LAHOTSKI, STEPHEN LAHOTSKI, WILLIAM LAHOTSKI, AND PAUL LAHOTSKI d.b.a. BLUE AND WHITE TRUCKING, 181 Phillips St., Throop, PA 18512. Representative: Joseph A. Keating, Jr., 121 S. Main St., Taylor, PA 18517, (717) 344-8030. Transporting (1) coal between points in Lackawanna County, PA, on the one hand, and, on the other, New York, NY, and Elizabeth and Newark, NJ, (2) waste or scrap materials not identified by subcategory, (3) used motor vehicles, between points in NY, NJ, and CT, and (4) construction materials, between points in WA, OR, CA, ID, MT, NV, and UT.


MC 158859 (Sub-3), filed June 21, 1982. Applicant: O. DEAN TRANSPORTATION, INC., 408 W. Williamsburg Rd., Sandston, VA 23150. Representative: P. Owen Dean (same address as applicant). (804) 277-7937. Transporting general commodities (except classes A and B explosives and commodities in bulk), between points in the U.S., under continuing contract(s) with Medline Industries, of Northbrook, IL and (2) rubber and plastic products, under continuing contract(s) with GenPak Corporation, or Glen Falls, NY, between points in the U.S.

MC 162559, filed June 18, 1982. Applicant: GARY L. CAPASSO, 22 Fenwick St., Ballston Spa, NY 12020. Representative: Gary L. Capasso (same address as applicant), (518) 885-5083. Transporting (1) medical supplies and equipment, under continuing contract(s) with Medline Industries, of Northbrook, IL and (2) rubber and plastic products, under continuing contract(s) with GenPak Corporation, or Glen Falls, NY, between points in the U.S.

MC 162568, filed June 21, 1982. Applicant: EXECLINE, INC., 997 Brook Road, Lakewood, NJ 08701. Representative: Ronald I. Shaps, 450 Seventh Avenue, New York, NY 10123, (212) 239-4610. Over regular routes: transporting passengers and their baggage, and express and newspapers in same vehicle with passengers, in motor vehicles not exceeding 21 passengers (excluding the driver), between Toms River, NJ and New York, NY (a) between junction Main St. and Water Street in Toms River, NJ and New York, NY as follows: from junction Main and Water Streets in Toms River, NJ over Water Street to junction access roads to Garden State Parkway, then over Garden State Parkway to junction exit 90, then over Chambers Bridge Road to junction State Highway 70, then over Chambers Bridge Road to junction Lanes Mill Road, then over Lanes Mill Road to junction Burnt Tavern Road, then over Burnt Tavern Road, to junction access roads to Garden State Parkway, then over Garden State Parkway to junction Interstate Highway 95 (New Jersey Turnpike) then over New Jersey Turnpike to New Jersey Turnpike Extension to the Holland Tunnel, then through the Holland Tunnel to New York, NY and return over the same route (b) between junction Main Street and Water Street in Toms River, NJ and New York, NY as follows: from junction Main and Water Sts. in Toms River, NJ over Water Street to junction access roads to Garden State Parkway, then over Garden State Parkway to junction exit 90, then over Chambers Bridge Road to junction Lanes Mill Rd., then over Lanes Mill Rd. to junction Burnt Tavern Rd., then over Burnt Tavern Road to junction access roads to Garden State Parkway, then over Garden State Parkway to junction Interstate Highway 95 (New Jersey Turnpike) then over New Jersey Turnpike to access roads to Interstate Highway 495, then over Interstate Hwy...
Motor Carriers; Permanent Authority Decisions; Restriction Removals; Decision-Notice

Decided: July 1, 1982.


Persons wishing to file a comment to an application must follow the rules under 49 CFR 1137.12. A copy of any application can be obtained from any applicant upon request and payment to applicant of $10.00.

Amendments to the restriction removal applications are not allowed.

Some of the applications may have been modified prior to publication to conform to the special provisions applicable to restriction removal.

Canadian Carrier Applicants

In the event an application to transport property, filed by a Canadian domiciled motor carrier, is unsuccessful, it will be reopened on the Commission's own motion for receipt of additional evidence and further consideration in light of the record developed in Ex Parte No. MC-157, Investigation Into Canadian Law and Policy Regarding Applications of American Motor Carriers For Canadian Operating Authority.

Findings

We find, preliminarily, that each applicant has demonstrated that its requested removal of restrictions or broadening of unduly narrow authority is consistent with the criteria set forth in 49 U.S.C. 10922(h).

In the absence of comments filed within 25 days of publication of this decision-notice, appropriate reformed authority will be issued to each applicant. Prior to beginning operations under the newly issued authority, compliance must be made with the normal statutory and regulatory requirements for common and contract carriers.

By the Commission, Removal Application Board, Members Shaffer, Ewing, and Williams.

Agatha L. Mergenovich,
Secretary.

MC 97841 (Sub-26)X, filed June 11, 1982. Applicant: GENERAL HIGHWAY EXPRESS, INC., 2280 Industrial Dr., P.O. Box 727, Sidney, OH 45365.
Representative: Jack R. Wells (same as above). Sub 26 certificate: Remove (1) all exceptions from its general commodities authority, except classes A and B explosives and household goods; sheets 1 and 16; and (2) the restriction prohibiting transportation of shipments moving to, from or through named points, sheet 16.

MC 119834 (Sub-9)X, filed June 17, 1982. Applicant: ROBERT N. TOOMY TRUCKING COMPANY INC., 1516 S. George St., York, PA 17404.
Representative: Edward N. Button, 635 Oak Hill Ave. Hagerstown, MD 21740. Lead No. MC-124144 and Subs 8, 16 and 17 permits; broaden to (A)(1) "metal products" from (a) wire cloth, lead, and (b) chains, cotter pins, hoisting equipment, trolleys, screws, washers and abrasive wheels, Sub 16; and (2) “food, chemicals and related products” from foodstuffs, food treating compounds, chemicals (except chemicals in liquid form or in bulk), and additives, in vehicles equipped with mechanical refrigeration and commodities (except or partially exempt from regulation) and/or materials, equipment and supplies used in the manufacture, preparation, sale and distribution of spices, extracts and convenience foods, Subs 8 and 17; and (B) "between points in the U.S. under continuing contract(s)") with named shippers, all Subs.

MC 124534 (Sub-6)X, filed June 24, 1982. Applicant: DYOLL DELIVERY SERVICE, INC., P.O. Box 56, Netcong, NJ 07857. Representative: George A. Olsen, P.O. Box 357, Old Chester Rd., Gladstone, NJ 07934. Lead certificate and No. MC-139725 Sub-4 permit, (1) remove special equipment exception from authority to transport general commodities (with exceptions), in lead; (2) broaden component parts of special ordnance equipment, radar and underwater sound devices, missile and missile handling equipment aircraft carriers, and special machinery manufactured to customer's specification, and pile hammers and parts, * * * rough steel and iron castings, to "electrical equipment, ordnance and accessories, machinery, and metal products", in Sub 4; (3) change airports and cities to city or county-wide authority: New York International Airport and La Guardia Airport (New York, NY), Newark Municipal Airport (Newark, NJ), Rockaway, NJ (Morris County), West Conshohocken and Avondale, PA (Montgomery and Chester Counties), in lead, (4) broaden to between points in the U.S. (except AK and HI) under a continuing contract(s) with named shipper, in Sub 4; and (5) remove ex-air restriction, in lead.

MC 125473 (Sub-13)X, filed June 28, 1982. Applicant: YAZOO TRUCKING CO., INC., P.O. Box 626, Yazoo City, MS 38694. Representative: Donald B. Morrison, P.O. Box 22628, Jackson, MS 39205. Subs 5, 7, and 8 Permits: (1) Broaden to "clay, concrete, glass or stone products" from dry clay in Sub 5; to "chemicals and related products" from manufactured fertilizer in Sub 5, fertilizer, fertilizer materials, urea and urea products in Sub 7, and dry manufactured fertilizer and dry fertilizer ingredients in Sub 9, (2) Remove the restrictions: to packages in Sub 5; to dry commodities in Sub 7; to containers in Subs 7 and 9, (3) Expand to between points in the U.S. under continuing contract(s) with named shippers in all Subs.

MC 146228 (Sub-1)X, filed June 26, 1982. Applicant: WHITING PUBLIC WAREHOUSES, INC., 9450 Buffalo St., Hamtramck, MI 48212. Representative: Daniel L. Whiting (same address as applicant). Lead certificate: remove facilities restriction and change existing one-way authority to radial authority in the transportation of general commodities with five exceptions, between Detroit, MI (facilities near Hamtramck and Detroit), on the one hand, and, on the other points in OH and IN.

MC 146807 (Sub-40)X, filed June 21, 1982. Applicant: S n W ENTERPRISES, INC., P.O. Box 1131, Wilkes Barre, PA 18702. Representative: Peter Wolff, 722 Pittston Ave., Scranton, PA 18505. Subs 2, 3, 4, 6, 8, 14, 15, 16, 17, 18, 19, 20, 22, 23 and 24: Broaden to (1)(a) "food and related products" from foodstuffs subs 2 and 8; from confectionary and chewing gum, sub 15; (b) "metal products" from steel wire rope, sub 3; from steel wire, sub 4; from wire products and dishwasher racks, sub 6; from wire, sub 14; from chains and gearing, sub 17; from iron and steel wire rope, sub 24; (c) "rubber and plastic products" from
plastic film, plastic sheeting and plastic bags, subs 16 and 19, from plastic sheeting, sub 23; (d) "coal and coal products" from coal, sub 20; (e) "furniture and fixtures" from store furnishings and furniture, sub 22; (t) to countywide authority: (a) Broome County (Johnson City, NY), sub 2; (b) Luzerne County (Hanover Township, PA) Peeria, Woodford and Tazewell Counties (Peeria, IL) Pettis County (Sedalia, MO) Harris, Brazoria, Galveston, Chambers, Liberty, Montgomery, Waller, Ft. Bend and San Jacinto Counties (Houston, TX) Kitsap, Jefferson and King Counties (Seattle, WA) Allegheny County (Leetsdale, PA) Bergen County (Peterboro, NJ), sub 3; (c) Luzerne County (Hanover Township, PA) Webb County (Laredo, TX), sub 4; (d) Luzerne County (Wilkes Barre, PA) Collin, Denton, Dallas, Ellis, Kaufman, Rockwall and Tarrant Counties (Dallas, TX) San Bernardino County (Cucamonga, CA) Jefferson and St. Louis Counties, MO. St. Louis, MO. St. Clair, Madison and Monroe Counties, IL. (St. Louis), sub 6; (e) Broome County (Johnson City, NY) Philadelphia, Delaware, Montgomery, Bucks, and Chester Counties, PA;Hunterdon, Mercer, Burlington, Camden, Gloucester and Salem Counties, NJ and New Castle County, DE (Philadelphia, PA); Allegheny County (Pittsburgh, PA); Camden, Hudson and Cumberland Counties (Gloucester, Jersey City and Vineland, NJ) sub 6; (f) Luzerne County (Hanover Township and Kingston, PA), Fulton, De Kalb, Cobb, Clayton, Henry, Cimmenett and Douglas Counties (Atlanta, GA) Denver, Arapahoe, Elbert, Douglas, Jefferson and Boulder Counties (Denver, CO) Harris, Brazoria, Galveston, Chambers, Liberty, Montgomery, Waller, Ft. Bend, San Jacinto and Ector Counties (Houston and Odessa, TX) Orlean,, St. Bernard, Plaquemines, Jefferson, St. Charles and St. Tammany Parishes, LA and Hancock County, MS (New Orleans, LA) Tulsa and Osage Counties (Tulsa, OK), sub 14; (g) Lackawanna and Luzerne Counties (Duryea and Scranton, PA), sub 15; (h) Schuylkill County (Pottsville, PA), sub 16; (i) Luzerne County (West Pittston, PA), sub 17; (j) Lackawanna and Luzerne County (Duryea and Scranton, PA), sub 18; (k) Schuylkill County (Pottsville, PA), sub 19; (l) Luzerne County (Wilkes Barre, PA), sub 20; (m) Luzerne County (Mountaintop, PA), sub 23; (n) Kaufman County (Terrill, TX), sub 22; (3) Remove (a) facility restrictions, subs 2, 8, 15, 17 and 18(b) remove "originating at/destined to" restriction, sub 8; (4) to radial, all subs.

[FR Doc. 82-18568 Filed 7-8-82; 8:45 am] BILLING CODE 7035-01-M

Intent To Engage in Compensated Intercorporate Hauling Operations

This is to provide notice as required by 49 U.S.C. 10524(b)(1) that the named corporations intend to provide or use compensated intercorporate hauling operations as authorized in 49 U.S.C. 10524(b).


1. Parent corporation and address of principal office: INE, INC., 2220 Toledo Road, Elkhart, Indiana 46515.

2. Wholly-owned subsidiaries which will participate in the operations, and State of incorporation: (l) Zook, Inc., 15978 County Road 38, Goshen, Indiana, 46526, an Indiana corporation. (ii) Rock Hill Trucking Co., Inc., P.O. Box 1046, Elkhart, Indiana, 46514, an Indiana corporation.

1. Parent corporation and address of principal office: Rock Hill Materials Company (a Pennsylvania Corporation), 339 School St., Catassauqua, PA 18032.

2. Wholly-owned subsidiaries which will participate in the operations, and State(s) of incorporation: (i) R. H. Aggregates, Inc. (Pennsylvania), (ii) Rock Hill Trucking Co., Inc. (Pennsylvania).

1. Parent Corporation: Southern Container Corp., P.O. Box J. Deer Park, NY 11729.

2. Wholly-owned subsidiaries which will participate in the operations and their respective States of incorporation: Penn State Container Corp. (a Pennsylvania corporation), 500 Richardson Drive, Lancaster, Pa. 17603.

Package & Display Developers, Inc. (a New York corporation), 115 Engineering Road, Hauppauge, N.Y. 11788.

Southern Container Management Corp. (a Delaware corporation), 115 Engineers Road, Hauppauge, N.Y. 11788.

Great Southern Trucking Co., Inc. (a North Carolina corporation), 500 Richardson Drive, Lancaster, Pa. 17603.

Metropolitan Corrugated, Inc. (a New Jersey corporation), R. 21, PO Box 840, Newport, R.I., 02840.

South Carolina Container Corp. (a South Carolina corporation), 1-28 at New Cut Road, Spartanburg, S.C. 29304.

Agatha L. Mergenovich, Secretary.

[FR Doc. 82-18563 Filed 7-8-82; 8:45 am] BILLING CODE 7035-01-M

[Finance Docket No. 29942]

Atchison, Topeka and Santa Fe Railway Co.; Exemption; Purchase; 2.1 Miles of Track From Missouri Pacific Railroad Co.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce Commission exempts the acquisition by Atchison, Topeka and Santa Fe Railway Company of six track segments (2.1 miles) of the Missouri Pacific Railroad Company in the vicinity of Caney, KS, from the requirements of 49 U.S.C. 11343.

DATES: This exemption is effective on August 9, 1982. Petitions for reconsideration must be filed by July 29, 1982 and petitions for stay must be filed by July 19, 1982.

FOR FURTHER INFORMATION CONTACT: Louis E. Gitomer, (202) 277-7245.

ADDRESSES: Send petition for reconsideration to: (1) Section of Finance, Room 5349, Interstate Commerce Commission, Washington, DC 20423; and (2) Michael W. Blaszak, 80 East Jackson Blvd., Chicago, IL 60604. Pleasings should refer to F.D. No. 29942.

SUPPLEMENTARY INFORMATION:

Additional information is contained in the Commission's decision. To purchase a copy of the full decision contact: TS Infosystems, Inc., Room 2227, 12th and Constitution Ave. NW., Washington, DC 20423, (202) 289-4537—DC metropolitan area, (800) 424-5403—Toll-free for outside the DC area.

Decided: July 1, 1982.

By the Commission, Chairman Taylor, Vice Chairman Gresham, Commissioners Gresham, Sterrett, Andre, and Simmons. Chairman Taylor was absent and did not participate. Commissioner Gresham did not participate.

Agatha L. Mergenovich, Secretary.

[FR Doc. 82-18553 Filed 7-8-82; 8:45 am] BILLING CODE 7035-01-M

[Finance Docket No. 29955]

Berlin Mills Railway, Inc., James River-Dixie/Northern Inc., James River Corp. of Virginia; Exemption Control

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce Commission has exempted Berlin Mills Railway, Inc, James River Dixie/ Northern, Inc, and James River Corp. of Virginia which will acquire control of
Meridian & Bigbee Railroad Company from the requirements of 49 U.S.C. 11343.


ADDRESSES: Send pleadings to: (1) Section of Finance, Room 5349, Interstate Commerce Commission, Washington, DC 20423.


FOR FURTHER INFORMATION CONTACT: Louis E. Gitomer, (202) 275-7245.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision contact: TS Infosystems, Inc., Room 2227, 12th and Constitution Ave., NW., Washington, DC 20423, (202) 289-4357, DC metropolitan area, (800) 424-5403, Toll-free for outside the DC area.

Decided: July 2, 1982.

By the Commission, Division 1, Commissioners Sterrett, Simmons, and Gradison. Commissioner Gradison did not participate. 

Agatha L. Mergenovich, Secretary.

[FR Doc. 82-18502 Filed 7-6-82; 8:45 am] BILLING CODE 7035-01-M

[Ex Parte No. 387 (Sub-166)]

Chesapeake & Ohio Railway Co.; Exemption For Contract Tariff ICC-CO-C-0017

AGENCY: Interstate Commerce Commission.

ACTION: Notice of provisional exemption.

SUMMARY: Petitioner is granted a provisional exemption under 49 U.S.C. 10505 from the notice requirements of 49 U.S.C. 10713(e). The contract tariffs to be filed may become effective on one day's notice. This exemption may be revoked if protests are filed within 15 days of publication in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Douglas Galloway, (202) 275-7278.

SUPPLEMENTARY INFORMATION: The Chesapeake and Ohio Railway Company (CO) filed a petition on June 24, 1982, seeking an exemption under 49 U.S.C. 10505 from the statutory notice provisions of 49 U.S.C. 10713(e). It requests that we permit its contract ICC-CO-C-0017 to become effective on one day's notice. The contract was filed to become effective on July 25, 1982 and involves the movement of petroleum coke.

Under 49 U.S.C. 10713(e), contracts must be filed on not less than 30 days' notice. However, relief can be granted under 49 U.S.C. 10505.

The petition shall be granted. Advancement of the contract effective date will allow the shipper to load two vessels at the Port of Newport News, VA in early July in an economically practical manner and aid the carrier in the effective use of its surplus equipment. An exemption will obviously be in the public interest.

The CO's contract may become effective on one day's notice. We will apply the following conditions which have been imposed in similar exemption proceedings:

Although the Commission permits the contract to become effective on one day's notice, this fact neither shall be construed to mean that this is a Commission approved contract for purposes of 49 U.S.C. 10713(g) nor shall it serve to deprive the Commission of jurisdiction to institute a proceeding on its own initiative or on complaint, to review this contract and to disapprove it.

Subject to compliance with these conditions, under 49 U.S.C. 10505(a) we find that the 30-day notice requirement in this instance is not necessary to carry out the transportation policy of 49 U.S.C. 10101(a) and is not needed to protect shippers from abuse of market power. Further, we will consider revoking this exemption under 49 U.S.C. 10505(d) if protests showing good cause are filed within 15 days of publication in the Federal Register.

This action will not significantly affect either the quality of the human environment or conservation of energy resources.

(49 U.S.C. 10505).

DATED: July 2, 1982.

By the Commission, Division 2, Commissioners Andre, Taylor, and Sterrett. Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

Agatha L. Mergenovich, Secretary.

[FR Doc. 82-18500 Filed 7-6-82; 8:45 am] BILLING CODE 7035-01-M

[Finance Docket No. 23388]

Chicago & North Western Railway Co.; Merger; Chicago Great Western Railway Co.; Petition To Reopen

AGENCY: Interstate Commerce Commission.

ACTION: Petition to reopen.

SUMMARY: In Finance Docket No. 29683, Soo Line R. Co.—Petition for Exemption, 386 I.C.C. 296 (1982), the Commission concluded that a reply filed by the Chicago and North Western Transportation Company to an exemption petition which was the subject of that proceeding, should be treated as a petition to reopen Finance Docket No. 23388, Chicago & N.W. Ry. Co.—Merger, 330 I.C.C. 12 (1967), and the latter proceeding should be reopened on the modified procedure to determine whether conditions imposed there should be removed because of changed circumstances. Accordingly, the Commission is reopening Finance Docket No. 23388 and setting it for hearing on the modified procedure.

DATES: (1) Opening statements of fact and arguments by petitioner and any party supporting petitioner shall be filed within 30 days of the service date, July 8, 1982, of the Commission's decision.

(2) Statements in opposition by protestants and any party supporting protestants should be filed within 60 days of the service date of the Commission's decision.

(3) Statements in reply by petitioner and any supporting party should be filed within 45 days of the service date of the Commission's decision.

ADDRESSES: Send pleadings to:

(1) Section of Finance, Room 5349, Interstate Commerce Commission, Washington, DC 20423.

(2) Petitioner's representatives: Stuart F. Gassner, One North Western Center, 165 North Canal Street, Chicago, IL 60606, (312) 559-6072. Pleadings should refer to Finance Docket No. 23388.

FOR FURTHER INFORMATION CONTACT: Louis E. Gitomer, (202) 275-7245.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision contact: TS Infosystems, Inc., Room 2227, 12th and Constitution Ave., NW., Washington, DC 20423, (202) 289-4357, DC metropolitan area, (800) 424-5403, Toll-free for outside the DC area.

Decided: July 1, 1982.

By the Commission, Chairman Taylor, Vice Chairman Gilliam, Commissioners Gresham, Sterrett, Andre, and Simmons. Commissioner Gresham did not participate.

Agatha L. Mergenovich, Secretary.

[FR Doc. 82-18500 Filed 7-6-82; 8:45 am] BILLING CODE 7035-01-M
The contract was filed to become a provisional exemption under 49 U.S.C. 10505 from the notice requirements of 49 U.S.C. 10713(e). The contract tariffs to be filed may become effective on one day’s notice. This exemption may be revoked if protests are filed within 15 days of publication in the Federal Register.

SUMMARY: Petitioner is granted a provisional exemption under 49 U.S.C. 10505 from the notice requirements of 49 U.S.C. 10713(e). The contract tariffs to be filed may become effective on one day’s notice. This exemption may be revoked if protests are filed within 15 days of publication in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Douglas Galloway, (202) 275-7278.

SUPPLEMENTARY INFORMATION: The Graham County Railroad filed a petition on June 15, 1982, seeking an exemption under 49 U.S.C. 10505 from the statutory notice provisions of 49 U.S.C. 10713(e). It requests that we permit its contracts ICC-GC-C-1 and ICC-GC-C-2 to become effective on one day’s notice. The contract was filed to become effective on July 14, 1982 and involves the movement of general commodities.

Under 49 U.S.C. 10713(e), contracts must be filed on not less than 30 days’ notice. However, relief can be granted under 49 U.S.C. 10505.

Graham is a new carrier. The actual commencement of its operations is dependent upon its contracts. An exemption will obviously be in the public interest.

Graham’s contract may become effective on one day’s notice. We will apply the following conditions which have been imposed in similar exemption proceedings:

Although the Commission permits the contract to become effective on one day’s notice, this fact neither shall be construed to mean that this is a Commission approved contract for purposes of 49 U.S.C. 10713(e) nor shall it serve to deprive the Commission of jurisdiction to institute a proceeding on its own initiative or on complaint, to review this contract and to disapprove it.

Subject to compliance with these conditions, under 49 U.S.C. 10505(a) we find the 30-day notice requirement in this instance is not necessary to carry out the transportation policy of 49 U.S.C. 10101(a) and is not needed to protect shippers from abuse of market power. Further, we will consider revoking this exemption under 49 U.S.C. 10505(d) if protests are filed within 15 days of publication in the Federal Register.

This action will not significantly affect either the quality of the human environment or conservation of energy resources. (49 U.S.C. 10505)

DATED: June 29, 1982.

By the Commission, Division 2, Commissioners Andre, Gilliam, and Taylor, Commissioner Taylor is assigned to this Division for the purpose of resolving tie votes. Since there was no tie in this matter, Commissioner Taylor did not participate.

Agatha L. Mergenovich, Secretary.

[FR Doc. 82-18680 Filed 7-6-82; 8:45 am]

BILLING CODE 7035-01-M

Union Pacific Railroad Co.; Exemption for Contract Tariffs ICC-UP-C-0054

AGENCY: Interstate Commerce Commission.

ACTION: Notice of provisional exemption.

SUMMARY: Petitioner is granted a provisional exemption under 49 U.S.C. 10505 from the notice requirements of 49 U.S.C. 10713(e). The contract tariffs to be filed may become effective on one day’s notice. This exemption may be revoked if protests are filed within 15 days of publication in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Tom Smerdon, (202) 275-7277.

SUPPLEMENTARY INFORMATION: The Union Pacific Railroad Company (UP) filed a petition on June 24, 1982, seeking an exemption under 49 U.S.C. 10505 from the statutory notice provisions of 49 U.S.C. 10713(e). It requests that we permit its contract ICC-UP-C-0054 filed on June 24, 1982, to become effective on one day’s notice. The contract involves the movement of tractors.

Under 49 U.S.C. 10713(e), contracts must be filed on not less than 30 days’ notice. There is no provision for waiving this requirement. However, the Commission has granted relief under the section 10505 exemption authority in exceptional situations.

The petition shall be granted. Due to economic conditions, the shipper has been forced to lay off some of its employees. Short notice effectiveness of the contract will provide immediate work for those employees involved in loading the tractors and preparing them for shipment. We find this to be the type of exceptional circumstance which warrants a provisional exemption.

Petitioner’s contract ICC-UP-C-0054 may become effective on one day’s notice. We will apply the following conditions which have been imposed in similar exemption proceedings.

If the Commission permits the contract to become effective on one day’s notice, this fact neither shall be construed to mean that this is a Commission approved contract for purposes of 49 U.S.C. 10713(e) nor shall it serve to deprive the Commission of jurisdiction to institute a proceeding on its own initiative or on complaint, to review this contract and to disapprove it.

Subject to compliance with these conditions, under 49 U.S.C. 10505(a) we find that the 30-day notice requirement in this instance is not necessary to carry out the transportation policy of 49 U.S.C. 10101(a) and is not needed to protect shippers from abuse of market power. Further, we will consider revoking this exemption under 49 U.S.C. 10505(d) if protests are filed within 15 days of publication in the Federal Register.

This action will not significantly affect either the quality of the human environment or conservation of energy resources. (49 U.S.C. 10505)

DATED: July 1, 1982.

By the Commission, Division 1, Commissioners Sterrett, Simmons, and Gradison. Commissioner Gradison did not participate.

Agatha L. Mergenovich, Secretary.

[FR Doc. 82-18684 Filed 7-6-82; 8:45 am]

BILLING CODE 7035-01-M

Union Pacific Railroad Co. and Oregon Short Line Railroad Co.; Exemption; Abandonment and Discontinuance in Lincoln County, WY

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts the Oregon Short Line Railroad Company of 0.04 mile of track at Elkolf, Lincoln County, WY, between Milepost 3.01 and Milepost 3.35, and the discontinuance of service by the Union Pacific Railroad Company over such line subject to the standard labor protection.

DATES: This exemption will be effective on August 9, 1982. Petitions to stay the effectiveness of the decision must be
filed by July 19, 1982, and petitions for reconsideration of the decision must be filed by July 29, 1982.

ADDRESS: Send pleadings to:
(1) Section of Finance, Room 5449,
Interstate Commerce Commission,
Washington, DC 20423.
(2) Petitioners' representative: Joseph D.
Anthofler, 1416 Dodge Street, Omaha,
Ne 68179.
Pleadings should refer to Finance Docket No. 29951.

FOR FURTHER INFORMATION CONTACT:
Louis E. Gitomer, (202) 275-7245.

SUPPLEMENTARY INFORMATION:
Additional information is contained in the Commission's decision. To purchase a copy of the full decision contact: TS Infosystems, Inc., Room 2227, 12th and Constitution Ave., NW., Washington, DC 20423, (202) 289-4357—DC metropolitan area, (301) 424-5403—Toll-free for outside the DC area.

Decided: June 28, 1982.

By the Commission, Chairman Taylor, Vice Chairman Gilliam, Commissioners Cresham, Sterret, Andre, and Simmons.
Agatha L. Mergenovich, Secretary.

Housing Guaranty Program; Investment Opportunity

The Agency for International Development (A.I.D.) has authorized guaranties of loans to a number of developing countries (Borrowers) as part of A.I.D.'s overall development assistance program. The proceeds of these loans will be used to finance shelter projects for low income families residing in the countries of the Borrowers. The following address of Borrower and loan amount indicate two projects that will soon be ready to receive financing and for which the Borrower plans to request competitive proposal from U.S. lenders or investment bankers:

Central American Bank for Economic Integration
Project: 596-HC-004(B) and 596-HC-005—$20,000,000-$25,000,000

Banco Centroamericano de Integracion Economica, Apartado 772,
Tegucigalpa, Honduras, Attention: Victor Diaz, Cable: BANCADIE,
Telex: 1103 HT.

Additional projects will be advertised from time to time as they become ready for borrowing.

The Borrower plans to request competitive bids in the latter part of July 1982, for a loan of from $20,000,000 to $25,000,000. The Borrower will contact interested investors with details as to the terms of the competitive bidding. Investors who are interested in bidding on the loan should contact the Borrower and provide a telex number at which the Borrower may send them details about the bidding. Selection of investment bankers and/or lenders and the terms of the loan are initially subject to the individual discretion of the Borrowers and thereafter subject to approval by A.I.D. The lenders and A.I.D. shall enter into a Contract of Guaranty, covering each of the loans. Disbursements under the loan will be subject to certain conditions required of the Borrowers by A.I.D. as set forth in implementation agreements between A.I.D. and the Borrowers.

The full repayment of the loans will be guaranteed by A.I.D. The A.I.D. guaranty will be backed by the full faith and credit of the United States of America and will be issued pursuant to authority in section 222 of the Foreign Assistance Act of 1961, as amended (the "Act").

Lenders eligible to receive an A.I.D. guaranty are those specified in Section 238(c) of the Act. They are: (a) U.S. citizens; (2) domestic U.S. corporations, partnerships, or associations substantially beneficially owned by U.S. citizens; (3) foreign corporations whose share capital is at least 95 percent owned by U.S. citizens; and, (4) foreign partnerships or associations wholly owned by U.S. citizens.

To be eligible for an A.I.D. guaranty, the loans must be repayable in full no later than the thirtieth anniversary of the disbursement of the principal amount thereof and the interest rates may be no higher than the maximum rate established from time to time by A.I.D.

Information as to the eligibility of investors and other aspects of the A.I.D. housing guaranty program can be obtained from: Director, Office of Housing and Urban Development, Agency for International Development, Room 625, SA/12, Washington, D.C. 20523, Telephone: (202) 632-9637.

Dated: June 30, 1982.

Fredrik A. Hansen,
Deputy Director, Office of Housing and Urban Development.

DEPARTMENT OF JUSTICE

Consent Decree Amendment Pursuant to Clean Air Act

In accordance with Departmental policy, 28 CFR 50.7, 38 FR 19029, notice is hereby given that on June 24, 1982 a proposed consent decree amendment in United States v. National Steel Corporation, Civil Action No. 79-73214, was lodged with the United States District Court for the Eastern District of Michigan, Southern Division. The proposed decree amendment makes substantial modifications to the existing Clean Air Act consent decree covering sources at National's Great Lakes Steel Division.

The Department of Justice will receive for a period of thirty (30) days from the
DEPARTMENT OF LABOR

Employment and Training Administration

Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period June 21, 1982–June 20, 1983.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued each of the group eligibility requirements of section 222 of the Act 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,

(2) that sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. Increased imports did not contribute importantly to workers separations at the firm.

TA-W-12,829; Gulf Oil Corp., Gulf Oil Co.—U.S. Div., Toledo, OH
Aggregate U.S. imports of refined petroleum products did not increase as required for certification.

TA-W-12,831; Marshell Mills, Inc., New York, NY
Aggregate U.S. imports of finished fabric did not increase as required for certification.

TA-W-12,796; Kaiser Steel Corp., Structural Fabrication Plant, Fontana, CA

TA-W-12,352; Queen Casuals, Inc., Philadelphia, PA

TA-W-12,352A; Queen Casuals, Inc., Punxsutawney, PA

TA-W-12,352B; Queen Casuals, Inc., Atco, NJ

In the following cases the investigation revealed that criterion (3) has not been met for the reasons specified.

TA-W-12,823; Teledyne-Stillman Manufacturing, Lakewood, NJ

TA-W-12,827; Cheboygan Manufacturing Co., Cheboygan, MI

TA-W-12,715; Door-Man Manufacturing Co., Royal Oak, MI

TA-W-12,716; Hipwell Industries, Inc., Fraser, MI

TA-W-12,729; Aquarius Dyeing & Finishing, Inc., Trenton, NJ

TA-W-12,352; Cheboygan, MI

TA-W-12,791; Ashland Oil, Inc., Findlay, OH
Aggregate U.S. Imports of refined petroleum products did not increase as required for certification.

TA-W-12,812; Aquarius Dyeing & Finishing, Inc., St. Johnsville, NY
Aggregate U.S. imports of finished fabric did not increase as required for certification.

TA-W-12,594; Feurer Leather Corp., Johnstown, NY

The investigation revealed that criterion (2) has not been met. Salas or production, or both, of the firm or subdivision have not decreased absolutely during the period under investigation.

TA-W-12,598; Karg Brothers, Johnstown, NY

The investigation revealed that criterion (2) has not been met. Sales or production, or both, of the firm or subdivision have not decreased absolutely during the period under investigation.
Unemployment Insurance Program Letters Interpreting Section 3304(a)(15) of the Federal Unemployment Tax Act

In the case of Lawrence Cabais, et al. v. Roscoe Egger, Commissioner of Internal Revenue, et al., the United States Court of Appeals for the District of Columbia Circuit entered a judgment on June 15, 1980, on the publication in the Federal Register of the Department of Labor Unemployment Insurance Program Letters at issue in the case, in compliance with the Freedom of Information Act. The Unemployment Insurance Program Letters, Numbers 24-80, 70-81 and Change 1 to 7-81, are published below in accordance with the Court's order.

Dated: July 1, 1982.

Albert Angrisani,
Assistant Secretary of Labor.

U.S. Department of Labor,
Employment and Training Administration,
Washington, D.C.

Classification: UI
Correspondence Symbol: TURL
Date: March 17, 1980
Expiration Date: February 28, 1981

Directive: Unemployment Insurance Program Letter No. 24-80
To: All State Employment Security Agencies
From: Office of the Deputy Assistant Secretary, Roberts T. Jones, Administrator, Office of Management Assistance

Subject: Pension Deduction Provisions, FUTA, Section 3304(a)(15)

1. Purpose. To inform State Employment Security Agencies (SESAs) of the requirements of the pension deduction provision of Section 3304(a)(15) of the Federal Unemployment Tax Act (FUTA), that the Federal law provision that will become effective for weeks of unemployment beginning after March 31, 1980; and el 31, 1980.

2. Reference. UIPL 10-77 and 37-79: Draft Language and Commentary to Implement the Federal Unemployment Tax Act (FUTA) requiring States, for weeks of unemployment beginning after September 30, 1979, to reduce an individual's weekly benefit amount by the weekly amount of a governmental or other pension, retirement or retired pay, annuity, or any other similar periodic payment which is based on the previous work of such individual. * * *

The effective date of this provision was extended by P.L. 95-19 to March 31, 1980. Although Congress is currently considering bills that would amend this provision of Federal law, as the SESAs were informed by the Regional Administrators following our telegram to them on January 14, 1980, there is no assurance that final Congressional action will occur before the current provision in Section 3304(a)(15) takes effect.

As we indicated in that telegram, both the Senate Finance Committee and the House Ways and Means Committee have reported out pension deduction provisions (H.R. 4012 and H.R. 5507, respectively) which differ only in effective dates. Under both bills, the present FUTA provision would be retained with provisions to: (a) require States to apply the provision to payments made under a plan maintained or contributed to by a base-period chargeable employer (although States would be permitted to apply the deduction to payments made by any employer); and (b) permit States to reduce benefits on less than a dollar-for-dollar basis to take into account the contributions made by the worker to the plan. States where payments are made. The Senate version would be effective for weeks of unemployment beginning after January 1, 1980; the House version for weeks of unemployment beginning after January 1, 1982.

We recommended in the telegram the following provisions to provide for maximum flexibility consistent with the proposals now under consideration in Congress:

"The amount of benefits payable to an individual for any week which begins after the effective date of the applicable provision in the Federal Unemployment Tax Act and which begins in a period with respect to which such individual is receiving a governmental or other pension, retirement or retired pay, annuity, or any other similar periodic payment which is based on the previous work of such individual shall be reduced (but not below zero) by an amount equal to the amount of such pension, retirement or retired pay, annuity, or other payment, which is reasonably attributable to such week; provided that, if the provisions of the Federal Unemployment Tax Act permit, the executive director may prescribe in regulations which are consistent with the Federal Unemployment Tax Act that—(a) the requirements of this paragraph shall only apply in the case of a pension, retirement or retired pay, annuity, or other similar periodic payment under a plan maintained (or contributed to) by a base-period chargeable employer (as determined under this Act), and/or that (b) the amount of any such reduction shall be determined taking into account contributions made by the individual for the pension, retirement or retired pay, annuity or other similar periodic payment."

4. Discussion. Many questions have been received as to the scope of the language now
in the Federal law—specifically, what kinds of payments are required to be deducted, how are lump-sum retirement payments handled, how does retroactive payment of pensions affect benefits already received, and how is the pension deduction applied when only one of several employers provided a pension?

First, because the Federal language specifies that the reduction must occur for "pensions"* * "based on the previous work of such individual"*, the reduction applies only to pensions or annuities collected by the person who actually earned them. It does not apply to, for example, a survivor's or widow's pension that is payable to a survivor or widow but not based on the previous work of that individual. No exhaustive list of the kinds of payments that are deductible is available; however, based on the broad language of the provision, we believe that the following must be deductible: primary social security old-age and disability retirement benefits, including those based on self-employment; State and local government pensions of all types; Federal Civil Service pensions, including disability pensions; private for-profit employer pensions; military retirement and disability retirement pensions; and Railroad Retirement annuities. Also included are benefits derived from IRA and Keogh plans on the basis that these benefits are the result of the individual's previous work, and, while they may be participated in by both employer and employee, are generally payable only because the individual, while employed, was not covered by any other pension plan but, instead, established his or her own pension plan with money set aside and exempt from tax for that purpose. Military service-connected disability compensation payable under 38 U.S.C. Chapter 11 is not deductible because it is based on disability rather than on the previous work of the individual, and bears no direct relationship to the level of prior remuneration or the length of the past service. Other types of disability compensation, such as temporary disability insurance and worker's compensation (including workers' compensation plans), which are not payable as a retirement or pension payment, also are not required by Section 310(a)(15) to be deducted from unemployment compensation.

Second, as to lump-sum retirement payments, the States have the option as to whether to treat them as "similar periodic payments" which are deductible under their laws, and if they treat them as such periodic payments they have the further option of providing in their laws whether the payments shall apply only to the week in which they were paid, or to the week following the last week worked prior to retirement, or whether they shall be allocated to the weeks or months or other applicable periods following the last week worked prior to retirement. Severance pay and separation payments are not required to be treated as lump-sum retirement payments, or as any other form of retirement, pension, or annuity required by Section 3304(a)(15) to be deducted from unemployment compensation.

Third, retroactive payment of pensions for weeks in which the individual has already received unemployment compensation may be treated as causing overpayments under the provisions of the State law applicable to benefit overpayments, as appropriate under the State law. The reason for this is that, under the Federal law provision, the deduction is required to apply only to weeks in which the individual is receiving the pension. Therefore, unemployment compensation payments made for any week for which pension payments are retroactively made may be recovered by the State agency, subject to waiver of recovery if applicable under the State law, or the State agency may choose not to recover benefits that were paid for weeks with respect to which the claimant receives a retroactive payment of social security of other retirement benefits.

Fourth, unless the Federal law is amended as described earlier, States will be expected to deduct from the weekly benefit amount the full amount of any pension received from any employer in the claimant's work history. Should the Federal law be amended, the full amount of pension received must be deducted from the weekly benefit amount but the deduction may be limited to pensions maintained or contributed by the base-period or chargeable employer. In a survey of current practice in the States with pension deduction provisions, it was found that one State prorates the amount of the pension to be deducted in cases where a claimant has more than one base-period employer but not all of those employers have contributed to the pension being received by the claimant. Under the provisions of Section 3304(a)(15), FUTA, this practice is no longer acceptable. It was found that most States make a dollar-for-dollar reduction by the amount of the pension payment received regardless of the proportion of base-period wages paid by the pension-providing employer. In any event, States must deduct, dollar-for-dollar, the amount of any pension payment received without regard to the proportion of base-period wages that may have been paid by the employer who contributed to or maintained the pension.

Absent amendment to Section 3304(a)(15), FUTA, employee contributions to the pension plan, whether OASIT, Civil Service, or private, cannot be taken into account in determining the amount of the reduction. The total weekly prorated amount of the pension must be deducted from the weekly benefit amount otherwise payable. Should the Federal law be amended as indicated in the telegram referred to above, States will be free to take into account, in determining the amount of the deduction, the employee's contribution to the retirement plan. In such cases the State can provide for not deducting any part of an employee-contributed pension, or it can provide for deduction of a representative percentage of the pension as determined under the State law.

SESA's may want to accumulate information on pension requirements in their data base in preparation for implementing this provision.

5. Action Required. State administrators are requested to: (a) Insure that the State law conforms to the requirements. and (b) construe their laws to provide for deduction of at least those types of payments discussed above.

6. Inquiries. Questions should be addressed to the appropriate Regional Office.

U.S. Department of Labor,
Employment and Training Administration,
Washington, D.C.

Classification: UI
Correspondence Symbol: TURL
Date: November 7, 1980
Expiration Date: October 31, 1981

To: All State Employment Security Agencies
From: Office of the Deputy Assistant Secretary, Roberts T. Jones, Administrator, Office of Management Assistance

Subject: Amendments Made to the Federal Unemployment Tax Act by P.L. 96-39


2. References. Sections 414, 415 and 416 of P.L. 96-39; Section 3304(a)(15), FUTA; Section 202, EUCA; 5 U.S.C., 8521(a)(1); and UIPL 24-80.

3. Background. These amendments modify the pension deduction provision in section 3304(a)(15). P.L. 96-364 specifies circumstances in which extended benefits are not payable on interstate claims, and increase the period of service necessary for former members of the Armed Forces to establish entitlement to unemployment compensation under Title 5 of the U.S.C.

4. Amendment to Section 3304(a)(15), FUTA, the Pension Deduction Provision. Section 414 of P.L. 96-364 amended section 3304(a)(15), FUTA, to require deduction of pension payments only in specified circumstances, and to allow States to consider an individual's contributions to the pension payment in determining the amount to be deducted. As revised, the pension deduction standard now provides as follows:

"the amount of compensation payable to an individual for any week which begins after March 31, 1980, and which begins in a period with respect to which such individual is receiving a governmental or other pension, retirement or retired pay, annuity, or any other similar periodic payment which is based on the previous work of such individual shall be reduced (but not below zero) by an amount equal to the amount of such pension, retirement or retired pay, annuity or other payment, which is reasonably attributable to such week [; except that—"

"(A) the requirements of this paragraph shall apply to any pension, retirement or retired pay, annuity, or other similar periodic payment only if—"

"(i) such pension, retirement or retired pay, annuity, or similar payment is under a plan maintained (or contributed to) by a base-period employer or chargeable employer (as determined under applicable law), and"

"(ii) in the case of such a payment not made under Social Security Act or the
Railroad Retirement Act of 1974 (or the corresponding provisions of prior law), services performed for such employer by the individual after the beginning of the base period (or remuneration for such services) affect eligibility for, or increase the amount of, such pension, retirement or retired pay, annuity, or other similar periodic payment."

The amendments made by P.L. 96-364 to Section 3304(a)(15) became effective on September 26, 1980. Section 414(b) of P.L. 96-364 provides that the new pension deduction standard is applicable for certification of the States for 1981 and subsequent years. Therefore, States have the option to implement the new Federal deduction standard as of September 26, 1980. However, full conformity and compliance with the requirements of section 3304(a)(15) of FUTA, as amended, is required for certification of State laws for the 12-month period beginning on November 1, 1980, and ending October 31, 1981. The requirements of section 3304(a)(15) prior to amendment by P.L. 96-364 remain effective through September 25, 1980. However, we do not recommend that these amendments be made retroactive except as is necessary where the State will have no pension deduction provision as of November 1, 1980, in which case the law should be made effective retroactively as of that date.

State laws which now provide for the deduction of pension payments in the circumstances prescribed by the Federal law prior to these amendments are not required to take further action in order to satisfy the requirements in the new amendments. However, we strongly recommend that States proceed now to take advantage of the less stringent condition under which pensions must be deducted from unemployment benefits pursuant to the Federal law requirement.

Section 3304(a)(15), FUTA as amended by P.L. 96-364, reflects only the minimum conditions under which deduction must be required by State law for certification under FUTA. Although a State may broaden the scope of its deduction of pension payments beyond the conditions in which deduction is required under the Federal law, it may not adopt less stringent conditions which fall short of the Federal requirement.

The requirement of the pension deduction standard in section 3304(a)(15), FUTA, as modified by the above cited amendments, is now applicable in less restrictive circumstances as noted above. The deduction is not only limited by the conditions contained in clauses (i) and (ii), but also gives States the option of limiting the deduction in unemployment benefits by taking into account an employee’s contribution to the pension fund. As will be explained below, the limitations specified by these new clauses mean that the reduction in unemployment compensation by the amounts of pension payments received by an individual will be required under Federal law only if the pension is under a plan maintained or contributed to by a base period or chargeable employer and then, only if the services performed for such employer affect eligibility for, or increase the amount of, the retirement payment. However, an exception in clause (ii), eliminating application of its provisions to payments made under the Social Security Act or the Railroad Retirement Act of 1974, those particular provisions are inapplicable in any case in which the individual’s base period employer contributed to or maintained the pension plan under such Acts.

The limitation specifying that the deduction of a pension payment is required only if the pension is derived under a plan that is a base period employer or chargeable employer contributed to or maintained is set forth in clause (i). Whether or not the employer is a chargeable employer or base period employer is to be determined under the provisions of the State law. The employer need not be both a base period employer and also chargeable with any benefits payable under the State law. If it is either a base period or a chargeable employer that contributes to or maintains the plan, the pension received from the plan must be deducted.

Furthermore, the plan must be the same as that under which the individual has established his right to the pension payments. For example, if an individual at company A retires and collects a pension from A under a particular plan maintained by that employer, but then goes to work for company B who has an entirely different plan, and is subsequently laid off, the pension payment from company A would not be deductible (assuming that A is no longer a base period employer). Conversely, if an individual retires from company C to collect Social Security and then goes to work for company D where the individual is also covered under the Social Security Act, and thereafter the individual is terminated, the Social Security pension would then be deductible since company D (base period employer) contributed to the same plan.

Clause (ii) also requires in addition that the “services performed for such employer by the individual after the beginning of the base period (or remuneration for such services)” must affect “eligibility for, or increase the amount of, such pension.” This means that if the services performed for the base period or chargeable employer did not affect either eligibility for or the amount of the pension received from the plan maintained or contributed to by a base period or chargeable employer, then the deduction is not required. The phrase “eligible for” pertains to the individual’s capability of satisfying the conditions necessary to qualify for the pension. Thus, if the individual qualifies for a pension on the basis of the services performed for the base period or chargeable employer, or if the amount of the pension payment is increased by reason of such services, the pension payment would then be deductible.

The provisions of clause (ii) allowing States to disregard pension payments if the base period employment did not affect eligibility for or increase the amount of the pension, is not applicable, however, to Social Security and Railroad Retirement pensions received by an individual. Clause (ii) states specifically that the conditions contained therein are applicable only “in the case of such a payment not made under the Social Security Act or the Railroad Retirement Act of 1974 (or the corresponding provisions of prior law).” Consequently, only the provisions in clause (i) apply to Social Security and Railroad Retirement payments, which means that those payments are deductible whenever the individual’s base period employer or the chargeable employer contributed to the plans provided under those Acts. It is not necessary that any contribution made on behalf of an individual under those plans or any services performed for such employers affect eligibility for or increase the amount of the individual’s pension.

Finally, under new section 3304(a)(15)(B), a State “may provide for limitations on the amount of any such reduction to take into account contributions made by the individual for the pension for the purpose of the option which is to allow the individual’s share for the contributions to the pension fund in determining the amount of pension to be deducted.”

Determinations and review decisions on pension deduction issues should include specific findings on each of the elements involved. The kinds of findings will depend upon the provision adopted by the State. For example, when a Social Security pension is involved, there should be a finding on whether the individual is a primary beneficiary, because only primary insurance benefits are required by the Federal requirement to be deducted. If the provision is limited to pensions maintained or contributed to by a base period employer, the findings should specifically indicate whether both meet the deduction requirements. It is also required that determinations and appeal decisions particularly include the method by which a monthly pension is pro-rated to a weekly amount.

A number of States that amended their laws to meet the requirements of section 3304(a)(15) prior to its amendment by P.L. 96-364, also included provisos to render those provisions inoperative if they were not required to be included in the State law as a condition for full tax credit against the tax.
imposed by the FUTA. Those provisions were included in anticipation of the possible deletion of the Federal pension deduction standard. Since no deletion occurred, a question has arisen as to the impact of the Federal law changes on these provisions. Whether or not those changes will require the States to invoke those provisions is, of course, a matter to be decided by State officials. However, since the prior provisions of section 3304(a)(15) are more restrictive than the revised provisions, a State law which contains the elements of the prior provision would nevertheless continue to be consistent with section 3304(a)(15) as amended. Therefore, it is strongly recommended that States take action or refrain from taking action under such provisions only if it is assured that the State law will meet the requirements of section 3304(a)(15), as amended by Pub. L. 96-364. The States are urged not to take action which would have the effect of leaving the State without any pension deduction provision because that would immediately place the State in the position of having its law inconsistent with the requirements in section 3304(a)(15). In this case, the States will claim from taking any action until the State legislature has had the opportunity to amend the law to assure consistency with the Federal requirement and thereby avoid any period in which the State does not meet those requirements.

5. Amendment to Section 202 of the Federal-State Extended Unemployment Compensation Act of 1970. Section 416 of Pub. L. 96-364 amended section 202 of the Federal-State Extended Unemployment Compensation Act of 1970 by adding a new subsection (c) which prohibits payment of extended benefits pursuant to an interstate claim if the claim was filed in an Agent State where an extended benefit period was not in effect. However, the first 2 weeks of extended benefits otherwise payable under such a claim must still be paid to an individual since the prohibition applies only to weeks beyond that period.

New subsection (c) of section 202 reads as follows:

"(c)(1) Except as provided in paragraph (2), payment of extended compensation shall not be made to any individual for any week if—

(A) extended compensation would (but for this subsection) have been payable for such week pursuant to an interstate claim filed in any State under the interstate benefit plan, and

(B) an extended benefit period is not in effect for such week in such State.

"(2) Paragraph (1) shall not apply with respect to the first 2 weeks for which extended compensation is payable (determined without regard to this subsection) pursuant to an interstate claim filed under the interstate benefit payment plan to the individual from the extended compensation account established for the benefit year.

"(3) Section 3304(a)(9)(A) of the Internal Revenue Code of 1986 shall not apply to any weekly benefit to which paragraph (1) or (2) applies.

This is a new Federal requirement that State laws must include in order to satisfy the provisions of section 3304(a)(11), FUTA, requiring payment of extended compensation as provided by the Federal-State Extended Unemployment Compensation Act of 1970. To meet this requirement, a State law must, as specified by section 416(b), include provisions implementing new subsection (c) of section 202 of the Federal-State Extended Benefit Payment Act which begins on and after June 1, 1981, unless the State legislature does not meet in a regular session which begins during 1981 and before April 1, 1981. In that event, the State must implement the requirement for extended benefit payment beginning on or after June 1, 1982. However, since the amendment is otherwise effective for weeks of unemployment beginning after October 1, 1980, a State has the option to implement the requirement with the week beginning October 5, 1980.

Under the provisions of new subsection (c), when an individual files an interstate claim for extended compensation under the interstate benefit payment plan such compensation shall be paid for the first 2 compensable weeks but may not be paid for any additional week unless an extended benefit period is in effect in the state for such weeks. If a claimant thereafter moves to another agent State and files an interstate claim under the interstate benefit program, he or she may receive extended compensation only if an extended benefit period is in effect for the week compensation is claimed. If such a period is not in effect, the liable State would be prohibited from paying extended compensation under that claim since the individual will have previously received "the first 2 weeks for which extended compensation is payable" pursuant to an interstate claim filed in a State with an "off" trigger. Since the restriction in new subsection (c) is only applicable to interstate claims filed under the interstate benefit payment plan, it does not apply so as to deny extended compensation to an individual who files a claim classified as either a visiting, transient, or courtesy claim.

When Canada is the agent State, the denial of extended benefits applies to the same extent as for any other claim filed from an Agent State that is not an Extended Benefit Period. Canada is not a party to the Federal-State Extended Unemployment Compensation Act.

The provision in new section 202(c)(3) rendering the requirements in section 3304(a)(10)(A), FUTA, inapplicable to any denial required by these amendments, was included to avoid the conflict that would otherwise have occurred in the Federal law upon enactment of new subsection (c). Paragraph (3) has no other effect.

Procedural instructions for implementing this new requirement and amendments to the current Extended Benefit regulations to reflect these changes will be issued at a later date.

6. Amendment Relating to length of Service Needed to Qualify for UCX Benefits. Section 415 of P.L. 96-364 also amended Title 5 of the United States Code to increase the length of service in the Armed Forces that is required for former members to establish eligibility for unemployment compensation. Under the provisions of subparagraph (A) of section 8521(a)(1) of Title 5, U.S.C., as amended, a service member must now have 365 days or more of active service in order to be eligible for unemployment compensation instead of the 90-day period formerly required by that section. The amendment applies with respect to any new claims filed for unemployment compensation on or after October 1, 1980. Instructions for implementing this change are being provided in a separate document.

The attachment contains draft language which can be used by States to implement the new pension deduction standard and the amendment providing for the cessation of extended benefits in the prescribed circumstances discussed earlier.

7. UIPL No. 24-80. This letter supplements UIPL No. 24-80 dealing with the Federal pension deduction standard prior to amendment by P.L. 96-364, except that in those cases the two letters are inconsistent, this letter supersedes UIPL No. 24-80.

8. Action Required. SESAs are requested to:

a. Take necessary action to assure by change in the State law that pension payments received by claimants are deductible under the State law as required by section 3304(a)(15), FUTA, as amended, and that extended compensation is denied in the circumstances required by new subsection (c) of section 202 of the Federal-State Extended Unemployment Compensation Act of 1970 as amended; and

b. Inform the regional offices of the necessity for action or no action invoking provisions included in existing pension deduction provisions which, when invoked, invalidate such provisions, and indicate what other action will be taken to assure that the State law continues to be applied consistent with the requirements of section 3304(a)(15), FUTA, if those provisions are involved.

9. Inquiries. Inquiries should be directed to your regional office.

Draft Language To Implement Section 3304(a)(15), FUTA, As Amended by P.L. 96–364—Federal Pension Deduction Standard

The following draft provision provides for reduction of pensions as required by the amendments to section 3304(a)(15) and includes two options for adjusting the pension to take into account contributions made by the individuals.

"For any week with respect to which an individual is receiving a pension (which shall include a governmental or other pension, retirement or retired pay, annuity, or any other similar periodic payment) under a plan maintained or contributed to by a base period or chargeable employer (as determined under applicable law), the weekly benefit amount payable to such individual for such week shall be reduced (but not below zero),

(a) by the pro-rated weekly amount of the pension after deduction of that portion of the pension that is directly attributable to the percentage of the contributions made to the plan by such individual; or

(Alternative to subsection (a))

(b) by one-half the pro-rated weekly amount of the pension if at least half but less than 100 percent of the contributions to the plan were provided by such individual; or
(b) by the entire pro-rated weekly amount of the pension if subsection (a) or subsection (c) does not apply; or

c) by no part of the pension if the entire contributions to the plan were provided by such individual, or by the individual and an employer (or any other person or organization) who is not a base period or chargeable employer (as determined under applicable law).

(d) No reduction shall be made under this section by reason of the receipt of a pension if the services performed by the individual during the base period (or any remuneration received for such services) for such employer did not affect the individual's eligibility for, or increase the amount of, such pension, retirement or retired pay, annuity, or similar payment. The conditions specified by this subsection shall not apply to pensions paid under the Social Security Act or the Railroad Retirement Act of 1974 (or the corresponding provision of prior law). Payments made under such Acts shall be treated solely in the manner specified by subsection (a), (b) and (c) of this section.

The provisions of the alternative to subsection (a) are designed to facilitate administration of this option by providing a practical means of adjusting the deduction to take into account the individual's contribution to the pension fund without extension calculations.

Draft Language To Implement New Section 202(c) of the Federal-State Extended Unemployment Compensation Act of 1970 as Amended by P.L. 96-364—Cession of Extended Benefit Period Under an Interstate Claim in a State When No Extended Benefit Period is in Effect

Following the enactment of P.L. 91-373, which established the permanent Federal-State extended benefits program, we issued the Draft Legislation to Implement the Employment Security Amendments of 1970—H.R. 14705. Each State received a copy of that document for use in implementing P.L. 91-373. A section was included on pages 119-123 setting forth recommended language to implement that extended benefit program. The following draft language is intended to be incorporated into the framework of that section and should be inserted as new subsection (g).

"(g)(1) Cession of extended benefits when paid under an interstate claim in a State where extended benefit period is not in effect. Except as provided in paragraph (2), an individual shall not be eligible for extended benefits for any week if:

(A) extended benefits are payable for such week pursuant to an interstate claim filed in any State under the interstate benefit payment plan, and

(B) no extended benefit period is in effect for such week in such State.

(2) Paragraph (1) shall not apply with respect to the first 2 weeks for which extended benefits are payable (determined without regard to this subsection) pursuant to an interstate claim filed under the interstate benefit payment plan to the individual from

U.S. Department of Labor,
Manpower Administration, Washington, D.C.
Classification: UIS
Correspondence Symbol: TURL
Date: June 9, 1981
Expiration Date: May 31, 1982.

Directive: Unemployment Insurance Program
Leiter No. 7-81 Change 1
To: All State Employment Security Agencies
From: T. James Walker, Administrator.

Administration and Regulation
Subject: Interpretation of Provisions in Section 3304(a)(15)(B), FUTA, Permitting State laws to Take into Account Employee Contributions to Pension Plans Under Pension Reduction Requirement

1. Purpose. To inform SBSAs of the interpretation of subparagraph (B) of section 3304(a)(15) of the Federal Unemployment Tax Act giving States the option of limiting by law the amount to be deducted from an individual's weekly benefit entitlement by an amount determined based on the previous work of the individual, by taking into account the individual's contributions for the pension.


3. Background. UIPL 24-80, dated November 7, 1980, contained an explanation of the amendments to section 3304(a)(15) made by section 414 of Pub. L. 90-364. With reference to subparagraph (B), relating to the option to take into account account contributions to pension plans, it was stated on page 5 of UIPL 7-81 that a State may eliminate from the pension amount to be deducted from a benefit amount payment "any part of the pension payment equivalent to the employee's share of the contributions to the pension fund" or "a representative percentage of the pension," as examples of acceptable types of limitations on pension reduction. In UIPL 7-81 it was further stated that subparagraph (B) gave States "broad latitude" in exercising the option; however, it also contained an expression of the view that any limitation adopted by a State "should be consistent with the basic purpose of the option which is to allow elimination of the individual's contributions to the pension fund in determining the amount of pension to be deducted." In UIPL 24-80, a similar view had been expressed earlier with respect to two bills in Congress late in 1979 and early in 1980 to amend the pension reduction requirement in language identical to subparagraph (B). The view was expressed on page 5 of UIPL 24-80 that State laws "can provide for deduction of a representative percentage of the pension as determined under the State law. [Emphasis added]. A more recent decision on the meaning of subparagraph (B) necessitates changes on page 5 of UIPL 7-81, and superseded the sentence on page 5 of UIPL 24-80 from which the above quote is taken.

Subparagraph (B) is an optional exception to the general rule which requires the deduction of pensions from unemployment benefits dollar for dollar, and is, therefore, to be narrowly construed to implement its purpose. Interpretation of its language is reflected in its legislative history, to reduce the pension offset amount by an amount "consistent with" or "related to" contributions toward the pension made by the worker. The "flexibility" given to the States, mentioned in the legislative history, refers to the amendments to section 3304(a)(15) which limited the deduction requirement (1) to pension payments made under a plan maintained or contributed to by a base period or chargeable employer, in contrast to pension payments based upon the previous work of the individual in his work history; and (2) to pension payments where eligibility for the pension or the amount of the pension is affected by work performed after the beginning of the base period (e.g., social security and railroad retirement pensions); and which further gave to the States the option to take into account by their laws contributions made by individuals for their pensions.

Reduction of the pension offset amount is "consistent with" the worker's contributions by the alternative to subparagraph (B) of section 3304(a)(15) which the views expressed by Congressman Brodhead, one of the conferees on the bill, a State limit "the offset to one-half the amount of the social security pension received by an individual who qualifies for unemployment benefits." Congressional Record, page H 9180, September 19, 1980. A similar statement was made and was given example by Congressman Corman, Chairman of the Subcommittee on Public Assistance and Unemployment Compensation of the House Ways and Means Committee, which had jurisdiction of the bill, with respect to a provision identical to subparagraph (B) in H.R. 5507, Congressional Record page H 623, February 6, 1980. A similar example was given by Senator Bradley, one of two co-sponsors of the amendment in H.R. 3904. Congressional Record, page S 12901, September 18, 1980. States would be permitted by the option to reduce the offset amount by "that part of a pension which reflects a return of employee contributions." Senate Report No. 72, page 3, December 10, 1979. States would be permitted to apply the reduction "in a manner which provides a reasonable adjustment" to take into account an employee's contributions to the pension plan. Ibid, page 12.

4. Interpretation of Subparagraph (B). It is clear from the legislative history that it was the intent of Congress to allow States to take into account employee contributions for a pension in an amount up to the proportion by which the employee contributed to the pension plan from which the payments are received. Subparagraph (B) is construed, in accordance with its language and related legislative history, as permitting a State to provide in its law for limiting the pension deduction otherwise required under subparagraph (A) of section 3304(a)(15) by reducing the offset amount by an amount that is the ratio of the employee's contributions to total contributions to the plan or system by both the employee and his or her employer(s).

From the statutory language and the examples given in the legislative history, it is clear that the amount of the pension that may be disregarded may be no greater than such ratio of employee's contributions.

In the case of pension plans or systems where the employee makes all of the contributions to the principal forming the
basis of the pension, none of the period would be deductible. This is so because if a base period or chargeable employer had not made any determinations as to the principal of the pension for the employee, the amount received as a pension would not fall within the scope of subparagraph (A)(i) of section 3304(a)(15), and the provisions of subparagraph (B) would not be reached.

5. Determination of Proportion of Employee Contributions. It will be necessary in any State law provision that is consistent with subparagraph (B) to provide for reasonably based determinations of the proportion of employee contributions to a pension plan or system, so that the amount of any pension to be disregarded for benefit reduction purposes will not exceed the ratio of the employee’s contributions to the total contributions to the principal of the plan or system by the employee and his or her employer(s). Because of the different types of pension plans and systems that exist, and the specific data that may be readily available to SESAs for making determinations of the ratios of employee contributions, it is recommended that the State laws confer broad authority for making reasonably based determinations.

Depending upon the type of plan or system and specific data available, the following rules apply:

a. General rule, where proportion of employee contributions to total contributions is known.
   (1) Add values of total employee and employer contributions to find amount of total contributions.
   (2) Divide amount of total employee contributions by total of all contributions to find proportion of contributions paid by employee.
   (3) Multiply the ratio representing employee contributions by the amount of the employee’s weekly pension to find amount of pension attributable to employee contributions.

Example: x, over his working life, contributed $2,500 to his employer’s (ABC’s) defined contribution pension plan. ABC also contributed $7,500 to the plan on x’s behalf. When x retires, he will receive $100 a week as a pension benefit. The portion of this pension attributable to x’s contributions is calculated as follows:

Total amount contributed on x’s behalf: $10,000 ($2,500 + $7,500).

Ratio of contributions attributable to x: $2,500/$10,000. 25%

Weekly pension amount attributable to x: $25 x 26 weeks

b. Rule where proportions of both employee and employer contributions are known.

Where the ratio of employee and employer contributions have been fixed at specified proportions in the plan or system over a substantial period of time preceding the employee’s retirement, such ratio can be adopted without further determination for the purposes of a subparagraph (B) type of provision. For example, under the system for primary social security and Federal civil service retirement, the employee contributions are set at 50 percent, and it is not necessary any further.

c. Rule where amount of employer contributions is not known.

In situations where it is not possible to determine exactly the aggregate amount of employer contributions paid to a pension plan on an individual’s behalf (as often is the case where the employee participates in a defined benefit plan), any method of computation that reasonably reflects or approximates the proportion of contributions made by the employee will be acceptable.

6. Scope of Letter. The interpretations contained in this letter apply solely to section 3304(a)(15), FUTA, and have no application to any other Federal statute.

7. Revised Page 5. This letter transmits a change to page 5 of UIPL 7-81.

8. Action Required. SESAs are requested to substitute the attached page 5 for the one contained in UIPL 7-81, November 7, 1980, and retain this Change 1 to UIPL 7-81. The substituted text is in the first paragraph. There are, in addition, revisions in the second paragraph for consistency with the changes in the first paragraph.

The interpretations contained in this letter are effective for the current benefit period beginning November 1, 1980. SESAs should apply these interpretations as soon as possible after receipt of this letter.

9. Inquiries. Questions should be directed to the appropriate Regional Office.

Attachment (Revised page 5, UIPL 7-81) reduction to take into account contributions made by the individual for the pension.* * * * Subparagraph (B) is construed, in accordance with its language and related legislative history, as permitting a State to provide in its law for limiting the pension deduction otherwise required under subparagraph (A) by reducing the offset amount by an amount that takes "into account contributions made by the individual for the pension." From the examples given in the legislative history, it is clear that the offset amount reflecting the individual’s contributions is intended to be in a maximum amount which is no greater than the proportion that is the ratio of the individual’s contributions made to the pension plan, from which pension payments are received, to total contributions made to the pension plan by the individual and employer(s) of the individual in the pension plan or system. Determinations and review decisions on pension deduction issues should include specific findings on each of the elements involved. The kinds of findings will depend upon the provision adopted by the State. For example, when a social security pension is involved, there should be a finding on whether the individual is a primary beneficiary, because only primary insurance benefits are required by the Federal requirement to be deducted. If the provision is limited to pensions maintained or contributed to by a base period employer, the findings should specifically indicate whether a base period employer is involved. When an individual is receiving more than one pension, it should be specifically found whether only one or all meet the deduction requirements. It is also required that determinations and appeal decisions particular to the method by which a monthly pension is prorated to a weekly amount, and the basis for the determination of the employee’s contribution and the amount taken into account in arriving at the amount deducted.

A number of States that amended their laws to meet the requirements of section 3304(a)(15) prior to its amendment by P.L. 96–364, also included provisions to render those provisions inapplicable if they were not required to be included in the State law as a condition for full tax credit against the tax imposed by the FUTA. Those provisions were included in anticipation of the possible deletion of the Federal pension deduction standard. Since no deletion occurred, a question has arisen as to the impact of the federal law changes on these provisions. Whether or not those changes will require the States to invoke those provisions is, of course, a matter to be decided by State officials. However, since the prior provisions of section 3304(a)(15) are more restrictive than the revised provisions, a State law which contains the elements of the prior provision would nevertheless continue to be consistent with section 3304(a)(15) as amended.

Therefore, it is strongly recommended that States take action or refrain from taking action under such provisions only if it is assured that

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total of partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than July 19, 1982.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than July 19, 1982.
The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 601 D Street, N.W., Washington, D.C. 20213.

Signed at Washington, D.C. this 30th day of June 1982.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

### APPENDIX

<table>
<thead>
<tr>
<th>Petitioner: Union/workers or former workers of</th>
<th>Location</th>
<th>Date received</th>
<th>Date of petition</th>
<th>Petition No.</th>
<th>Articles produced</th>
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<td>Airco Carbon (ILGWU)</td>
<td>St. Mary's, PA</td>
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<td>6/21/82</td>
<td>TA-W-13,598</td>
<td>Graphite electrodes, carbon and graphite products.</td>
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<td>Irvingness Mining Co. (workers)</td>
<td>Cave-in-Rock, Ill.</td>
<td>8/24/82</td>
<td>6/21/82</td>
<td>TA-W-13,606</td>
<td>Flourpam, barts, zinc and lead concentrates.</td>
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<tr>
<td>S &amp; S Products Inc. (workers)</td>
<td>Wyandotte, Mi.</td>
<td>5/13/82</td>
<td>4/28/82</td>
<td>TA-W-13,610</td>
<td>Wheel covers, trim rings, wheel caps and heater plugs.</td>
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Labor Surplus Area Classifications Under Executive Orders 12073 and 10582; Additions to Annual List of Labor Surplus Areas

**AGENCY:** Employment and Training Administration, Labor.

**ACTION:** Notice.

**DATE:** The additions to the annual list are effective on July 1, 1982.

**SUMMARY:** The purpose of this notice is to announce additions to the annual list of labor surplus areas.

**FOR FURTHER INFORMATION CONTACT:** James W. Higgins, Assistant Chief, Division of Labor Market Information, 601 D Street, N.W., Attention: TEEPA, Washington, D.C. 20213, Telephone: 202-376-6860.

**SUPPLEMENTARY INFORMATION:** Executive Order 12073 requires executive agencies to emphasize procurement set-asides in labor surplus areas. The Secretary of Labor is responsible under that Order for classifying and designating areas as labor surplus areas.

Under Executive Order 10582, executive agencies may reject bids or offers of foreign materials in favor of the lowest offer by a domestic supplier, provided that the domestic supplier undertakes to produce substantially all of the materials in areas of substantial unemployment as defined by the Secretary of Labor. The preference given to domestic suppliers under Executive Order 10582 has been modified by Executive Order 12290. Federal

Procurement Regulations Temporary Regulation 57 (41 CFR Chapter 1, Appendix), issued by the General Services Administration on January 15, 1981 (46 FR 3519), implements Executive Order 12290. Executive agencies should refer to Temporary Regulation 57 in procurements involving foreign businesses or products in order to assess its impact on the particular procurements.

The Department of Labor's regulations implementing Executive Orders 12073 and 10582 are set forth at 20 CFR Part 654, Subparts A and B. Subpart A requires the Assistant Secretary of Labor to classify jurisdictions as labor surplus areas pursuant to the criteria specified in the regulations and to publish annually a list of labor surplus areas. Pursuant to those regulations the Assistant Secretary of Labor published the annual list of labor surplus areas on June 4, 1982 (47 FR 24474).

Subpart B of Part 654 states that an area of substantial unemployment for purposes of Executive Order 10582 is any area classified as a labor surplus area under Subpart A. Thus, labor surplus areas under Executive Order 12073 are also areas of substantial unemployment under Executive Order 10582.

The areas described below have been classified by the Assistant Secretary of Labor as labor surplus areas pursuant to 20 CFR 654.5(c) and are added to the annual list of labor surplus areas, effective July 1, 1982. The following additions to the annual list of labor surplus areas are published for the use of all Federal agencies in directing procurement activities and locating new plants or facilities.


Albert Angressan,
Assistant Secretary of Labor.

**ADDITIONS TO THE ANNUAL LIST OF LABOR SURPLUS AREAS, JULY 1, 1982**

<table>
<thead>
<tr>
<th>Location</th>
<th>Petition No.</th>
<th>Civil jurisdiction included</th>
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<tbody>
<tr>
<td>Alabama: Huntsville City</td>
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<td>Huntsville City in Madison County, Alabama.</td>
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<tr>
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ADDITIONS TO THE ANNUAL LIST OF LABOR
SURPLUS AREAS, JULY 1, 1982—Continued

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Massachusetts:

Ashburnham Town     | Ashburnham Town in Bristol County, Ashburnham Town |
Adams Town          | Adams Town in Berkshire County, Adams Town |
Athol Town          | Athol Town in Worcester County, Athol Town |
Ayer Town           | Ayer Town in Middlesex County, Ayer Town |
Berkeley Town       | Berkeley Town in Bristol County, Berkeley Town |
Bourne Town         | Bourne Town in Barnstable County, Bourne Town |
Boynton Town        | Boynton Town in Worcester County, Boynton Town |
Brimfield Town      | Brimfield Town in Hampden County, Brimfield Town |
Brookfield City     | Brookfield City in Plymouth County, Brookfield City |
Dighton Town        | Dighton Town in Bristol County, Dighton Town |
Douglas Town        | Douglas Town in Worcester County, Douglas Town |
Falmouth Town       | Falmouth Town in Barnstable County, Falmouth Town |
Gardiner Town       | Gardiner Town in Worcester County, Gardiner Town |
Gloucester City     | Gloucester City in Essex County, Gloucester City |
Haverhill City      | Haverhill City in Essex County, Haverhill City |
Kingston Town       | Kingston Town in Plymouth County, Kingston Town |
Lynn City           | Lynn City in Essex County, Lynn City |
Montana Town        | Montanas Town in Essex County, Montanas Town |
Middlefield Town    | Middlefield Town in Hampden County, Middlefield Town |
Montague Town       | Montague Town in Franklin County, Montague Town |
New Bedford City    | New Bedford City in Bristol County, New Bedford City |
Newburyport City    | Newburyport City in Essex County, Newburyport City |
Plainfield Town     | Plainfield Town in Hampden County, Plainfield Town |
Shirley Town        | Shirley Town in Middlesex County, Shirley Town |
Taunton City        | Taunton City in Bristol County, Taunton City |
Winston Town        | Winston Town in Bristol County, Winston Town |

ADDITIONS TO THE ANNUAL LIST OF LABOR
SURPLUS AREAS, JULY 1, 1982—Continued

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Office of Pension and Welfare Benefit Programs

[Prohibited Transaction Exemption 82-115]

Exemption From the Prohibitions for Certain Transactions Involving Pension Equity Growth Trust Located in Salt Lake City, Utah (Exemption Application No. D-2525)

AGENCY: Department of Labor, Pension and Welfare Benefit Programs Office.

ACTION: Grant of Individual Exemption.

SUMMARY: This exemption will permit certain prohibited transactions between Pension Equity Growth Trust (the Trust) and certain parties in interests with respect to the Trust subject to specified conditions. The proposed exemption would also exempt certain prohibited transactions between the Trust and employees benefit plans purchasing or selling an interest in the Trust.

FOR FURTHER INFORMATION CONTACT: Mr. David Stander of the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216, (202) 523-8861. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On April 6, 1982, notice was published in the Federal Register (47 FR 14811) of the pendency before the Department of Labor (the Department) of a proposal to grant an exemption from the restrictions of certain sections of the Employee Retirement Income Security Act of 1974 (the Act) and from certain sanctions resulting from the application of section 4975 of the Internal Revenue Code of 1954 (the Code), for the above-described transactions. The notice set forth a summary of facts and representations contained in the applications for exemption and referred interested persons to the application for a complete statement of the facts and representations. The application has been available for public inspection at the Department in Washington, D.C. The notice also invited interested persons to submit comments on the requested exemption to the Department. In addition the notice stated that any interested person might submit a written request that a public hearing be held relating to this exemption. No public comments and no requests for a hearing were received by the Department.

Since the publication of the notice of pendency, the applicant has proposed certain amendments to the written agreements establishing the Trust. The Department has reviewed these proposed changes, such as the elimination from the list of permissible investments, the investment in precious gems of investment grade and precious metals, and has determined that, because they related solely to the internal operations of the Trust, the proposed change do not materially affect the transactions which are the subject of this exemption.

Additionally, the applicant has represented that the Trust has received a favorable determination letter from the Internal Revenue Service qualifying the Trust under section 401(a) of the Code. Accordingly, the Department herein amends the effective date stated in the notice of proposed exemption.

The effective date of this exemption is Federal Register of the grant of this individual exemption.

The notice of pendency was issued and the exemption is being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

General Information

The attention of interested persons is directed to the following:

1. The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)[2] of the Code does not relieve a fiduciary or other party in interest or disqualified person with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code. These provisions include any prohibited
transactions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his or her duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does the fact the transaction is the subject of an exemption affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption does not extend to transactions prohibited under section 406(b)(2) of the Act and section 4975(c)(1)(F) of the Code.

(3) This exemption is supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption or transitional rule is not dispositive of whether the transaction is, in fact, a prohibited transaction.

Exemption

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75-1 (40 FR 16471, April 28, 1975), and based upon the entire record, the Department makes the following determinations:

(a) The exemption is administratively feasible;

(b) It is in the interests of the Trust and of its participants and beneficiaries; and

(c) It is protective of the rights of the participants and beneficiaries of the Trust.

Accordingly, the following exemption is hereby granted under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 and Revenue Procedure 75-28.

Section I. Exemption for Certain Transactions Involving Pension Equity Growth Trust

a) Effective the date of publication in the Federal Register of the grant of this exemption, (hereinafter, the Effective Date) the restrictions of sections 406(a), 406(b)(2) and 407(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (D) of the Code, shall not apply to the transactions described below if the applicable conditions set forth in Section IV are met.

1) Transactions Between Parties In Interest and the Trust: General.

Any transaction between the Trust and a party-in-interest with respect to a plan that has an interest in the Trust (Participating Plan), provided that such party-in-interest is not Pension Equity Advisers, Incorporated (the Investment Manager), the trustees of the Trust (the Trustees), or any other trust or fund maintained by the Investment Manager, Trustees or affiliates thereof), or any acquisition or holding by the Trust of employer securities or employer real property, if, at the time of the transaction, acquisition or holding, the interest of the plan, together with the interests of any other plans maintained by the same employer or employee organization in the Trust, does not exceed 5 percent of the total assets in the Trust.

2) Special Transactions Not Meeting the Criteria of Section I(a)(1) Between Employers of Employees Covered by a Multiple Employer Plan and the Trust.

Any transaction between an employer (or an affiliate of an employer) of employees covered by a multiple employer plan that is a Participating Plan, and the Trust or any acquisition or holding by the Trust of employer securities or employer real property, if, at the time of the transaction, acquisition or holding—

(a) The interest of the multiple employer plan in the Trust does not exceed 10 percent of the total assets in the Trust, and the employer is not a "substantial employer" with respect to the plan (within the meaning of section 4001(a)(2) of the Act), or

(b) The interest of the multiple employer plan in the Trust exceeds 10 percent of the total assets in the Trust, but the employer is not a "substantial employer" with respect to the plan and would not be a "substantial employer" within the meaning of section 4001(a)(2) of the Act if "5 percent" were substituted for "10 percent" in that definition.

3) Acquisition, Sales or Holdings of Employer Securities and Employer Real Property.

A. Except as provided in subsection (B) of this section (3), any acquisition, sale or holding of employer securities and any acquisition, sale or holding of employer real property by the Trust which does not meet the requirements of paragraphs (a)(1) and (a)(2), if no commission is paid to the Investment Manager or to the employer, or any affiliate of the Investment Manager or the employer in connection with the acquisition or sale of employer securities or the acquisition, sale or lease of employer real property; and

(i) In the case of employer real property—

(aa) Each parcel of employer real property and the improvements thereon held by the Trust are suitable (or adaptable without excessive cost) for use by different tenants, and

(bb) The property of the Trust that is leased or held for lease to others, in the aggregate, is dispersed geographically.

(ii) In the case of employer securities—

(aa) The Investment Manager is not an affiliate of the issuer of the security, and

(bb) If the security is an obligation of the issuer, either:

1. The Trust owns the obligation at the time the plan acquires an interest in the Trust, and interests in the Trust are offered and redeemed in accordance with valuation procedures of the Trust applied on a uniform or consistent basis, or

2. Immediately after acquisition of the obligation: (1) not more than 25 percent of the aggregate amount of obligations issued in the issue and outstanding at the time of acquisition is held by the Trust, and interests in the Trust are offered and redeemed in accordance with valuation procedures of the Trust applied on a uniform or consistent basis, or

B. In the case of a Participating Plan that is not an eligible individual account plan (as defined in section 407(d)(3) of the Act), the exemption provided in subsection (A) of this paragraph (3) shall be available only if, immediately after the acquisition of the securities or real property, the aggregate fair market value of employer securities and employer real property with respect to which the Investment Manager or its affiliates has investment discretion does not exceed 10 percent of the fair market value of all the assets of the Participating Plan with respect to which the Investment Manager has such investment discretion.

C. For purposes of the exemption contained in subsection (A) of this paragraph (3), the term "employer securities" shall include securities issued by, and the term "employer real property"...
property” shall include real property leased to, a person who is a party-in-interest with respect to a Participating Plan by reason of a relationship to the employer described in section 3(14) (E), (G), (H) or (I) of the Act.
(b) Effective upon the Effective Date, the restrictions of section 406(a)(1) (A), (B), (C), and (D) and section 406(b) (1) and (2) of the Act and the sanctions resulting from the application of section 4975 of the Code by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the transactions described below, if the conditions of Section IV are met.

(1) Transactions with Persons Who Are Parties in Interest by Virtue of Being Certain Service Providers or Certain Affiliates of Service Providers. Any transaction between the Trust and a person who is a party-in-interest with respect to a plan that has an interest in the Trust, if—
   (a) The person is a party-in-interest (including a fiduciary) solely by reason of providing services to the plan, or solely by reason of a relationship to a service provider described in section 3(14) (F), (G), (H) or (I), of the Act, or both, and the person neither exercised nor has any discretion or authority, control, responsibility or influence with respect to the investment of plan assets in, or held by, the Trust, and
   (b) The person is not an affiliate of the Investment Manager.

(2) Certain Leases and Goods. The furnishing of goods to the Trust by a party-in-interest with respect to a Participating Plan or the leasing of real property owned by the Trust to such party-in-interest and the incidental furnishing of goods to such party-in-interest by the Trust, if—
   (a) In the case of goods, they are furnished to or by the Trust in connection with real property owned by the Trust;
   (b) The party-in-interest is not the Investment Manager or any affiliate of the Investment Manager, or any other collective investment fund maintained by the Investment Manager; and
   (c) The amount involved in the furnishing of goods or leasing of real property in any calendar year (including the amount under any other lease or arrangement for the furnishing of goods in connection with the real property investments of the Trust with the same party-in-interest, or any affiliate thereof) does not exceed the greater of $25,000 or 0.5 percent of the fair market value of the assets of the Trust on the most recent valuation date of the Trust prior to the transaction.

(3) Management of Real Property. Any services provided to the Trust by the Investment Manager or by an affiliate of the Investment Manager in connection with the management of the real property owned by the Trust, if the compensation paid to the Investment Manager or its affiliate does not exceed the cost of the services to the Investment Manager or its affiliate.

(4) Transactions Involving Places of Public Accommodation. The furnishing of services, facilities and any goods incidental to such services and facilities by a place of public accommodation owned by the Trust, to a party-in-interest with respect to a plan that has an interest in the Trust, if the services, facilities and incidental goods are furnished on a comparable basis to the general public.

Section II. Excess Holdings Exemption for Employee Benefit Plans
(a) Effective upon the Effective Date, the restrictions of sections 406(a), 406(b)(2) and 407(a) of the Act and the sanctions imposed by section 4975 of the Code by reason of section 4975(c)(1) (A) through (D) of the Code shall not apply to any acquisition or holding of qualifying employer securities or qualifying employer real property (other than through the Trust) by a plan that has an interest in the Trust, if (1) the acquisition or holding constitutes a prohibited transaction solely by reason of being aggregated with employer securities or employer real property held by the Trust; (2) the requirements of either paragraph (a)(1) or paragraph (a)(2) of Section I of this exemption are met; and (3) the applicable conditions set forth in Section IV of this exemption are met.

Section III. Exemption for Certain Transactions Involving the Purchase and Sale of Units of Beneficial Interest in the Trust
Effective upon the Effective Date, the restrictions of section 406(a)(1)(A) and 406(a)(1)(D) of the Act and section 4975(c)(1)(A) and section 4975(c)(1)(D) of the Code shall not apply to the purchase and sale of units of beneficial interest in the Trust if no more than reasonable compensation is paid therefore and each purchase and sale is authorized in writing by a fiduciary of the employee benefit plan who is independent of the Investment Manager and any of its affiliates, if the applicable conditions of Section IV are met.

Section IV. General Conditions
(a) At the time the transaction is entered into, and at the time of any subsequent renewal thereof that requires the consent of the Investment Manager or any affiliate, the terms of the transaction are not less favorable to the Trust than the terms generally available in arm’s-length transactions between unrelated parties.
(b) The Investment Manager or any affiliate maintains for a period of six years from the date of the transaction the records necessary to enable the persons described in paragraph (c) of this Section IV to determine whether the conditions of this exemption have been met, except that (1) a prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of the Investment Manager or any affiliate, the records are lost or destroyed prior to the end of the six-year period, and (2) no party interest shall be subject to the civil penalty that may be assessed under section 502(i) of the Act, or to the taxes imposed by section 4975(a) and (b) of the Code, if the records are not maintained, or are not available for examination as required by paragraph (c) below.
(c)(1) Except as provided in section 2 of this paragraph (c) and notwithstanding any provisions of subsections [a][2] and [b] of section 504 of the Act, the records referred to in paragraph (b) of this Section IV are unconditionally available at their customary location for examination during normal business hours by:
   (A) any duly authorized employee or representative of the Department or the Internal Revenue Service,
   (B) any fiduciary of a Participating Plan who has authority to acquire or dispose of the interests in the Trust of the Participating Plan or any duly authorized employee or representative of such fiduciary,
   (C) any contributing employer to any Participating Plan or any duly authorized employee or representative of such employer, and
   (D) any participant or beneficiary of any Participating Plan, or any duly authorized employee or representative of such participant or beneficiary.
(2) None of the persons described in subparagraphs (B) through (D) of this paragraph (c) shall be authorized to examine trade secrets of the Investment Manager or any affiliate, or commercial or financial information which is privileged or confidential.

Section V. Definitions and General Rules
For the purpose of this exemption,
(a) An “affiliate” of a person includes—
   (1) any persons directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person.
(2) any officer, director, employee, relative of, or partner in any such person, and
(3) any corporation or partnership of which such person is an officer, director, partner or employee.

(b) The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(c) The term "relative" means a "relative" as that term is defined in section 3(15) of the Act (or as that term is defined in section 4975(e)(6) of the Code), or a brother a sister, or a spouse of a brother, or sister.

(d) The term "multiple employer plan" means an employee benefit plan that satisfies at least the requirements of section 3(37)(A)(i), (ii) and (v) of the Act and section 414(f)(1)(A), (B) and (E) of the Code.

(e) The time as of which any transaction, acquisition or holding occurs is the date upon which the transaction is entered into, the acquisition is made or the holding commences. In addition, in the case of a transaction that is continuing, the transaction shall be deemed to occur until it is terminated. If any transaction is entered into, or an acquisition is made, on or after the date of granting of this exemption, or a renewal that requires the consent of the Trust occurs on or after the date of granting of this exemption, and the requirements of this exemption are satisfied at the time the transaction is entered into or renewed, respectively, or at the time the acquisition is made, the requirements will continue to be satisfied thereafter with respect to the transaction or acquisition and the exemption shall apply thereafter to the continued holding of the property so acquired. Notwithstanding the foregoing, this exemption shall cease to apply to a holding exempt by virtue of Section I(a)(1) as such time as the interest of the Participating Plan exceeds the percentage interest limitation of Section I(a)(1), unless no portion of such excess results from the increase in the assets allocated to the Trust by the Participating Plan. For this purpose, assets allocated do not include the reinvestment of Trust earnings. Nothing in this paragraph (e) shall be construed as exempting a transaction entered into by the Trust which becomes a transaction described in section 4975 of the Code or section 406 of the Act or section 4975 of the Code while the transaction is continuing, unless the conditions of the exemption were met either at the time the transaction was entered into or at the time the transaction would have become prohibited but for this exemption.

(f) Each Participating Plan shall be considered to own the same proportionate undivided interest in each asset of the Trust as its proportionate interest in the total assets of the Trust as calculated on the most recent preceding valuation date of the Trust.

The proposed exemption, if granted, will be subject to the express conditions that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transactions to be consummated pursuant to the exemption.

Signed at Washington, D.C., this 25th day of June 1982.
Alan D. Lebowitz,
Assistant Administrator for Fiduciary Standards.

Wage and Hour Division
Certificates Authorizing the Employment of Learners at Special Minimum Wages

Notice is hereby given that pursuant to section 14 of the Fair Labor Standards Act (52 Stat. 1062, as amended; U.S.C. 214), Reorganization Plan No. 8 of 1950 (3 CFR 1949-53 Comp., p. 1004), and Administrative Order No. 1-76 FR 108949), the firms listed in this notice have been issued special certificates authorizing the employment of learners at hourly wage rates lower than the minimum wage rates otherwise applicable under section 6 of the Act. For each certificate, the effective and expiration dates, number or proportion of learners and the principal product manufactured by the establishment are as indicated. Conditions on occupations, wage rates, and learning periods which are provided in certificates issued under the supplemental industry regulations cited in the captions below are as established in those regulations.

The following certificates were issued under the apparel industry learner regulations (29 CFR 522.1 to 522.9, as amended and 29 CFR 522.20 to 522.25, as amended). Each of the following normal turnover certificates authorize 10 learners.


Each learner certificate has been issued upon the representations of the employer which, among other things were that employment of learners at special minimum rates is necessary in order to prevent curtailment of opportunities for employment, and that experienced workers for the learner occupations are not available.

The certificate may be annulled or withdrawn as indicated therein, in the manner provided in 29 CFR Part 528. Any person aggrieved by the issuance of any of these certificates may seek a review or reconsideration thereof on or before July 28, 1982.

Signed at Washington, D.C. this 30th day of June 1982.
Arthur H. Korn,
Authorized Representative.

FR Doc. 82-18482 Filed 7-4-82; 0:45 am
BILLING CODE 4510-27-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES
Design Arts Advisory Panel (Fellowships); Notice of Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), as amended, notice is hereby given that a meeting of the Design Arts Advisory Panel (Fellowships) to the National Council on the Arts will be held on August 2-3, 1982, from 9:00 a.m.-5:30 p.m. and on August 4, from 9:00 a.m.-5:00 p.m. in room 1428 of the Columbia Plaza Office Complex, 2401 E Street, NW., Washington, D.C. 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the Federal Register of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and (9)(b) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National
Duquesne Light Co. et al.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 53 to Facility Operating License No. DPR-66 issued to Duquesne Light Company, Ohio Edison Company, and Pennsylvania Power Company (the licensees), which revised Technical Specifications for operation of the Beaver Valley Power Station, Unit No. 1 (the facility) located in Beaver County, Pennsylvania. The amendment is effective as of the date of issuance.

The amendment revises the reactor coolant system heatup and cooldown curves, and the bases for these curves. 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 application for the amendment provides a detailed description of the changes made and the reasons for the changes. The application also includes a comparison of the new and old curves, and the bases for these curves.

The amendment relates to the inservice testing program for the Beaver Valley Power Plant. The amendment permits the licensee to modify the reactor coolant system heatup and cooldown curves, and the bases for these curves, in a manner that is consistent with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The amendment is effective as of the date of issuance.

The application for the amendment was made in accordance with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The application for the amendment is available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C., and at the B. F. Jones Memorial Library, 663 Franklin Avenue, Aliquippa, Pennsylvania 15001. A copy of the application for amendment may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, 1717 H Street, N.W., Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 30th day of June, 1982.

For the Nuclear Regulatory Commission.

Steven A. Varga, Chief, Operating Reactors Branch No. 1, Division of Licensing.

BILLING CODE 7537-01-M
The United States Nuclear Regulatory Commission's regulations in 10 CFR Part 51, notice is hereby given that a Draft Environmental Statement (DES) prepared by the Commission's Office of Nuclear Material Safety and Safeguards, related to the proposed operation of the Teton Solution Mining Project located at the Leuenberger site in Converse County, Wyoming is available for inspection by the public in the Commission's Public Document Room (PDR) at 1717 H Street, NW., Washington, D.C. 20555. Based upon successful R&D testing, Teton Exploration Drilling Co., Inc. (the Applicant) has applied under Docket No. 40-8781 for a Source and Byproduct Material License approving commercial-scale uranium solution mining of approximately eighty acres by injecting a carbonate/bicarbonate lixiviant into the orebody. Copies of the DES are being provided to the State Planning Coordinator, Office of the Governor, 2320 Capitol Avenue, Cheyenne, Wyoming 82002 and the Converse County Library, 300 Walnut Street, Douglas, Wyoming 82633. Request for copies of the Draft Environmental Statement (identified as NUREG-0925) should be addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Division of Technical Information and Document Control.

The Applicant's Environmental Report and supplements are also available for public inspection at the above-designated locations. Notice of the availability of the Applicant's Environmental Report was published in the Federal Register on May 4, 1981 (46 FR 25020).

Interested persons may submit written comments on the DES for the Commission's consideration to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Uranium Recovery Licensing Branch. Federal, state and local agencies are being provided with copies of the document. All comments received by the Commission will be made available for public inspection at the Commission's Public Document Room in Washington, D.C. Comments are due by August 23, 1982. Upon consideration of comments submitted with respect to the draft environmental statement, the Commission's staff will prepare a final environmental statement, the availability of which will be published in the Federal Register.

Dated at Silver Spring, Maryland this 30th day of June, 1982.

For the Nuclear Regulatory Commission.
Rose A. Scarano, Chief, Uranium Recovery Licensing Branch, Division of Waste Management.

OFFICE OF PERSONNEL MANAGEMENT

National Eligibility Committee for the Combined Federal Campaign; Meeting

Note.—This document originally appeared in the Federal Register of Thursday, July 8, 1982. It is reprinted in this issue to meet requirements for publication on the Tuesday, Friday schedule assigned to the Office of Personnel Management.

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the Director of the Office of Personnel Management announces the following meeting:

NAME: National Eligibility Committee for the Combined Federal Campaign.

DATE AND TIME: July 23, 1982, at 10 a.m.

PLACE: The OPM Auditorium (Room GJ-14, on the Ground Floor), U.S. Office of Personnel Management, 1900 E Street, NW., Washington, D.C.

Type of Meeting
Open

Interested persons may submit written statements with the committee in advance of or at the start of the meeting. Written statements submitted in advance of the meeting may be addressed to the Committee in the care of the Secretary of the committee, whose name and address are set forth in this Notice under the heading, “Contact Person.” Written statements submitted at the start of the meeting may be filed with the Committee at the place of the meeting. Oral comments will not be permitted at the meeting, except with the leave of the Chairman or a majority of the Committee. In the event that leave is given for oral comment, no person will be permitted to make an oral statement at the meeting unless such person (1) has advised the Secretary of the Committee in writing at least 48 hours in advance of the meeting that the person wishes to be heard at the meeting (clearly specifying the matter on which the person wishes to be heard); (2) has submitted a written statement relating to the matter on which such person wishes to be heard; and (3) wishes to be heard on a matter that is contested by or before the Committee. Persons, if any, given leave to make oral comments shall each be confined in their oral comments to five (5) minutes.
SECURITIES AND EXCHANGE COMMISSION  

[Release No. 34-18859; File No. SR-AMEX-82-0]  

Self-Regulatory Organizations; Proposed Rule Change by American Stock Exchange, Inc. Relating to Distribution Criteria for Original Listing of Common Stock and Warrant Issues  

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 17, 1982, the American Stock Exchange filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.  

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change  

The American Stock Exchange is proposing to amend Sections 102 and 105 of the AMEX Company Guide (i) to modify public float and holder requirements of existing distribution criteria for evaluating the listing eligibility of common stock and warrant issues and (ii) to provide for alternative listing criteria based on prior trading volume.  

Specifically, the proposed modification would require: (i) a minimum public distribution of 500,000 shares, exclusive of insider holdings, including at least 150,000 of such shares held in lots of 100 to 1,000 shares, and (ii) a minimum of 1,000 public shareholders, including not less than 800 holders of lots of 100 shares or more among which at least 500 holders must hold lots of 100 to 1,000 shares. The present rule requires a public distribution of 400,000 shares with at least 150,000 shares held in lots of 100 to 500 shares and requires at minimum of 1,200 public stockholders, with not less than 800 holders of lots of 100 shares or more, including at least 500 holders of 100 to 500 shares.  

Under the proposal, where a company cannot provide reasonably accurate data relating to the above distribution criteria, the Amex would still be able to consider listing the company's securities if the company had a minimum of 500,000 shares publicly held and a daily trading volume of approximately 2,000 shares for the six months preceding the application. The Amex, in judging the suitability of a listing under this alternative provision, would also review other factors that might affect auction market trading and would not consider securities that trade infrequently or that lack wide public distribution, even though daily trading volume in the security may amount to 2,000 or more shares.  

II. Self-Regulatory Organization's Statement of the Purpose of and Statutory Basis for, the Proposed Rule Change  

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule changes. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B) and (C) below, of the most significant aspects of such statements.  

A. Self-Regulatory Organization's Statement of the Purpose of and Statutory Basis for the Proposed Rule Change  

(a) Purpose. The purpose for amending the rules is to update the Exchange's present distribution criteria for stock and warrant issues to reflect the changes in trading activity since the guidelines were formulated. The modification includes an increase in the size of the public float for stock issues, expansion of the round-lot category, and a reduction in the number of odd-lot holders by narrowing the gap between the existing specified number of round-lot holders and total holders.  

Alternative criteria based on pre-listing volume are proposed for evaluating applicants about which holder information is difficult to obtain because of significant holdings in "street" or nominee name.  

(b) Basis. The proposed amendments are consistent with Section 6(b) of the Exchange Act and further the objectives of Section 6(b)(5) in that they are designed to protect investors and the public interest and are not designed to regulate matters not related to the purposes of the Act or the administration of the Exchange.  

B. Self-Regulatory Organization's Statement on Burden on Competition  

The Exchange has determined that the proposed rule change will have no impact on competition.
III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within thirty-five days of the date of publication of this notice in the Federal Register 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 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.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, Washington, D.C., 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the rule changes that are filed with the Commission, and all written communications relating to the proposed rule changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. Sec. 552, will be available for inspection and copying in the Commission's Public Reference Room, 1100 L Street, N.W., Washington, D.C. (450 5th Street, N.W., Washington, D.C., after July 23, 1982). 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 in the caption above and should be submitted on or before July 30, 1982.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: June 30, 1982.

George A. Fitzsimmons,
Secretary.
Practice, Internal Revenue Service, until such regulations are amended to reflect this change. Existing provisions in regulations concerning appeals from recommended decisions of the Director of Practice to the Secretary shall remain in full force and effect.

The duties of the Director of Practice performs pursuant to 31 CFR Part 15, Post-Employment Conflict of Interest, remain with the General Counsel. References in that Part to the Director of Practice shall be considered to be references to the General Counsel, or his or her designee, until these regulations are amended.

James I. Owens,
Acting Commissioner.

Office of the Secretary

Series E-1989 Notes; Interest Rate
July 2, 1982.

The Secretary announced on July 1, 1982, that the interest rate on the notes designated Series E-1989, described in Department Circular—Public Debt Series—No. 17–82 dated June 23, 1982, will be 14 1/2 percent. Interest on the notes will be payable at the rate of 14 1/2 percent per annum.

Paul H. Taylor,
Fiscal Assistant Secretary.

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE


On June 28, 1982, the President notified the Chairman of the United States International Trade Commission of his disapproval of the determination of the Commission in Investigation No. 337-TA-99, Certain Molded-In Sandwich Panel Inserts and Methods for their Installation. Following is the text of the President's determination.

William E. Brock,
United States Trade Representative.


The United States International Trade Commission (USITC), following a finding of a violation of Section 337 of the Tariff Act of 1930, as amended, has ordered excluded from entry into the United States imports of molded-in sandwich panel inserts (panel inserts) that were held to infringe U.S. Letters Patent No. 3,182,015, until that patent expires in November of 1983. A cease and desist order was issued to the importer of the panel inserts prohibiting it from contributing to or inducing the infringement of U.S. Letters Patent Nos. 3,392,225 and 3,271,498 which cover processes by which panel inserts are installed. Finally, the USITC issued cease and desist orders to three purchasers of the imported panel inserts directing them not to use imported panel inserts to practice the methods covered by the process patents until the second of those patents expires in July of 1985.

The President is authorized by Section 337(g) to disapprove USITC determinations for domestic or foreign policy reasons. The statute does not authorize partial disapprovals or changes in the remedies. I have notified the USITC today of my decision to disapprove its determination in this case.

The effect of the cease and desist orders directing the three purchasers not to use imported products when practicing a process in the United States that infringes a process patent may not be in compliance with U.S. international obligations. The orders may result in less favorable treatment in requirements affecting purchase and use being accorded imported products than the treatment being accorded domestic products. The three orders do not stop the infringement of the process patents in the U.S. Because of the statutory limits on USITC jurisdiction, those orders can only act as restrictions on the purchase and use of the imported products.

My disapproval of the USITC determination in this case in no way circumscribes the USITC authority to issue cease and desist orders. Cease and desist orders are more flexible remedies than exclusion orders and are appropriate in cases where an importer is the wrongdoer. The discriminatory effect upon imported products of the three orders directed to the users of those products forms the basis of my decision to disapprove in this case.

My decision is based upon narrow grounds and does not mean that the petitioner in this case is left without legal remedies. It can pursue its rights both through the courts and the USITC. Denial of the USITC determination here does not imply there would be a rejection of another remedy which would fully protect the legitimate patent rights of the petitioner without unnecessarily discriminating against imported products.

The exclusion from the U.S. market of products which infringe U.S. patents or the issuance of cease and desist orders preventing the importation, advertising or sale of such infringing products is an entirely appropriate use of Section 337 because of the practical difficulties in achieving workable remedies in our courts. A narrowly drafted cease and desist order such as that issued to the importer in this case also is appropriate. Where, as here, however, adequate remedies are available under U.S. law which do not discriminate between foreign and domestic products in preventing infringement of U.S. process patents, I must defer the American judicial system.

Implementation of Duty Concessions of Certain Television Receiver Components and Printed Circuit Boards

Correction
In FR Doc. 82–17475 appearing on page 28201 in the issue of Tuesday, June 29, 1982, make the following correction:

In the table at the bottom of page 28201, the TSUS item now reading "058.16" should have read "065.16".

BILLING CODE 3105–01–M
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(e)(3).

CONTENTS

1. Commodity Futures Trading Commission
2. Equal Employment Opportunity Commission
3. Federal Deposit Insurance Corporation
4. Nuclear Regulatory Commission
5. Occupational Safety and Health Review Commission

1. COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 3 p.m., July 8, 1982.
PLACE: 2033 K Street, N.W., Washington, D.C., 8th Floor Conference Room.
STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance Briefing.

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254–6314.

AGENCY HOLDING THE MEETING: Commodity Futures Trading Commission.

2. EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

DATE AND TIME: Tuesday, July 13, 1982, 9:30 a.m. (Eastern Time).
PLACE: Commission Conference Room No. 5240 on the fifth floor of the Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20506.
STATUS: Part will be open to the public and part will be closed to the public.

4. FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting
Pursuant to the provisions of the “Government in the Sunshine Act” (5 U.S.C. 552b), notice is hereby given that at 4:45 p.m. on July 2, 1982, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to (1) receive bids for the purchase of certain assets of and the assumption of the liability to pay deposits made in Belle-Bland Bank, Bland, Missouri, which was closed by the Missouri Commissioner of Finance as of the close of business on Friday, July 2, 1982; (2) accept the bid for the transaction submitted by Eagle Bank of Gasconade County, Bland, Missouri, a newly-chartered State bank; (3) approve the application of Eagle Bank of Gasconade County, Bland, Missouri, for Federal deposit insurance and for consent to purchase certain assets of and assume the liability to pay deposits made in Belle-Bland Bank, Bland, Missouri; and (4) provide such financial assistance, pursuant to section 13(e) of the Federal Deposit Insurance Act (12 U.S.C. 1823(e)), as was necessary to effect the purchase and assumption transaction.

In calling the meeting, the Board determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Director C. T. Conover (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days’ notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the “Government in the Sunshine Act” (5 U.S.C. 552b (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: July 6, 1982.
Federal Deposit Insurance Corporation.
Hoyle L. Robinson, Executive Secretary.

BILLING CODE 6714-01-M

5. FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting
Pursuant to the provisions of the “Government in the Sunshine Act” (5 U.S.C. 552b), notice is hereby given that at 7:30 p.m. on Friday, July 2, 1982, the

BILLING CODE 6714-01-M

BILLING CODE 6714-01-M

Federal Register
Vol. 47, No. 132
Friday, July 9, 1982

FR 82-5-FOIA-95, concerning a request for systematic conciliation guidance.

Note.—Any matter not discussed or concluded may be carried over to a later meeting.


3. FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Cancellation of Agency Meetings
Pursuant to the provisions of the “Government in the Sunshine Act” (5 U.S.C. 552b), notice is hereby given that the meetings of the Corporation’s Board of Directors scheduled for 2:00 p.m. (open session) and 2:30 p.m. (closed session) on Tuesday, July 6, 1982, have been cancelled.

No earlier notice of the cancellation of the meetings was practicable.

Dated: July 6, 1982.
Federal Deposit Insurance Corporation.
Hoyle L. Robinson, Executive Secretary.

BILLING CODE 6714-01-M

BILLING CODE 6714-01-M

This Notice Issued July 8, 1982.

BILLING CODE 6714-01-M

BILLING CODE 6714-01-M
Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider a request from the Comptroller of the Currency that the Corporation, pursuant to section 10(b) of the Federal Deposit Insurance Act, assist in an examination of a national bank.

In calling the meeting, the Board determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), in concur with Director C. T. Conover (Comptroller of the Currency), that Corporation business required its consideration of the matter on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matter in a meeting open to public observation; and that the matter could be considered in a closed meeting pursuant to subsections (c)(8) and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8) and (c)(9)(A)(ii)).

The meeting was held in Room 6020 of the Federal Deposit Insurance Corporation Building located at 550 17th Street, NW., Washington, D.C.

Dated: July 6, 1982.
Federal Deposit Insurance Corporation.
Hoyle L. Robinson,
Executive Secretary.

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 9:05 P.M. on Monday, July 5, 1982 the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider the following matters:

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.;

Names of employees authorized to be exempt from disclosure pursuant to provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552c(c)(2) and (c)(6)).

Recommendations regarding the liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 48,000-L—Midtown National Bank, Pueblo, Colorado
Case No. 45,290-SR—the Peoples Bank of the Virgin Islands, Charlotte Amalie, Virgin Islands
Memorandum and Resolution re: The Hamilton National Bank of Chattanooga, Chattanooga, Tennessee

The establishment of the Deposit Insurance National Bank of Oklahoma City, Oklahoma City, Oklahoma, to assume the insured deposits of Penn Square Bank, National Association, Oklahoma City, Oklahoma.

In calling the meeting, the Board determined, on motion of Chairman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), in concur with Director C. T. Conover (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(2), (c)(6), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(6), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Chairman's Office, Room 6023 of the Federal Deposit Insurance Corporation Building located at 550 17th Street, NW., Washington, D.C.

Dated: July 6, 1982.
Federal Deposit Insurance Corporation.
Hoyle L. Robinson,
Executive Secretary.

NUCLEAR REGULATORY COMMISSION

DATE: Week of July 12, 1982.
PLACE: Commissioners' Conference Room, 1717 H Street, N.W., Washington, D.C.
STATUS: Open and Closed.

MATTERS TO BE DISCUSSED: Monday, July 12:

10:00 a.m.: Discussion of Proposed Rulemaking—Accreditation of Qualification Testing Organizations (public meeting)

Tuesday, July 13:

2:00 p.m.: Briefing on Status of the ATWS Rulemaking (public meeting)

Wednesday, July 14:

10:00 a.m.: Discussion of 10 CFR Part 61—"Licensing Requirements for Land Disposal of Radioactive Waste" (public meeting)

2:00 p.m.: Discussion of Safety Goals and Implementation Program (public meeting)
Thursday, July 15:
10:00 a.m.:
   Briefing on Staff Plans for Quality Assurance (public meeting)
2:00 p.m.:
   Briefing by Executive Branch (Closed—Exemption 1)
3:30 p.m.:
   Affirmation/Discussion Session (public meeting)
Affirmation and/or Discussion and Vote:
   a. Partial Vacating of Commission Order of May 22, 1979, on Preservation of Records of TMI-2 Accident
   b. Draft Policy Statement on Treatment of Psychological Stress Contentions in Proceedings Other than TMI-1 Restart
   c. Draft Immediate Effectiveness Order for San Onofre 2 and 3

AUTOMATIC TELEPHONE ANSWERING SERVICE FOR SCHEDULE UPDATE: (202) 634-1498. Those planning to attend a meeting should reverify the status on the day of the meeting.

CONTACT PERSON FOR MORE INFORMATION: Walter Magee (202) 634-1410.

Walter Magee,
Office of the Secretary.
July 2, 1982.

BILLING CODE 7590-01-M
Part II

Department of Health and Human Services

Food and Drug Administration

Human Food Ingredients; Generally Recognized as Safe
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 172, 182, and 184
[Docket No. 77N-0039]

GRAS Status of Ammonium Alginate, Calcium Alginate, Potassium Alginate, and Sodium Alginate; Amendment of Food Additive Regulation for Propylene Glycol Alginate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that ammonium alginate, calcium alginate, potassium alginate, and sodium alginate are generally recognized as safe (GRAS) as direct human food ingredients with limitations. These substances are made from certain brown algae and may be used as emulsifiers, stabilizers, or thickeners or for other purposes in accordance with the limitations in these regulations. Additionally, the agency is amending the food additive regulation for propylene glycol alginate. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective August 9, 1982, objections to amendment of § 172.858 by August 9, 1982.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 27, 1978 (43 FR 3725), FDA published a proposal to affirm that ammonium alginate, calcium alginate, potassium alginate, and sodium alginate are GRAS for use as direct human food ingredients and to amend the food additive regulation for propylene glycol alginate (21 CFR 172.858). The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on alginates, reports of the mutagenic tests for ammonium, potassium, and sodium alginates and propylene glycol alginate, teratogenic tests for propylene glycol alginate, and the report of the Select Committee on GRAS Substances (the Select Committee) have been made available for public review in the Dockets Management Branch (address above). Copies of these documents also are available for public purchase from the National Technical Information Service as announced in the proposal.

In addition to proposing to affirm the GRAS status of ammonium, calcium, potassium, and sodium alginates and to amend the food additive regulation for propylene glycol alginate, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for these substances, other than for the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of the prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of the alginates recognized by issuance of appropriate regulations under Part 181 — Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Parts 184, 186).

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for ammonium alginate, calcium alginate, potassium alginate, sodium alginate, or propylene glycol alginate were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for a use of these substances under conditions different from those set forth in this regulation has been waived.

Nineteen comments were received. Four comments were from alginate producers and their trade association, 14 comments were from food manufacturers and their trade associations, and one comment was from a physician. Most of the comments concerned the proposed maximum levels of alginates in various food products. A summary of the comments and the agency’s responses follow.

1. One comment from a trade association for food manufacturers stated that none of its members had been invited to submit data in the 1971 National Academy of Sciences/National Research Council (NAS/NRC) survey of the food industry (phase II survey). Therefore, according to the comment the proposal did not reflect accurately some current uses and use levels of the various alginates. This association surveyed its members and provided a compilation of use data in its comment. Because the member firms are suppliers of bulk food ingredients, the data represented their best estimates of levels occurring in finished food products. A related comment from an individual food manufacturer also stated that the firm had not been invited to submit data in the phase II survey. This comment also provided use information. Another comment from a food manufacturer noted that data on propylene glycol alginate had not been requested in the phase II survey, but that information on propylene glycol alginate had been requested in the 1977 (phase III) survey to which the commenter had responded. This comment did not include a recapitulation of those data, however.

FDA acknowledges that the phase II survey did not request data on propylene glycol alginate. Because that survey was intended to determine the use of GRAS ingredients, and propylene glycol alginate is not a GRAS ingredient, the only data received on the food additive propylene glycol alginate were those provided voluntarily by several of the firms surveyed. These data were used in developing the proposed amendment to the propylene glycol alginate food additive regulation. The phase III survey, which primarily requested use information on direct food additives, colors, and flavors, does include propylene glycol alginate. FDA has now received the phase III data, and these data have been incorporated into this final rule.

2. Eight comments requested increases in alginate limitations for various food categories without providing supporting information to indicate that these levels were current good manufacturing practice. Two comments requested alterations in the proposed limitations specifically to permit expanded use of the alginates. One comment requested that the limitations for “all other food categories” be raised to 1.0 percent for calcium, potassium, and propylene glycol alginates but only presented information on current uses at levels below those requested. A similar request to raise all foods to 4.0 percent for sodium alginate and to 1.0 percent for ammonium alginate presented no supporting use information. Three other related comments requested higher limitations in order to encompass products currently under development.

FDA emphasizes that the safety evaluation of the alginates has been based upon known current uses and use levels. The agency decision to adopt
these uses and levels as limitations was based on the Select Committee’s and FDA’s view that although current use of the alginites presents no health risks, the safety of significantly increased alginate use cannot be assessed at this time. The agency does not have sufficient safety data to determine whether uses of these substances at significantly increased levels are GRAS. Consequently, the agency advises that it cannot raise use level limitations nor add food use categories and technical effects, unless it is presented with evidence that the levels, technical effects, and food categories represent current good manufacturing practice and are safe.

The agency has revised this final rule to provide for increased levels of use of these substances in certain food categories. FDA has done so based on comments advising the agency that these increases reflect current uses and based on data that have been presented to the agency that these increased levels of use are safe.

Other requests for changes in use levels to include products under development are denied. The GRAS review and this proceeding consider current uses only. Uses under development represent potentially expanded levels of consumption and therefore must be the subjects of GRAS or food additive petitions. The safety of any petitioned new uses will need to be supported by additional toxicological data.

3. Seven comments objected to the proposed limitations for propylene glycol alginate. Three of these comments stated that the proposed maximum level for propylene glycol alginate in sweet sauces (0.4 percent) was below current good manufacturing practice of 0.5 percent. The other comments made a similar assertion about the level proposed for all other food categories (0.1 percent). The requested increases in this level ranged from 0.15 to 0.6 percent. A number of specific food categories were enumerated to support the requests. Among the food categories enumerated were condiments and relishes at 0.6 percent, confections and frostings at 0.5 percent, and jams and jellies at 0.4 percent. In addition, the phase III survey indicated that propylene glycol alginate is used at levels of 1.1 percent in fats and oils, 0.6 percent in gelatins/puddings, and 1.7 percent in seasonings.

FDA has carefully considered the requested modifications in the maximum use levels for propylene glycol alginate. The newly reported levels of use are higher than the levels voluntarily reported in the 1971 NSA/NRC survey. However, the agency concludes that these usage levels, and those reported in the phase III NAS/NRC survey, represent current uses; that adequate safety data have been compiled as part of this GRAS review to support the conclusion that the relatively small additional exposures expected from the increases in the specific food categories indicated are safe; and that § 172.858 should be amended as set forth in this document. The request to raise the level for all other foods to 0.6 percent is denied, however, because those uses above 0.3 percent have been included by the increases in specific food categories. The level for “all other food categories” is increased to 0.3 percent to include many current low levels of propylene glycol alginate use that were reported in these comments. The amended section includes the use of propylene glycol alginate in seasonings at 1.7 percent, fats and oils at 1.1 percent, gelatins/puddings at 0.6 percent, condiments and relishes at 0.6 percent, sweet sauces at 0.5 percent, confections and frostings at 0.5 percent, jams and jellies at 0.4 percent, and for all other food categories at 0.3 percent.

4. Eight comments objected to the proposed limitations for calcium alginate. All stated that those limitations are lower than current good manufacturing practice. The comments specifically requested that the calcium alginate use level for gravies and sauces be raised to 0.4 percent from the proposed level of 0.1 percent, and that use of calcium alginate in a number of other food categories be permitted at levels ranging from 0.01 to 0.6 percent. The specific requested uses were 0.5 percent for jams and jellies, 0.4 percent for confections and frostings, 0.4 percent for alcoholic beverages, 0.6 percent for egg products, 0.5 percent for fats and oils, and 0.5 percent for sweet sauces. A number of other current uses for specific food categories and general food use were requested at levels up to 0.3 percent.

FDA has carefully considered these requested modifications in maximum use levels. The agency concludes that available safety data compiled during this GRAS review are sufficient to support these newly reported, current uses and use levels. Therefore, FDA has amended § 184.1724 to provide for the specific uses of calcium alginate enumerated in the comment and to raise the “all other foods” category to 0.3 percent. The use level for baked goods will be retained at 0.002 percent, however, because of the relatively large consumption of foods in this category.

5. Nine comments requested increases in levels of use for sodium alginate. They requested raising the use levels for baked goods from the proposed 0.33 percent to levels ranging from 0.5 to 1.0 percent and adding pimento ribbon used to stuff olives at levels ranging from 3 to 6 percent. One request asked that sodium alginate be permitted for use in confections and frostings at 0.3 percent.

After careful consideration of these requests and the safety data compiled during this GRAS review, FDA has reviewed § 184.1724 to provide for use of sodium alginate in condiments and relishes at 1 percent (6 percent in pimiento ribbon used to stuff olives) and in confections and frostings at 0.3 percent. Baked goods have also been increased to 1.0 percent but deleted as a separate category listing and included in the “all other foods” category.

6. One comment requested that potassium alginate be permitted in gelatins and puddings at 0.7 percent and in processed fruits and fruit juices at 0.25 percent to cover these current uses of this ingredient. Both of these uses had been included in the proposal under all other food categories at 0.01 percent.

7. After further consideration of the safety data compiled during this GRAS review, FDA has revised proposed § 184.1610 to provide for use of potassium alginate in these specified food categories at the requested levels.

8. Three comments pointed out that although sodium alginate is the substance added to certain food products, the presence of calcium salts in the products causes, intentionally or inadvertently, the formation of calcium alginate. The comments contended that it is therefore the calcium alginate that produces the technical effect, although the comments acknowledged that the extent of conversion of the calcium salt is highly variable, depending upon the food and the amount of calcium available. Based upon this information, two of the comments requested that calcium alginate limitations be set equal to those for sodium alginate.

The agency disagrees with these requests for increased uses of calcium alginate. The proposed use levels for sodium alginate and calcium alginate were those reported in the NAS/NRC Phase II survey of food manufacturers. Because FDA is concerned that a significant increase in alginate consumption may not be GRAS, the proposal restricted the use of the alginites to current use levels. The information provided by the comments indicates that these two alginites are not currently used at identical levels. Furthermore, information provided by
these comments indicates that it is not technologically feasible to use calcium alginate at the levels current for sodium alginate. Therefore, the agency does not agree that the uses and use levels permitted for sodium alginate should also be permitted for calcium alginate.

The agency recognizes that once an ingredient is added to a food, and the food is processed, the chemical identity of the ingredient may change. Therefore, compliance with specific use levels cannot be ensured through detection and quantitation of each added ingredient in the finished food. Instead, FDA interprets "maximum level, as served" as the amount of the ingredient added to food. Therefore, the use limitations must be set on the basis of the added ingredient, sodium alginate, and not the ingredient it may form (calcium alginate).

Because of these considerations, the agency has concluded that this final rule should contain limitations for calcium alginate and sodium alginate based upon current and not identical use levels. Specific use levels identified in the comments as current good manufacturing practice have been incorporated.

8. Two comments stated that other polysaccharides, namely the various gums, have been affirmed as GRAS without specific limitations. These comments questioned whether there was sufficient evidence to single out alginites for specific restrictions.

These comments are in error. FDA's regulations provide specific limitations on the use of all polysaccharide gums that the agency has affirmed as GRAS. In the preambles to the proposed regulations for all these gums, FDA has also clearly stated that it was setting specific limitations on use of these gums that were not to be exceeded (39 FR 20041; July 28, 1973 and 39 FR 34201, 34203, 34205, 34207, and 34209; September 23, 1974). FDA's GRAS regulations provide specific limitations on the use of these gums because of toxicity questions that are similar or identical to the toxicity questions raised for the alginites. Therefore, the requirements that uses of the various alginites not exceed the specific limitations established in this final rule are entirely consistent with past agency actions.

9. A comment noted that the World Health Organization/Food and Agricultural Organization's (WHO/FAO) recommended Acceptable Daily Intake (ADI) limits were 100 to 200 times the intakes that could result from current alginate production. The comment requested that the level for "all other food categories" for all alginates be raised to 1.0 percent.

The general issue of raising use limitations above current use levels has been discussed in comment 2 above. It must be emphasized again that GRAS usage levels, whether they be good manufacturing practice levels or specific limitations, represent current use levels, not judgments of safety based upon "no effect" levels from toxicity studies. Thus, the fact that the recommended WHO/FAO ADI limits are considerably higher than current usage has no relevance to this rulemaking.

Furthermore, the WHO/FAO report on alginites commented on the paucity of toxicity studies. The last evaluation by WHO/FAO was conducted in 1984. The teratology study that displayed maternal toxicity and that was the basis for the Select Committee's recommendations on alginites was published in 1972. Thus, the WHO/FAO was not aware of this study at the time it made its evaluation. FDA has therefore concluded that this final rule should limit alginate use to current good manufacturing practice usage levels and food categories as set forth below.

10. Two comments responded to the FDA request for data on the heavy metals content of alginites. The data submitted indicate that the lead, arsenic, and total heavy metal content of alginites are well within the limits (lead 10 parts per million (ppm), arsenic 3 ppm, total heavy metals 40 ppm) prescribed by the Food Chemicals Codex, 3d Ed. (1981). The maximum level attained by any of the metals of interest was 9.6 ppm for zinc. Lead levels averaged about 1.5 ppm, while selenium averaged 1 ppm or less. Mercury, cadmium, and arsenic all averaged considerably less than 1 ppm. One of the comments indicated that any heavy metal contamination caused by algae harvested from contaminated waters would be removed during normal alginate processing. FDA has independently analyzed samples of alginites from the same product batches analyzed by one of the comments. The levels the agency found were well within levels prescribed by Food Chemicals Codex and similar to those in the comments. There appears to be no need, therefore, to develop additional heavy metal specifications for the safe use of these products at this time.

11. Five comments requested approval of the use of sodium alginate at levels of up to 6.0 percent in cured pimiento ribbon or other restructured food.

There currently is no specific provision for restructured food in the food categories listed in §170.3(n) (21 CFR 170.3(n)). Such restructured food must be described by current food categories. The only restructured food specifically described in the comments and for which use data were supplied was cured pimiento ribbon. This food is apparently used exclusively in the production of stuffed olives, which would be classified in the food category "condiments and relishes." In view of the Select Committee's conclusion that the safety of increased levels above current practice is unknown, the agency cannot consider raising the limitation for the entire category of condiments and relishes to 6.0 percent for this one use.

As noted in comment 5 above, FDA has revised proposed §184.1724 to provide for use of sodium alginate as a texturizer, formulation aid, and stabilizer and thicker in condiments and relishes at the level of 1.0 percent permitted for "all other food categories" and specifically in pimiento ribbon used to stuff olives at levels up to 6.0 percent.

12. One comment noted that, contrary to the proposed regulations, alginites are obtained from brown algae only, and that the calcium salt is prepared from the sodium alginate salt and calcium chloride rather than from alginic acid. The comment also requested that the regulations be amended to permit the alginate salts to be produced from "common reactants" rather than from specifically required substances. The comment suggested that all references to manufacturing methods be deleted.

The comment is correct that brown algae is the source of the alginic acid from which alginites are derived. Accordingly, the final rule states that alginites are prepared from alginic acid that is isolated from brown algae. Furthermore, the agency agrees that common reactants may be used to produce the alginate salts. Therefore, the final regulation for calcium alginate indicates that this substance may be prepared by metathesis from sodium alginate and calcium salts or by neutralization of alginic acid with calcium pH control agents. The final regulations also state that sodium, potassium, and ammonium alginites are prepared from alginic acid by neutralization with appropriate pH control agents.

FDA does not agree that all reference to manufacturing methods should be removed however. The absence of a production method in the regulations might be interpreted as prior agency GRAS approval of products prepared by methods that are as yet undeveloped. The agency wishes to avoid such an interpretation. FDA has addressed this issue before (39 FR 34174, 34195;
13. A request was received to alter the standard statement in regulations for affirmed GRAS substances that refers to a specific edition or revision of the Food Chemicals Codex. The comment suggested that the phrase “currently effective edition” would obviate the necessity of amending regulations when new editions appear. The comment was prompted in part by the fact that a new edition of the Food Chemicals Codex (3d ed.) has recently been prepared and is now available.

A declaration such as that suggested by the comment would constitute prior agency approval of any future specification changes that might be made by NAS/NRC in the Food Chemicals Codex. FDA considered this idea but rejected it because the agency would be effectively waiving its right, and that of the public, to review and comment on new specifications before they become effective. FDA therefore plans to review each new edition or supplement of the Food Chemicals Codex and then issue a proposal in the Federal Register for comment. Although this process will result in some delay in the adoption of new Food Chemicals Codex Specifications, the agency concludes that the proposal and final rulemaking procedure should not be omitted.

14. A comment from a trade association for manufacturers of bulk food products stated that it was unclear to the association’s members whether the proposed alginates limitations should be applied to bulk food products or to finished food products.

FDA advises that all limitations are intended to apply to the finished food as served. Bulk food products that will be incorporated into finished foods will be considered to be intermediate mixes. Such mixes, contributing only a portion of the total weight of the finished food product, may contain incrementally greater percentages of GRAS ingredients. However, the labeling provisions for food substances affirmed as GRAS for direct addition to food (21 CFR 184.1(f)) states in §184.1(f)(3) that directions for the use of ingredients or intermediate mixes shall be adequate to provide a final food product that complies with any limitations prescribed for the ingredient. Thus, the alginates levels in bulk food products or intermediate mixes may be higher than the prescribed limitations, provided that the bulk food is not also sold as a finished food, and that its labeling is sufficiently informative to permit the manufacturers of finished foods to comply with the limitations.

15. One food manufacturer submitted information on the use of sodium alginate and calcium alginate as flavor adjuvants in baked goods and baking mixes. The comment requested that this use be included in the final regulation.

The proposed regulation for sodium alginate contained a provision for its use as a flavor adjuvant in puddings and gelatins and in “all other food categories.” The proposed regulation for calcium alginate did not include this technical effect. The evidence presented in the comment indicates that although it is calcium alginate that principally produces the intended technical effect, sodium alginate is the ingredient actually used in the formulation. By reasoning identical to that given in response to comment 7 above, only the sodium alginate final regulation need contain this technical effect. Because the “baked goods” food category is included in “all other food categories” in the final regulation, no change is necessary to provide for this use of sodium alginate.

16. One comment from a physician expressed concern that the quantities of alginates and other polysaccharide gums being used in food might pose a risk of bodily depletion of certain essential divalent cations, calcium in particular. The comment requested that FDA consider the aggregate use of these substances.

FDA shares this concern. However, even though the comment was on the use of alginates and gums in general, this rule concerns the use of alginates only. Thus, the evaluation of this comment is limited to its bearing on alginate use. Agency scientists trained in nutrition have examined the available literature on this topic. They also have considered the total daily intake of alginates with ion-binding potential as calculated from available consumption data. The agency concludes that current total intake of alginates does not present a hazard with respect to bodily depletion of essential divalent cations. Because specific limitations have been established for the use of alginates, any future increase in alginate use levels would require FDA approval through the GRAS or food additive petition procedures outlined in §170.35 or §171.1 (21 CFR 171.1). The agency will specifically consider the possible hazard presented by ion-binding during the scientific review of any future petitions or proposals for the use of polysaccharides in foods.

17. One comment from a trade association discussed the difficulties associated with the use of food categories as defined in §170.3(n). The comment requested that two food categories proposed for propylene glycol alginate be more fully described in the regulation, corresponding to the description in §170.3(n). The comment further stated that even the food categories in §170.3(n) were unclear and insufficiently descriptive to permit proper categorization of members’ products. The comment also noted that bulk food products (intermediate mixes) might be used in several food categories, thus presenting the manufacturer with a possible compliance problem.

The food category descriptions used in the regulations for substances affirmed as GRAS or regulated as food additives are not intended to be complete repetitions of the food category definitions in §170.3(n). The brief category title used is intended only to provide a quick, general identity of the food category. It is unnecessary to define completely each food category in every food additive or GRAS regulation, because a separate definition section has been included in the general provisions for food additive regulations. Section 170.3(n) is frequently cited in GRAS or food additive regulations to alert the reader to the location of the definitions for the food categories.

FDA recognizes that occasionally there may be difficulty in identifying the correct food category for a food product. The definitions listed in §170.3(n) are an attempt to include all food products while keeping the number of definitions to a workable minimum. As indicated in §170.3(n), food products are included in these categories according to the detailed classification lists contained in Exhibit 33B of the NAS/NRC phase II survey report. A food manufacturer who is having difficulty in categorizing a product should consult these classification lists or request FDA assistance. A copy of the NAS/NRC Comprehensive Exhibits Master may be ordered from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161. The order number is PB 221-949, and the price code is A15. The most recent price quoted for this NTIS code number is $18.00.

When intermediate mixes are used in products from different food categories, it is the responsibility of the producer of the finished food to ensure that the food is in compliance with the pertinent regulations. It is the responsibility of the intermediate mix manufacturer to label the mix to properly guide the users of the mix. The labeling provisions for intermediate mixes, §184.1(f)(3), are more fully discussed in comment 14 above.

No comments were received providing evidence of prior-sanctioned uses...
different from the uses described in the proposal. Therefore, FDA believes the final regulations cover all such uses, and no prior sanction regulation is being promulgated.

The format of the final regulations is different from that in the proposal and in previous GRAS affirmation regulations. The agency has modified the form in which the specific limitations on the use of these ingredients are presented. This change has no substantive effect but is made merely for clarity. The agency has determined under 21 CFR 25.24 (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this rule, and the agency has determined that the rule is not a major rule as defined by that Order.

List of Subjects

21 CFR Part 172
Food additives; Food preservatives; Spices and flavorings.

21 CFR Part 182
Generally recognized as safe (GRAS) food ingredients; Spices and flavorings.

21 CFR Part 184
Direct food ingredients; Food ingredients; Generally recognized as safe (GRAS) food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(a), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(a), 348, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. Part 172 is amended by revising §172.858 to read as follows:

§172.858 Propylene glycol alginate.

The food additive propylene glycol alginate (CAS Reg. No. 9005-37-2) may be used as an emulsifier, flavoring agent, formulation aid, stabilizer, surfactant, or thickener in foods in accordance with the following prescribed conditions:

(a) The additive meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 256, which is incorporated by reference (copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20405), and the additional specification that it shall have up to 85 percent of the carboxylic acid groups esterified with the remaining groups either free or neutralized.

(b) The additive is used or intended for use in the following foods as defined in §170.3(n) of this chapter, when standards of identity established under section 401 of the act do not preclude such use:

1. As a stabilizer in frozen dairy desserts, in fruit and water ices, and in confections and frostings at a level not to exceed 0.5 percent by weight of the finished product.

2. As an emulsifier, flavoring adjunct, stabilizer, or thickener in baked goods at a level not to exceed 0.5 percent by weight of the finished product.

3. As a stabilizer, or thickener in cheeses at a level not to exceed 0.9 percent by weight of the finished product.

4. As an emulsifier, stabilizer, or thickener in fats and oils at a level not to exceed 1.1 percent by weight of the finished product.

5. As an emulsifier, stabilizer, or thickener in gelatins and puddings at a level not to exceed 0.6 percent by weight of the finished product.

6. As a stabilizer or thickener in gravies and in sweet sauces at a level not to exceed 0.5 percent by weight of the finished product.

7. As a stabilizer in jams and jellies at a level not to exceed 0.4 percent by weight of the finished product.

8. As an emulsifier, stabilizer, or thickener in condiments and relishes at a level not to exceed 0.6 percent by weight of the finished product.

9. As a flavoring agent or flavoring in seasonings and flavors at a level not to exceed 1.7 percent by weight of the finished product.

10. As an emulsifier, flavoring agent, formulation aid, stabilizer or thickener, or surface active agent in other foods, where applicable, at a level not to exceed 0.3 percent by weight of the finished product.

(c) To ensure safe use of the additive, the label of the food additive container shall bear, in addition to the other information required by the act:

1. The name of the additive, "propylene glycol alginate" or "propylene glycol ester of alginic acid".

2. Adequate directions for use.

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§§182.7133, 182.7187, 182.7610, and 182.7724 (Removed)

2. Part 182 is amended by removing §182.7133 Ammonium alginate, §182.7187 Calcium alginate, §182.7610 Potassium alginate, and §182.7724 Sodium alginate.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. Part 184 is amended:

a. By adding new §184.1133, to read as follows:

§184.1133 Ammonium alginate.

(a) Ammonium alginate (CAS Reg. No. 9005-34-9) is the ammonium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Ammonium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 18, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20405.

(c) In accordance with §184.1(b)(2), the ingredient is used in food only within the following specific limitations:

<table>
<thead>
<tr>
<th>Category of food</th>
<th>Maximum level of use in food (as served) (percent)</th>
<th>Functional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confections, frostings,</td>
<td>0.4</td>
<td>Stabilizer, thickener,</td>
</tr>
<tr>
<td>§170.3(n)(9) of this chapter.</td>
<td></td>
<td>§170.3(n)(12) of this chapter.</td>
</tr>
<tr>
<td>Fats and oils,</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>§170.3(n)(12) of this chapter.</td>
<td></td>
<td>Do.</td>
</tr>
<tr>
<td>Gelatins, puddings,</td>
<td>0.5</td>
<td>Do.</td>
</tr>
<tr>
<td>§170.3(n)(9) of this chapter.</td>
<td></td>
<td>Do.</td>
</tr>
<tr>
<td>Gravies and sauces,</td>
<td>0.4</td>
<td>Do.</td>
</tr>
<tr>
<td>§170.3(n)(9) of this chapter.</td>
<td></td>
<td>Do.</td>
</tr>
<tr>
<td>Jams and jellies,</td>
<td>0.4</td>
<td>Do.</td>
</tr>
<tr>
<td>§170.3(n)(9) of this chapter.</td>
<td></td>
<td>Do.</td>
</tr>
<tr>
<td>Sweet sauces,</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>§170.3(n)(43) of this chapter.</td>
<td></td>
<td>Do.</td>
</tr>
</tbody>
</table>
Category of food | Maximum level of use in food (as served) (percent) | Functional use
--- | --- | ---
All other food categories. | 0.1 | Humectant, 
§ 170.3(i)(16) of this chapter; stabilizer, thickener, 
§ 170.3(j)(28) of this chapter.

(d) Prior sanctions for ammonium alginate different from the uses established in this section do not exist or have been waived.

b. By adding new § 184.1187, to read as follows:

§ 184.1187 Calcium alginate.

(a) Calcium alginate (CAS Reg. No. 9005-35-0) is the calcium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Calcium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents, or from sodium alginate by metathesis with appropriate calcium salts.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 239, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

| Category of food | Maximum level of use in food (as served) (percent) | Functional use
--- | --- | ---
All other food categories. | 0.3 | Do.

(d) Prior sanctions for calcium alginate different from the uses established in this section do not exist or have been waived.

c. By adding new § 184.1610, to read as follows:

§ 184.1610 Potassium alginate.

(a) Potassium alginate (CAS Reg. No. 9005-36-1) is the potassium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Potassium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 239, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

| Category of food | Maximum level of use in food (as served) (percent) | Functional use
--- | --- | ---
Gelatins and puddings, 
§ 170.3(n)(25) of this chapter. | 4.0 | Firming agent, 
§ 170.3(o)(10) of this chapter; flavor enhancer, 
§ 170.3(o)(10) of this chapter; stabilizer, thickener, 
§ 170.3(j)(28) of this chapter.
Hard candy, 
§ 170.3(n)(25) of this chapter. | 10.0 | Stabilizer, thickener, 
§ 170.3(j)(28) of this chapter.
Confections and frostings, 
§ 170.3(n)(29) of this chapter. | 0.3 | Do.
Condiments and relishes, 
§ 170.3(n)(9) of this chapter, except preserved ribbon for stuffed olives. | 1.0 | Texturizer, 
§ 170.3(j)(32) of this chapter; formulation aid.
Emulsifier, 
§ 170.3(n)(8) of this chapter; thickener, 
§ 170.3(i)(28) of this chapter.
Emulsifier, 
§ 170.3(n)(11) of this chapter; flavor enhancer, 
§ 170.3(i)(10) of this chapter; stabilizer, thickener, 
§ 170.3(j)(28) of this chapter; processing aid, 
§ 170.3(j)(28) of this chapter; stabilizer and thickener, 
§ 170.3(j)(28) of this chapter; flavor enhancer, 
§ 170.3(i)(10) of this chapter; stabilizer, thickener, 
§ 170.3(j)(28) of this chapter; surface active agent, 
§ 170.3(i)(28) of this chapter.

(d) Prior sanctions for potassium alginate different from the uses established in this section do not exist or have been waived.

c. By adding new § 184.1724, to read as follows:

§ 184.1724 Sodium alginate.

(a) Sodium alginate (CAS Reg. No. 9005-38-3) is the sodium salt of alginic acid, a natural polyuronide constituent of certain brown algae. Sodium alginate is prepared by the neutralization of purified alginic acid with appropriate pH control agents.


(c) In accordance with § 184.1(b)(2), the ingredient is used in food only within the following specific limitations:

| Category of food | Maximum level of use in food (as served) (percent) | Functional use
--- | --- | ---
Confections and frostings, 
§ 170.3(n)(29) of this chapter. | 0.1 | Stabilizer, thickener, 
§ 170.3(j)(28) of this chapter.
Gelatins and puddings, 
§ 170.3(n)(25) of this chapter. | 0.7 | Do.
Processed fruits and fruit juices, 
§ 170.3(n)(25) of this chapter. | 0.25 | Do.
All other food categories. | 0.01 | Do.

(d) Prior sanctions for sodium alginate different from the uses established in this section do not exist or have been waived.

Any person who will be adversely affected by the amendment of § 172.858 may at any time on or before August 9, 1982, submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered, and each
numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall be effective August 9, 1982.

[Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1794-1796 as amended (21 U.S.C. 321(s), 348, 371(a))]

Dated: June 17, 1982.

Note.—Incorporation by reference was approved by the Director of the Office of the Federal Register on May 27, 1982, and is on file at the Office of the Federal Register.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-14639 Filed 7-6-82; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Parts 182 and 184
[Docket No. 79N–0068]

GRAS Status of Corn Silk and Corn Silk Extract

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that corn silk and corn silk extract are generally recognized as safe (GRAS) as direct human food ingredients, with specific limitations. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency. Sufficient information has been received to support affirmation of corn silk and corn silk extract as GRAS under current conditions of use.

EFFECTIVE DATE: August 9, 1982.


SUPPLEMENTARY INFORMATION: In the Federal Register of May 15, 1979 (44 FR 28332), FDA published a proposal to remove corn silk from the GRAS list in § 182.20 (21 CFR 182.20). The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on corn silk and the report of the Select Committee on GRAS Substances (the Select Committee) are available for public review in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5000 Fishers Lane, Rockville, MD 20857.

Copies of these documents also are available for public purchase from the National Technical Information Service, as announced in the proposal.

The agency also gave notice that it is unaware of any prior-sanctioned food ingredient uses for corn silk. Persons asserting uses based upon approvals granted by the U.S. Department of Agriculture or FDA before September 8, 1958 were given notice to submit proof of these sanctions, so that the safety of the prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of corn silk recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184, 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that use at any future time.

No reports of prior-sanctioned uses of corn silk or corn silk extract were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for a use of corn silk or corn silk extract under conditions different from those set forth in this regulation has been waived.

The agency's proposal contained the conclusion of the Select Committee which stated, in part, "that in view of the lack of information on the identity of the product used in foods and of relevant biological studies concerning it, there is insufficient data upon which to base an evaluation of corn silk when it is used as a food ingredient." (May 15, 1979; 44 FR 28333–28334).

Based upon its own evaluation of all information available on the ingredient, FDA agreed with the Select Committee's conclusion. (May 15, 1979; 44 FR 28334). Subsequent inquiries by the agency to food manufacturers also failed to produce the necessary identity and toxicity information on the corn silk product that is added to food. The agency therefore proposed to remove corn silk and its essential oils, oleoresins, and natural extractives from the GRAS list (§ 182.20).

One comment from a trade association was received in response to the proposal. The comment supplied a recently published article from the scientific literature (J. Agric. Food Chem., Vol. 26, p. 1290, 1978) providing information on the volatile components of corn silk. The comment also referenced the eighth edition of the National Formulary (NF VIII, 559–560, 1948), and supplied manufacturer specifications for two extracts of corn silk. The comment stated that the method of manufacture for corn silk and corn silk extracts is essentially the same as described in the eighth edition of the National Formulary, and that these descriptions would help clarify the identity of the products that were studied in experimental animals, as reported in the agency's proposal. The comment also indicated that corn silk and corn silk extracts have been used as food flavors since at least 1952.

FDA has reviewed this information and finds that it provides sufficient data to review the GRAS status of corn silk and its extracts. On the basis of this information and the information that was already before the Select Committee, the agency concludes that corn silk and alcohol extracts of corn silk may be affirmed as GRAS as food flavoring ingredients. FDA is affirming the GRAS status of these substances with specific limitations, however, because available data are limited and only support current conditions of use. The current levels of use of these substances were reported in the National Academy of Sciences/National Research Council 1972 survey, and the agency confirmed them with the comment.

The agency is not adopting specifications for corn silk or corn silk extracts at this time because this information is available from only one manufacturer. The agency will work with the Committee on Codex Specifications of the National Academy of Sciences to develop acceptable specifications for corn silk and corn silk extract. If acceptable specifications are developed, the agency will incorporate them into this regulation at a later date. Until specifications are developed, commercial corn silk and corn silk
extract should comply with the description in the regulation and should be of food-grade purity (21 CFR 170.30(h)(1) and 182.1(b)(3)).

The format of the final regulation is different from previous GRAS affirmation regulations. FDA has modified paragraph (c) of §184.1262 to make clear that GRAS affirmation is based upon specific limitations on the use of this ingredient in food, including the categories of food, maximum levels of use, and functional-use listed. This change has no substantive effect but is made merely to clarify the effect of the regulation.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this rule, and the agency has determined that the rule is not a major rule as defined by the Order.

List of Subjects in 21 CFR

Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1794–1798 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.20 [Amended]

1. Part 182 is amended in §182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates) by removing the entry for “Corn silk—Zea mays L.”

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

2. Part 184 is amended by adding new §184.1262 to read as follows:

§184.1262 Corn silk and corn silk extract.

(a) Corn silk is the fresh styles and stigmas of Zea mays L. collected when the corn is in milk. The filaments are extracted with dilute ethanol to produce corn silk extract. The extract may be concentrated at a temperature not exceeding 60°C.

(b) The Food and Drug Administration, in cooperation with the National Academy of Sciences, is developing food-grade specifications for corn silk and corn silk extract. In the interim, this ingredient must be of a suitable purity for its intended use.

(c) In accordance with §184.1(b)(2), the ingredients are used in food only within the following specific limitations:

<table>
<thead>
<tr>
<th>Category of food</th>
<th>Maximum level of use in food (as served)</th>
<th>Functional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baked goods and</td>
<td>30 Flavored agent, §170.30(n)(12) of this chapter.</td>
<td>Do.</td>
</tr>
<tr>
<td>baking mixes, §170.30(n)(11) of this chapter.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonalcoholic beverages, §170.30(n)(13) of this chapter.</td>
<td>20</td>
<td>Do.</td>
</tr>
<tr>
<td>Frozen dairy desserts, §170.30(n)(9) of this chapter.</td>
<td>10</td>
<td>Do.</td>
</tr>
<tr>
<td>Soft candy, §170.30(n)(8) of this chapter.</td>
<td>20</td>
<td>Do.</td>
</tr>
<tr>
<td>All other food categories.</td>
<td>4</td>
<td>Do.</td>
</tr>
</tbody>
</table>

*Parts per million.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date. This regulation shall be effective August 9, 1982.


William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs

BILLING CODE 4160-01-M

21 CFR Parts 182 and 186

[Docket No. 78N-0111]

GRAS Status of Sulfamic Acid

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that sulfamic acid is generally recognized as safe (GRAS) as an indirect human food ingredient. FDA is denying a request in a comment that the agency also affirm ammonium sulfamate as GRAS for indirect human food use. The safety of sulfamic acid has been evaluated under the comprehensive safety review conducted by the agency.

EFFECTIVE DATE: August 9, 1982.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–4750.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 13, 1979 (44 FR 13257), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents also are available for public purchase from the National Technical Information Service as announced in the proposal.

In addition to proposing the above action, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for sulfamic acid other than for the proposed conditions of use. Persons asserting additional or extended uses, in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, sb that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of sulfamic acid approved by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184, 186), as appropriate.

FDA also gave notice that failure to submit proof of applicable prior sanction in response to the proposal would constitute a waiver of the right to assert the sanction at any future time.

No reports of prior-sanctioned uses for sulfamic acid were submitted in
response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for use of sulfamic acid under conditions different from those set forth in this regulation has been waived.

In its original proposal, FDA proposed to establish food grade specifications for sulfamic acid because, however, the agency has reconsidered the necessity for imposing food grade specifications on indirect GRAS substances, such as sulfamic acid. Because indirect uses usually result in extremely low levels of consumer exposure to the ingredient and the impurities it contains, the agency has concluded that, as a general rule, food-grade specifications are not necessary to assure the safety of an indirect GRAS substance. FDA finds that the general requirements that indirect GRAS ingredients be of a purity suitable for their intended use in accordance with § 170.30(h)(1) and used in accordance with current good manufacturing practice are sufficient to ensure safety of sulfamic acid as an indirect GRAS ingredient and that no additional specifications are necessary. Therefore, FDA has modified the final regulation governing the use of sulfamic acid as an indirect GRAS ingredient, § 186.1093(b) (21 CFR 186.1093(b)) by removing the specifications. FDA published a proposal in the Federal Register of June 25, 1982 (47 FR 27817) to amend its procedural regulations in Part 186 to reflect clearly this new policy regarding specifications for indirect GRAS substances.

Two comments were submitted in response to the FDA proposal and supporting data and information on sulfamic acid. A summary of these comments and the agency's response follows:

1. One comment requested that, in addition to sulfamic acid, ammonium sulfamate be affirmed as GRAS for indirect human food use because the ammonium salt of sulfamic acid is less toxic than sulfamic acid. The comment stated that very little, if any, ammonium sulfamate would migrate to food from indirect use, and ammonium salts in general present little safety concern as food ingredients at the levels normally encountered.

FDA is denying the requested affirmation of GRAS status of ammonium sulfamate. The agency does not agree with the comment's assertion concerning the safety of ammonium salts in general. Although several ammonium salts are either approved food additives or GRAS food ingredients, this fact is no basis for assuming that other ammonium salts are also safe for food use. Although FDA agrees with the comment regarding the migration characteristics of pure ammonium sulfamate and its reduced toxicity compared to that of sulfamic acid, the purity of the ammonium sulfamate proposed for use by the comment is not completely established. The comment proposes to generate the ammonium sulfamate (in situ [i.e., in the packaging material itself] from urea and sulfamic acid, without further purification for possible chemical by-products [e.g., biuret and cyanoic acid] formed during the reaction. The comment has provided no scientific information on the levels of these by-products that might be expected to migrate to food or information on their potential toxicity. Because of the possibility of low dose toxicity and the absence of specific safety information, FDA is unable to affirm the GRAS status of ammonium sulfamate generated in situ from urea and sulfamic acid for use as an indirect human food ingredient.

However, if the required information is supplied in a petition, FDA will reconsider issuing a GRAS or food additive regulation for indirect human food uses of ammonium sulfamate not included in this regulation. Future FDA approval of this substance may be sought through the GRAS or food additive petition procedures outlined in § 170.35 and § 171.1 (21 CFR 171.1) for any new uses of ammonium sulfamate.

2. The second comment requested changes in the proposed specifications for sulfamic acid. In particular, the comment requested that the minimum assay requirement be reduced from the proposed 98 percent to 91 percent, and that the specification for residue on ignition be increased from the proposed 0.05 percent to 0.8 percent. Although the commercial grade of sulfamic acid is less pure than the sulfamic acid described in the proposal, the comment pointed out that the impurities are themselves GRAS substances, e.g., sulfuric acid, ammonium sulfate, urea, and magnesium oxide. Moreover, the commercial grade of sulfamic acid meets the specification for heavy metals as presented in the proposal. In objecting to the proposed assay test, the comment argued that the test only provided an estimate of total acidity, and that it was not adequate for measuring the actual sulfamic acid content.

In light of the FDA decision not to require food-grade specifications for sulfamic acid, the issues raised by the comment are moot. The commercial grade of sulfamic acid currently used in the manufacture of food packaging is acceptable to FDA for this purpose.

The agency has determined under 20 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt.

In accordance with Executive Order 12291, FDA has analyzed the economic effects on this rule, and the agency has determined that the rule is not a major rule as defined by the Order.

List of Subjects in 21 CFR

Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

Part 186

Food ingredients, Generally recognized as safe (GRAS) food ingredients, Indirect food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(n), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 182 and 186 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.90 [Amended]

1. In Part 182, § 182.90 Substances migrating to food from paper and paperboard products is amended by removing the entry for "sulfamic acid" from the list of substances.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

2. In Part 186 by adding new § 186.1093, to read as follows:

§ 186.1093 Sulfamic acid.

(a) Sulfamic acid (H3N2O3S, CAS Reg. No. 5329–14–6) is a white crystalline solid manufactured from urea, sulfur trioxide, and sulfuric acid. It is soluble and highly ionized in water.

(b) In accordance with § 186.1(b)(1), the ingredient is used as an indirect food ingredient with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as an indirect human food ingredient is based upon the current good
manufacturing practice of using this ingredient in the manufacture of paper and paperboard that contact food.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date. This regulation is effective August 9, 1982.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended [21 U.S.C. 321(e), 348, 371(a)])

Dated: June 15, 1982.
William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-18441 Filed 7-8-82; 8:45 am]
BILLING CODE 4160-01-M
Food and Drug Administration
21 CFR Parts 182 and 184
[Docket No. 81N-0314]

Sulfiting Agents; Proposed Affirmation of GRAS Status With Specific Limitations; Removal From GRAS Status as Direct Human Food Ingredient

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to affirm that potassium metabisulfite, sodium bisulfite, sodium metabisulfite, and sulfur dioxide are generally recognized as safe (GRAS), with specific limitations, as direct human food ingredients. In addition, FDA is proposing not to affirm potassium bisulfite and sodium sulfite as GRAS as direct human GRAS. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATE: Comments by September 7, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive safety review of human food ingredients classified as GRAS or subject to a prior sanction. The agency has issued several notices and proposals (see the Federal Register of July 20, 1973 (38 FR 20400)) initiating this review, under which the safety of potassium bisulfite, potassium metabisulfite, sodium bisulfite, sodium metabisulfite, sodium sulfite, and sulfur dioxide has been evaluated. In accordance with the provisions of § 170.35 (21 CFR 170.35), the agency proposes to affirm, with specific limitations, the GRAS status of potassium metabisulfite, sodium bisulfite, sodium metabisulfite, and sulfur dioxide, and to remove potassium bisulfite and sodium sulfite from GRAS status.

Potassium bisulfite (KHSO₃), also referred to as potassium acid sulfite or potassium hydrogen sulfite, consists of colorless crystals with a reported decomposition melting point of 190° C. It is soluble in water but insoluble in alcohol. Potassium bisulfite is prepared by passing sulfur dioxide through a solution of potassium carbonate, evaporating the resultant solution, and crystallizing the product. Potassium metabisulfite (K₂S₂O₅), also identified as potassium pyrosulfite, exists as white or colorless free-flowing crystals. It, too, has a decomposition melting point of 190° C. Potassium metabisulfite is only slightly soluble in water and in alcohol, and it is insoluble in ether. It is prepared by heating potassium bisulfite until it loses water or by treating aqueous potassium bisulfite with excess sulfur dioxide. Sodium bisulfite (NaHSO₃), commonly called sodium acid sulfite or sodium hydrogen sulfite, is normally available as a mixture with sodium metabisulfite. The mixture consists of white or yellowish-white crystals or granular powder. Because sodium bisulfite decomposes, it has no reported melting point. It is soluble in water and slightly soluble in alcohol. Sodium bisulfite is prepared by passing sulfur dioxide through a solution of sodium carbonate until the solution is saturated. Sodium bisulfite then crystallizes from the solution. Sodium metabisulfite (Na₂S₂O₅), or sodium pyrosulfite, exists as colorless or white to yellowish crystalline powder. It is freely soluble in water but only slightly soluble in alcohol. Sodium metabisulfite is generated either by treating aqueous sodium bisulfite or sodium carbonate with excess sulfur dioxide or by heating sodium bisulfite until it loses water. The latter process occurs below the melting point, so a melting point is not available for this compound. Sodium sulfite (Na₂SO₃) is a white or tan to slightly pink powder. It is soluble in water and slightly soluble in alcohol. Sodium sulfite is reported to decompose before melting. Sodium sulfite is synthesized by reacting alkali with an aqueous solution of sodium bisulfite. Sulfur dioxide (SO₂), occasionally referred to as sulfurous anhydride, is a colorless, nonflammable gas having a strong, characteristic suffocating odor. At normal atmospheric pressure, it has a boiling point of —10° C. Sulfur dioxide is produced by burning elemental sulfur in air, by roasting pyrites, or by reducing calcium sulfate with coke.

The sulfiting agents have been employed for centuries in food processing as sanitizing agents for food containers and fermentation equipment; as preservatives to reduce or prevent microbial spoilage of food; as selective inhibitors of undesirable microorganisms in the fermentation industries; and as antioxidants and inhibitors of enzyme-catalyzed oxidative discoloration and nonenzymatic browning during the preparation, storage, and distribution of many foods.

The inorganic sulfites function by liberating sulfur dioxide under conditions of use. Choice among the various sulfiting agents depends in large measure upon the stability required for the intended use. The sulfites tend to oxidize during storage, thus decreasing the amount of available sulfur dioxide. The metabisulfites are more stable than the bisulfites, which are, in turn, more stable than the sulfites. The functional effects of the sulfiting agents are related to their sulfur dioxide content. When dissolved in water, the sulfites form sulfuric acid and sulfite and bisulfite ions, the relative proportions of each depend upon the pH of the solution.

Each of the six sulfiting agents is listed in Part 182 (21 CFR Part 182) as a GRAS ingredient for use as a chemical preservative. The inclusion of potassium metabisulfite (21 CFR 182.3616), potassium metabisulfite (21 CFR 182.3637), sodium bisulfite (21 CFR 182.3739), sodium metabisulfite (21 CFR 182.3766), sodium sulfite (21 CFR 182.3798), and sulfur dioxide (21 CFR 182.3862) in the GRAS list was effectuated by a regulation published in the Federal Register of November 20, 1939 (24 FR 9368) and subsequent recodification.

Several specific food additive uses of the sulfiting agents have been approved by FDA: (1) Sulfur dioxide is permitted as a bleaching agent for food starches, as described in § 172.692(b) (21 CFR 172.692(b)); (2) sodium metabisulfite and neutral or alkaline sodium sulfite are permitted as additives to boiler water used in the preparation of steam that will contact food, as described in § 173.310(c) (21 CFR 173.310(c)); (3) sodium sulfite and sodium metabisulfite are permitted as components of cellophane for food packaging, as described in § 177.1200(c) (21 CFR 177.1200(c)); (4) sodium sulfite and sodium metabisulfite are permitted as constituents of water-insoluble hydroxyethyl cellulose film, as described in § 177.1400 (21 CFR 177.1400); and (5) potassium metabisulfite, sodium bisulfite, sodium metabisulfite, and sulfur dioxide are permitted as sterilizing and preservative agents in the treatment of wine, as described in 27 CFR 240.1031.

In addition to the GRAS and regulated food additive uses of the sulfiting agents identified above, prior sanctions and advisory opinion letters for these substances have been issued by FDA.
Because of their prior-sanctioned status, sodium sulfite and sulfur dioxide may be used at levels from 200 to 300 parts per million (ppm) in molasses, dried fruits, and foods that are not good sources of vitamin B₂. In addition, sodium bisulfite solution is prior sanctioned for use as a dip to prevent darkening of fresh-peeled, uncooked potatoes, and sodium bisulfite is also prior-sanctioned as a dip to control the incidence of black spot in shrimp. Advisory opinions have addressed the following food uses of specific sulfiting agents: (1) potassium metabisulfite is permitted at levels up to 1 percent by weight as a stabilizer for preparation of dry vitamin A palmitate; (2) sodium bisulfite is permitted in wash water for mushrooms; (3) sodium bisulfite is permitted as a preservative in citron brining; (4) sulfur dioxide is permitted at levels up to 400 ppm in corn syrups that are subsequently applied to meats; and (5) sodium sulfite is permitted at levels up to 1 percent in the wash water of sweet potatoes.

Several food standards contain references to the optional use of unspecified safe and suitable preservatives or to the optional use of antioxidant preservatives listed in Subpart D of Part 182. Except for maximum levels of sulfur dioxide content in specific nutritive sweeteners listed in Part 168 (21 CFR Part 168), none of the sulfiting agents appear in the food standards.

In 1971, the National Academy of Sciences/National Research Council (NAS/NRC) surveyed a representative cross-section of food manufacturers to determine the specific foods in which sulfiting agents are used and the levels of usage. However, a number of problems associated with this survey created uncertainties about its result. The Select Committee on GRAS Substances (the Select Committee), which was selected by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB), was aware of the problems with the 1971 NAS/NRC survey. Instead of waiting for a new survey to correct these problems, the Select Committee decided to estimate consumer exposure to sulfiting agents on the basis of its own review of the pertinent scientific literature. In its report, which it issued in 1976, the Select Committee noted that a number of studies indicated that there is a substantial decrease in sulfur dioxide equivalents between processing and consumption. After review of these studies, the Select Committee concluded that:

Losses of SO₂ through volatilization can and do occur during processing, in subsequent storage, and in home preparation. Oxidation of sulfite to sulfate can also occur at all stages, and sulfate can react with a number of food ingredients. All of these factors tend to lower the amount of available sulfite in foods as eaten.

The daily intake of SO₂ via sulfited foods consumed in the United States does not exceed 2 mg per kg body weight for adults, except in unusual circumstances, and probably is no more than 0.2 mg per kg for the bulk of the adult population. There is no reason to suspect that sulfur intakes of infants and children will exceed 0.2 mg per kg daily. Actual analysis of foods as consumed by various age groups is desirable if more realistic estimates of daily SO₂ intakes are to be obtained.

Because of the uncertainties associated with the results obtained from its 1971 survey, NAS/NRC resurveyed the sulfiting agents in 1977. On the basis of this second survey, NAS/NRC reported that the following total amounts of sulfiting agents are added to foods in the United States:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Total pounds added to foods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium bisulfite</td>
<td>220,000</td>
</tr>
<tr>
<td>Sodium metabisulfite</td>
<td>4,900,000</td>
</tr>
<tr>
<td>Sodium sulfite</td>
<td>92,000</td>
</tr>
<tr>
<td>Sulfur dioxide</td>
<td>15,000</td>
</tr>
<tr>
<td>Sodium metabisulfite</td>
<td>2,200,000</td>
</tr>
</tbody>
</table>

*None reported.*

Additionally, in the Federal Register of May 31, 1977 (42 FR 27678), FDA issued a notice requesting the submission of data and information regarding the extent of use of certain GRAS or prior-sanctioned human food ingredients, including some sulfiting agents. In response to this notice, FDA received data about additional human food uses for some of the sulfiting agents. Furthermore, a comment submitted to FDA in response to the proposed regulation to affirm gelatin as a GRAS agent. These substances are particularly useful in such foods as processed fruits and fruit juices, processed vegetables and vegetable juices, in alcoholic beverages, and in some baked goods, condiments, and sweet sauces.

Sulfiting agents also have been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 1,903 abstracts on sulfiting agents was reviewed, and 143 particularly pertinent reports have been summarized in a scientific literature review.

The scientific literature review includes the following information, as summarized in the report of the Select Committee:

The primary detoxication mechanism for sulfite in rats, and presumably in other mammalian species, is by oxidation to sulfate; only a small proportion is converted to organic sulfate. In four hours, 55 percent of the sulfur of intubated sodium metabisulfite solution (equivalent to about 1.0 g SO₂ per kg body weight) was recovered as inorganic sulfate in the urine of rats. In dogs, 80 mg of sodium bisulfite per kg per hour (corresponding to 49 mg SO₂ per kg per hour) infused for three hours into the splenic vein was completely metabolized to sulfate. In rats, mice, and monkeys 70 to 95 percent of the 35S of ingested Na₂SO₃ (10 to 50 mg SO₂ per kg body weight) was absorbed from the intestine and voided in the urine of all three species within 24 hours. Most of the remaining 35S was eliminated in the feces; 2 percent or less was found in the carcass. No free sulfate was detected in the urine or rats even after a single oral dose of sodium bisulfite (400 mg SO₂ per kg) indicating a large capacity to rapidly oxidize sulfate.

A sulfite oxidase has been isolated from the livers of rats, dogs, and cattle. Tissue distribution of the enzyme in the rat shows highest activity in liver, heart, and kidney, with lower activity in several other tissues, and very low activity in lung. It is not known whether human tissues show a similar distribution of sulfite oxidase activity. A congenital deficiency of hepatic sulfite oxidase has been described in man. In this rare hereditary metabolic disorder, S-sulfoxysteine is excreted in the urine. It is noteworthy that Olney et al. have found this compound [COOH-CH-
(NH₂)CH₂-S-SO₃H] to produce lesions in the retinas and arcuate nuclei of the hypothalamus in 5-day-old rats injected subcutaneously at levels of 80 to 800 mg per kg body weight, but not a level of 6 mg per kg; similar brain damage also occurred in adult rats injected intracerebrally at a level of 30 mg per kg.

It is possible, based on studies in rabbits, that the small portion of oral sulfite that may not be immediately oxidized could react with disulfide bonds of plasma proteins to form S-sulfonates in the plasma. The authors theorize that the formation of plasma S-sulfonates may protect the tissues from exposure to sulfite, but because the chemical reaction is reversible, these products might also serve as carrier forms of sulfite to release it in the tissues at a later time. The action of sulfite on proteins and peptides to produce S-sulfonates and disulfides has been reviewed by Meister. Such thiosulfate esters are converted to sulfite by reaction with glutathione. This conversion is catalyzed reversibly by an enzyme in rat liver for glutathione disulfide and cystine but not for disulfide groups in proteins. S-sulfocysteine is converted to thiosulfate, pyruvate, and ammonia when fed to rats.

Sulfites can produce direct effects on tissues presumably as a consequence of disturbance of acid-base balance. Root and Franz gave dogs up to 1.0 g of sulfite per day for more than a year without evidence of gross or microscopic tissue changes. Larger doses caused vomiting but no other symptoms appeared. Humans receiving 1.0 g of sodium sulfite per day (about 17 mg per kg) had no gastrointestinal symptoms but abdominal pain and vomiting occurred at doses of 4 to 5.8 g per day (about 70 to 100 mg per kg). Lafontaine and Goblit found doses of sulfite in excess of 3.5 mg per kg to induce gastrointestinal irritation leading to vomiting in man and suggested that the vomiting reflex protects against acute toxicity.

Enzymes inhibited by sulfites in vitro include a number that require nicotinamide adenine dinucleotide (NAD) or pyridoxal as cofactors, peroxidase, and acetylcholine esterase; alkaline phosphatase was inhibited in vivo. Bisulfite in vitro in excess (118 mg of sodium bisulfite to 5 mg of yeast ribonuclease) has been shown to react over a period of several hours with some nucleic acid components to alter their structure; for example, the deamination of cystosine to uracil. However, treatment of calf thymus DNA with excess of bisulfite under similar conditions, even for 72 hours, resulted in no deamination of cytosine. Such reactions have not been demonstrated to occur in vivo. However, the authors suggest their findings imply that the mutagenic properties of bisulfite [to be considered shortly] are due to its reaction with single-stranded DNA.

Sodium sulfite added to the diet of rats and fed for periods up to 1.5 years produced evidence of vitamin E deficiency as measured by effects on the enameled organs of the teeth. Such evidence appeared only at levels of 500 mg of sodium sulfite per kg body weight and higher.

Interpretation of the biological effects of sulfiting agents in many experimental studies is difficult because sulfite reacts with thiamine. Thus, some of the observed effects attributed to sulfiting agents may well be due to the destruction of thiamine and with the resulting avitaminosis, rather than to direct action of sulfiting agents on the tissues. The relationship between thiamine content of the food and sulfite content has been studied by Wilmes in rats and by several others in laboratory animals and man. Typically, the animal experiments showed that sulfite was toxic at a level of 50 mg SO₂ per kg to animals on diets deficient in thiamine but when adequate thiamine levels were maintained, animals survived 300 mg of sulfite per kg per day without significant influence on weight or food utilization. However, a study by Bhagat and Lockett indicates that some stored sulfured diets may be toxic to rats. Rat diet containing 0.6 percent solid sodium metabisulfite (about 400 mg SO₂ per kg body weight) did not support normal rate of growth when fed as freshly prepared, but normal growth rate was restored by addition of thiamine. When the sulfite diet was stored at room temperature for 75 days or more before feeding, reduced growth rate occurred and normal rate was not restored by addition of thiamine. The authors offered no explanation of this effect.

An experiment involving 12 human volunteers (6 female, 6 male) was particularly significant with respect to evaluating sulfite tolerance. After a normal diet for 15 days, all subjects were placed on a thiamine deficient diet (120 µg thiamine per 1000 kcal) for another 15 days. Six of the subjects received the same beverages without added SO₂ for 25 days. Sulfite administration was then discontinued for 10 days and all 12 subjects were given 100 mg of thiamine orally each day for two days. All volunteers were examined clinically, including neurophysiological examination of motor conduction and reflex action, before, during and after the experiment and no clinical changes could be detected. Tests for activity of a number of enzymes, and measurements such as serum electrophoresis, thymol turbidity, hematoct, and erythrocyte count were conducted and the data exhibited no signs of any disturbance caused by sulfite.

It has been shown by Thomas and Berryman that the usual acceptable amounts of sulfite present in foods such as dehydrated fruits and vegetables which are normally sulfited, do not cause significant destruction of the thiamine content of a mixed meal including meat and other sources of thiamine.

Acute LD₅₀ values for sulfiting agents by several routes of administration and in several species are given in (the table below).

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>Chemical</th>
<th>LD₅₀ (mg/ kg)</th>
<th>SO₂ equiv (mg/ kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>i.p.</td>
<td>Sodium bisulfite</td>
<td>675</td>
<td>416</td>
</tr>
<tr>
<td></td>
<td>i.v.</td>
<td>Sodium bisulfite</td>
<td>130</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td>l.c.</td>
<td>Sodium sulfite</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>l.v.</td>
<td>Sodium sulfite</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>l.v.</td>
<td>Sodium sulfitine</td>
<td>1,040</td>
<td>1,040</td>
</tr>
<tr>
<td>Rat</td>
<td>i.p.</td>
<td>Sodium bisulfite</td>
<td>1,040</td>
<td>1,040</td>
</tr>
<tr>
<td></td>
<td>i.v.</td>
<td>Sodium bisulfite</td>
<td>650</td>
<td>400</td>
</tr>
<tr>
<td></td>
<td>l.c.</td>
<td>Sodium bisulfite</td>
<td>115</td>
<td>71</td>
</tr>
<tr>
<td></td>
<td>l.v.</td>
<td>Sodium bisulfite</td>
<td>2,000</td>
<td>2,000</td>
</tr>
<tr>
<td></td>
<td>l.v.</td>
<td>Potassium metabisulfite</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Rabbit</td>
<td>i.p.</td>
<td>Sodium bisulfite</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td></td>
<td>i.v.</td>
<td>Sodium bisulfite</td>
<td>1,000</td>
<td>1,000</td>
</tr>
<tr>
<td></td>
<td>l.c.</td>
<td>Sodium bisulfite</td>
<td>300</td>
<td>185</td>
</tr>
<tr>
<td></td>
<td>l.v.</td>
<td>Sodium bisulfite</td>
<td>65</td>
<td>40</td>
</tr>
<tr>
<td>Hamster</td>
<td>i.p.</td>
<td>Sodium bisulfite</td>
<td>65</td>
<td>58</td>
</tr>
<tr>
<td>Dog</td>
<td>i.p.</td>
<td>Sodium bisulfite</td>
<td>244</td>
<td>150</td>
</tr>
</tbody>
</table>

* As a 0.5 percent aqueous solution.
* As a 3.5 percent aqueous solution.

Sodium bisulfite fed to groups of rats for a year at various levels (0.0125 to 2.0 percent of the diet) led to the following conclusions: on diets containing less than 0.1 percent bisulfite no significant effect on growth occurred; on diets containing more than 0.1 percent bisulfite, growth rate and animal size decreased as SO₂ concentration increased; on diets containing 0.25 percent bisulfite or more,
pathological changes observed were polyneuritis, bleached incisors, visceral organ atrophy, renal tubular casts, bone marrow atrophy, stunting of growth and spectacle eyes; the level of bisulfite at which histological changes began to appear was estimated to be about 0.1 percent (about 62 mg SO₂ per kg body weight).

It is to be noted that while no toxicological studies of sulfite adducts of carbonyl compounds have come to the attention of the Panel, experiments in histological differences of sodium glucose sulfate per day for 25 days revealed no sign of any disturbance caused by this compound.

One-month-old male and female Wistar rats were given potassium metabisulfite in drinking water (700 mg SO₂ equivalent per liter) for 20 months. The dosage level of the metabisulfite was 190 mg SO₂ per kg body weight during the first 15 days, 50 to 78 mg SO₂ per kg at the end of 60 days and 29 to 40 mg SO₂ per kg at the end of 20 months.

There were significant differences between the control and experimental animals in mortality, rate of growth, feed consumption, clinical signs, and in the weight and histological appearance of heart, kidneys, adrenals, and gonads. Leucocyte count was slightly elevated in experimental males and splenomegally occurred in some females. There were 19 and 10 percent reductions, respectively, in the reproduction rates in the F₁ and F₂ generations of the metabisulfite-treated F₁ females, and significantly fewer F₁ and F₂ males born in the treated group. There were no malformations in the young. Such reproductive effects were not observed by Lockett and Natoff who gave sodium metabisulfite solution containing 750 ppm of SO₂ equivalent per liter to rats as drinking water over three generations. Daily dosage varied from 75 mg SO₂ per kg body weight to 170 mg per kg, depending on volume of solution consumed and animal weight. No differences were found in growth rates between the experimental and control animals. There were no effects on fertility, postnatal survival, lactation, behavior or general health. There was no significant difference in body weight or organ weight between test and control rats, and no carcinogenesis could be attributed to the SO₂. Gastric mucosal hyperplasia was not observed.

More recently, Til et al. mixed sodium metabisulfite in the diet of rats (given added thiamine) and fed them for more than two years and more than three generations. They found the "no observed adverse effect" level to be 0.215 percent (equivalent to 72 mg SO₂ per kg body weight per day determined by analysis of the diet as fed). At a level of 2 percent metabisulfite there was slight growth retardation in the F₁, and F₂ generations. At levels of 1 percent or higher, occult blood was present in the feces, and hyperplastic changes were noted in the gastric mucose, but there was no evidence of carcinoma. At high metabisulfite levels, 6 to 8 percent, the glandular portion of the stomach showed ulcers, papillomatous elevations, erosions, and inflammatory changes occurred in about 2 percent metabisulfite or above, and splenic enlargement with marked hematoepiosis took place with levels of 4 percent or above. No dose-related effects of metabisulfite on reproductive factors such as litter size, female fertility, birth weight or mortality of the young were found, but there was a significant reduction in the number of F₂ generation offspring at sulfite levels of 0.5 percent or above.

The same authors studied the effect of feeding sodium metabisulfite to pigs for up to 48 weeks. Diets were supplemented with extra thiamine to avoid deficiency to the vitamin. They found the no observed adverse effect level of sodium metabisulfite to be 0.35 percent (equivalent to about 120 mg SO₂ per kg body weight at the beginning of the experiment and about 20 mg per kg at the end); growth was decreased at the 0.83 percent level (due to lowered palatability of the diet as indicated by paired-feeding), and mild inflammatory and hyperplastic changes in the stomach were noted in several animals fed 0.83 or 1.72 percent sulfite. Except for some pigmentation of the cecal mucosa resembling pseudomelanosis coli, no histopathological changes were noted in any of the tissues.

Cattle (herd of 600) consuming daily silage containing 45 g of sodium metabisulfite (67 mg SO₂ per kg body weight per day) showed no adverse effects after more than five years of feeding. A cow in her third month of pregnancy receiving a dosage of about 100 mg SO₂ per kg per day for 180 days showed no adverse effects, calved normally, and the calf was normal. It should be noted, however, that experience with ruminants should not be equated with monogastric animals since the former appear to tolerate considerably larger amounts of sulfites.

From the foregoing acute and chronic administration studies it is evident that the level of sulfite that produces no observed toxic effects varies from about 30 to 100 or more mg of SO₂ per kg body weight per day, depending on the species and experimental conditions. This wide range may be related to the variable amounts of thiamine used in the experimental diets of reported studies. The FAO/WHO considers 35 mg SO₂ per kg body weight per day as the no observed adverse effect level in the rat.

Teratologic evaluations of intubated sodium bisulfite, sodium metabisulfite, and potassium metabisulfite have been made in several species. The compounds were administered daily on day 6 through day 15 of gestation in mice and rats; and day 6 through day 10 in hamsters. For sodium bisulfite the doses were up to 150, 110, and 120, respectively; for sodium metabisulfite in mice, rats, and hamsters, up to 160, 110, and 120, respectively; for potassium metabisulfite in mice and rats up to 125 and 155, respectively. In no instance were significant effects observed on nidation or on maternal or fetal survival. The number of abnormalities found in either the soft or skeletal tissues of the test groups did not differ from the number occurring spontaneously in the sham-treated controls.

When sodium metabisulfite was injected in the air cell of fertilized eggs at 0 hour the calculated LD₅₀ (based on an average egg weight of 50 g) was 19.5 mg per kg, and when injected after 96 hours of incubation the LD₅₀ was 34.9 mg per kg, and at 96 hours, 162 mg per kg. Significant elevations of levels of abnormalities attributable to temporary growth retardation were noted, and a low level of structural anomalies involving the head and/or limbs was encountered. A second laboratory tested potassium metabisulfite on chick embryos and found it to be quite embryotoxic; yolk treatment was more toxic than air cell treatment; the evidence was inconclusive with respect to teratological effects. A third laboratory found sodium bisulfite to be toxic to chick embryos when injected into either the air cell or the yolk with greater toxicity following air cell administration. No significant teratogenic findings were reported. A fourth laboratory found sodium sulfate to be toxic on air cell injection into eggs at 0 and 96 hours of incubation (LD₅₀ 20.7 and 16.7 mg per kg of egg, respectively) but not significantly toxic on yolk injection. Because there were no serious structural abnormalities compared to untreated or solvent treated controls, it was concluded that sodium sulfate is not teratogenic under these conditions.

When a great excess of sodium bisulfite is present, the deamination of cystosine to uracil in vitro in single standard DNA is optimal at pH 5. At
higher pH values the rate is considerably reduced, but the authors suggest the possibility that a potential hazard of sulfite as a mutagen agent in vivo may exist based on this model chemical reaction in vitro. In at least four microorganisms (E. coli, phage T4 phage and a yeast) sulfite has been shown to be a mutagen, and the increase of the mutation follows the expected pattern predicted by the model chemical reaction. However, there is no evidence of sulfite causing mutations or cancer in mammals in vivo.

Sodium bisulfite was not mutagenic in the host-mediated assay in mice, the dominant lethal assay in rats, or the in vivo cytogenetic assay in rats at doses up to 150 mg per kg; it showed no mutagenic activity on human tissue culture cells in vitro at levels up to 200 mg per ml. In similar tests conducted on sodium metabisulfite by another laboratory, no mutagenic activity was observed in the host mediated, dominant lethal, or cytogenetic assays, but mitotic inhibition and widespread damage to anaphase cells were noted when sodium metabisulfite was added to human embryonic lung cells growing in tissue culture. No mutagenic activity was exhibited by sodium sulfite or potassium metabisulfite in in vitro plate and suspension microcell assays using Salmonella typhimurium, strains TA-1535, TA-1537, and TA-1538, and Saccharomyces cerevisae, either unactivated or activated with liver, lung, or testis homogenates from mice, rats, and monkeys.

Effects of SO2, sodium sulfite, and sodium bisulfite on three tissue culture cell lines (mouse fibroblast strain L cells (NCTC 929), mouse liver cells (NCTC 1769), and HeLa cells) were studied by Thompson and Pace. If the culture media were high in protein, the cells tolerated concentrations of sulfite of 500 ppm with no inhibition and as much as 2000 ppm with only a moderate degree of growth inhibition. If the media contained a low concentration of protein, the toxicity of sulfite was increased nearly tenfold. HeLa cells were more sensitive to sulfite than the mouse cell lines.

Human lymphocyte cells in tissue culture received a single exposure to 100 ml air containing 5.7 ppm SO2 which was bubbled through the medium after 0, 1, 2, or 3 days of incubation. Cell growth and DNA synthesis were reduced and chromosomal abnormalities, mainly chromosomal clumping, were observed. The authors suggest that lymphocyte damage caused by sulfur dioxide exposure may explain the reduced immunological responses of laboratory animals after SO2 inhalation in vivo. Other workers have found that rabbits exposed seven hours per day for 113 days to air containing 8 ppm SO2 showed a reduced formation of agglutinins and conclude that chronic exposure to low SO2 concentrations decreases the effectiveness of the immune response and resistance to infections.

The Select Committee considered the possibility that inhalation exposure would add an additional burden of SO2 that should be considered in discussion of exposure to sulfiting agents in foods. Conditions might exist where the load of inhaled SO2 could be equal to or greater than that of dietary SO2. However, there is evidence to indicate that at prevailing levels, most air-borne SO2 is rapidly oxidized to sulfate before inhalation or in the respiratory tract. Because the sulfuric acid formed has greater irritant properties than sulfuric acid, it is difficult to make dose-response interpretations. From the information available, the Select Committee is unable to estimate the contribution made to total SO2 load from that present in inspired air.2

Qualified scientists of the Select Committee have evaluated all available safety information on the sulfiting agents. In the Select Committee's opinion:

Based upon chronic toxicity tests in animals, primarily in rats, the no observed adverse effect level of SO2 is estimated to be in the range of 30 to 100 mg of SO2 per kg of body weight per day. These values are considerably higher than the estimated average per capita consumption of about 0.2 mg of SO2 equivalent per kg body weight per day, and well above the estimates of up to 2 mg per kg body weight per day that some individuals may consume if they select foods and beverages relatively high in SO2 content. The margin of only about fifteenfold between the SO2 that may be ingested by high-intake consumers and the lowest estimated no observed adverse effect level is relatively narrow. However, consideration of the significance of this difference should recognize the difficulties in estimating with confidence the components which are the basis of the calculated margin.

While the biological effects of sulfiting agents are still incompletely understood, certain conclusions are warranted. There is no reason to believe that the direct, local, irritating effects of sulfite, as seen in high-dose acute toxicity tests, constitute a hazard from ingestion of sulfiting agents as they are presently used in foods. Orally administered sulfite is very rapidly oxidized to sulfate in all species studied. The metabolic removal of sulfite appears to be the critical defense mechanism, and this points to the important role of the enzyme, sulfite oxidase. Congenital deficiency of hepatic sulfite oxidase has been described as a rare metabolic disorder in man. There is also a paucity of data on the normal development of this enzyme with age in various species, and on the possible effects of dietary factors and disease on sulfite oxidase activity. Moreover, sulfite is capable of deaminating cytosine in vitro and inhibiting several enzymes requiring NAD or pyridoxal as cofactors which suggests that sulfite might be toxic in vivo if sulfite oxidase activity were sufficiently impaired. The metabolic mechanism were sufficiently overloaded, to prevent rapid oxidation of ingested sulfite to sulfate. Information in these respects would be helpful in assessing any special risk factors that may apply for select subpopulations.

While there is no evidence that the sulfiting agents are teratogenic, there is evidence that directly added sulfite produces mutations in bacteria by alteration of nucleic acids. None of the available mammalian in vivo studies confirms these observations. Because the same organisms are not affected in the host-mediated assay, it seems reasonable to infer that rapid destruction of sulfite by the host's sulfite oxidase provides protection.3

The Select Committee concludes that no evidence in the available information on potassium bisulfite, potassium metabisulfite, sodium bisulfite, sodium metabisulfite, sodium sulfite, and sulfur dioxide demonstrates, or presents reasonable grounds to suspect, a hazard to the public when these substances are used at levels that are now current and in the manner now practiced. However, the Select Committee also states that it is not possible to determine, without additional data, whether a significant increase in consumption would constitute a dietary hazard.

FDA has undertaken its own evaluation of all available information on sulfiting agents and concurs with the conclusions of the Select Committee. Based upon available safety data, the

2 Ibid. pp. 6-13.
agency concludes that potassium metabisulfite, sodium bisulfite, sodium metabisulfite, and sulfur dioxide should be affirmed as GRAS with specific limitations placed upon their use. The treatment levels set forth in this proposal for various food categories are the maximum levels reported to the NAS/NRC in their 1977 survey of food manufacturers on the use of GRAS ingredients. The agency encourages the submission of other food uses for these ingredients that may not have been reported during the 1977 survey as comments on this proposal. Each report of an additional use should include the maximum treatment level and the resulting residue level of the sulfiting agent remaining in the food when consumed, so that the agency may determine whether a significant increase in consumption of sulfiting agents will result from these new reported uses. FDA will address any changes in the regulatory status of the subject compounds when it issues the final rule.

Regarding potassium bisulfite and sodium sulfite, FDA proposes to revoke their GRAS status as direct human food ingredients. No evidence was provided to NAS/NRC during either the 1970 or the 1977 survey of the food industry to indicate that potassium bisulfite is used in foods. Although total poundage information was provided on sodium sulfite, the only food use reported for sodium sulfite was as a boiler water additive. This use of sodium sulfite is covered by § 173.310. No information pertaining to the GRAS use of sodium sulfite is currently available, and FDA is assuming that its use in the washing of sweet potatoes and any other uses have been discontinued.

As discussed earlier, a prior sanction exists for the use of sodium sulfite and sulfur dioxide at levels of 200 to 300 parts per million in molasses, dried fruits, and other foods that are not good sources of vitamin Bi. However, FDA is not proposing to revise Part 181 (21 CFR Part 181) to list specifically this prior sanctioned use for which the agency has no evidence that this use of sodium sulfite and sulfur dioxide is a current use. If current evidence of this use is submitted in response to this proposal, FDA will consider establishing a prior sanction regulation under Part 181 or affirming the reported use as GRAS under Part 184.

In previous GRAS affirmation proposals, FDA emphasized that use information (i.e., foods to which the ingredient is added, the intended technical effect, and the levels of addition) is very important in assessing the safety of GRAS food ingredients. Because the agency does not have any evidence of food use for potassium bisulfite or sufficient information relating to the GRAS food uses of sodium sulfite, FDA cannot establish limitations on the use of these sulfiting agents. Consequently, the agency is proposing not to affirm potassium bisulfite and sodium sulfite as GRAS and to remove them from the list of substances that are GRAS. FDA will reconsider their regulatory status if adequate use information of the type cited above is submitted. FDA is especially interested in comments on potassium bisulfite because this ingredient is a possible substitute for sodium bisulfite. The agency considers such a substitution desirable because of FDA’s interest in reducing the level of total sodium consumption in the United States. Comments on the uses of potassium bisulfite and sodium sulfite should provide specific information on the maximum treatment level and resulting residue level remaining in the food as consumed, food categories, and technical effects. Alternatively, persons seeking FDA approval of the use of potassium bisulfite and sodium sulfite may submit a GRAS or food additive petition in accordance with §§ 170.35 and 171.1.

Copies of the scientific literature review on sulfiting agents; reports of teratogenic and mutagenic evaluations for potassium metabisulfite, sodium bisulfite, and sodium metabisulfite; a report of the mutagenic evaluation for sodium sulfite; and the report of the Select Committee are available for review at the Dockets Management Branch (address above), and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, as follows:

<table>
<thead>
<tr>
<th>Title</th>
<th>Order No.</th>
<th>Price code</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfiting agents (selective literature review).</td>
<td>PB-221-217</td>
<td>A09</td>
<td>$12.00</td>
</tr>
<tr>
<td>Potassium metabisulfite (teratologic evaluation).</td>
<td>PB-245-529/AS</td>
<td>A03</td>
<td>6.00</td>
</tr>
<tr>
<td>Potassium metabisulfite (mutagenic evaluation).</td>
<td>PB-245-465/AS</td>
<td>A03</td>
<td>6.00</td>
</tr>
<tr>
<td>Sodium bisulfite (teratologic evaluation).</td>
<td>PB-221-785</td>
<td>A03</td>
<td>6.00</td>
</tr>
<tr>
<td>Sodium bisulfite (mutagenic evaluation).</td>
<td>PB-245-456/AS</td>
<td>A06</td>
<td>9.00</td>
</tr>
<tr>
<td>Sodium metabisulfite (teratologic evaluation).</td>
<td>PB-221-785</td>
<td>A03</td>
<td>6.00</td>
</tr>
<tr>
<td>Sodium metabisulfite (mutagenic evaluation).</td>
<td>PB-221-825</td>
<td>A06</td>
<td>9.00</td>
</tr>
<tr>
<td>Sodium sulfite (mutagenic evaluation).</td>
<td>PB-245-488/AS</td>
<td>A03</td>
<td>6.00</td>
</tr>
</tbody>
</table>

The format of the proposal is different from that in previous GRAS affirmation regulations. The agency has modified the form in which the specific limitations on the use of these ingredients is presented. This change has no substantive effect but is made merely to clarify the effect of the regulation.

This proposed action does not affect the current use of sulfiting agents in pet food or animal feed, nor does it affect the regulated or prior-sanctioned food uses of sulfiting agents addressed in this document.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and has determined that the effect of this proposal is to maintain current known uses of the substances covered by this proposal by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal, and the agency has determined that it will not result in a major rule as defined by the Order.

List of Subjects in 21 CFR

<table>
<thead>
<tr>
<th>Part 182</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Part 184</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.</td>
</tr>
</tbody>
</table>

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1785, as amended (21 U.S.C. 321(s), 344, 371(a)) and under authority delegated
to the Commissioner of Food and Drugs
[21 CFR 5.10], it is proposed that Parts
182 and 184 be amended as follows:

PART 182—SUBSTANCES
GENERALLY RECOGNIZED AS SAFE

§§ 182.3616, 182.3637, 182.3739, 182.3766,
182.3798, and 182.3862 [Removed]

1. Part 182 is amended by removing
§ 182.3616 Potassium bisulfite,
§ 182.3637 Potassium metabisulfite,
§ 182.3739 Sodium bisulfite, § 182.3766
Sodium metabisulfate, § 182.3798
Sodium sulfate, and § 182.3862 Sulfur
dioxide.

PART 184—DIRECT FOOD
SUBSTANCES AFFIRMED AS
GENERALLY RECOGNIZED AS SAFE

2. Part 184 is amended:

a. By adding new § 184.3637 to read as follows:

§ 184.3637 Potassium metabisulfite.

(a) Potassium metabisulfite (K₂S₂O₅, CAS
Reg. No. 004429-42-9) is also referred to as
potassium pyrosulfite. It is prepared by
heating potassium bisulfite until it loses water or
by treating aqueous potassium bisulfite with excess
sulfur dioxide.

(b) The ingredient meets the
specifications of the Food Chemicals
Codex, 3d Ed. (1981), p. 279, which is
incorporated by reference. Copies are
available from the National Academy
Press, 2101 Constitution Ave. NW.,
Washington, DC 20418, or available for
inspections at the Office of the Federal
Register, 1100 L St. NW., Washington, DC
20008.

(c) In accordance with § 184.1(b)(2),
the ingredient is used to treat food;
except food recognized as a source of
vitamin B₉, only within the following
specific limitations:

<table>
<thead>
<tr>
<th>Category of food</th>
<th>Maximum treatment level in food (percent)</th>
<th>Functional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baked goods and baking mixes, § 170.3(n)(1) of this chapter.</td>
<td>0.0045</td>
<td>Dough, strengthening, § 170.3(o)(6) of this chapter; texturizer, § 170.3(o)(32) of this chapter.</td>
</tr>
<tr>
<td>Beverages, alcoholic, § 170.3(n)(2) of this chapter.</td>
<td>0.3</td>
<td>Antimicrobial agent, § 170.3(o)(2) of this chapter; antioxidant, § 170.3(o)(3) of this chapter.</td>
</tr>
<tr>
<td>Condiments and relishes, § 170.3(n)(8) of this chapter.</td>
<td>0.035</td>
<td>Antimicrobial agent, § 170.3(o)(2) of this chapter.</td>
</tr>
<tr>
<td>Daily product analogs, § 170.3(n)(10) of this chapter.</td>
<td>0.03</td>
<td>Do.</td>
</tr>
<tr>
<td>Fish products, § 170.3(n)(12) of this chapter.</td>
<td>0.085</td>
<td>Do.</td>
</tr>
<tr>
<td>Grain products and pastas, § 170.3(n)(23) of this chapter.</td>
<td>0.035</td>
<td>Antimicrobial agent, § 170.3(o)(2) of this chapter; pH control agent, § 170.3(o)(23) of this chapter.</td>
</tr>
<tr>
<td>Processed fruits and fruit juices, § 170.3(n)(32) of this chapter.</td>
<td>0.025</td>
<td>Antimicrobial agent, § 170.3(o)(2) of this chapter; antioxidant, § 170.3(o)(3) of this chapter.</td>
</tr>
<tr>
<td>Processed vegetables and vegetable juices, § 170.3(n)(36) of this chapter.</td>
<td>0.1</td>
<td>Antimicrobial agent, § 170.3(o)(2) of this chapter; antioxidant, § 170.3(o)(3) of this chapter; processing aid, § 170.3(o)(24) of this chapter.</td>
</tr>
<tr>
<td>Sweet sauces, toppings, and syrups, § 170.3(n)(42) of this chapter.</td>
<td>0.004</td>
<td>Antimicrobial agent, § 170.3(o)(2) of this chapter; antioxidant, § 170.3(o)(3) of this chapter; oxidizing and reducing agent, § 170.3(o)(23) of this chapter.</td>
</tr>
</tbody>
</table>

b. By adding new § 184.3739 to read as follows:

§ 184.3739 Sodium bisulfite.

[a] Sodium bisulfite (NaHSO₂, CAS
Reg. No. 007631-90-5) is also referred to
as sodium acid sulfite or sodium
dihydrogen sulfite. It is prepared by
passing sulfur dioxide through a solution
of sodium carbonate until it is saturated
and then crystallizing the sodium
bisulfite from solution.

(b) The ingredient meets the
specifications of the Food Chemicals
Codex, 3d Ed. (1981), p. 279, which is
incorporated by reference. Copies are
available from the National Academy
Press, 2101 Constitution Ave. NW.,
Washington, DC 20418, or available for
inspections at the Office of the Federal
Register, 1100 L St. NW., Washington, DC
20008.

(c) In accordance with § 184.1(b)(2),
the ingredient is used to treat food;
except food recognized as a source of
vitamin B₉, only within the following
specific limitations:

<table>
<thead>
<tr>
<th>Category of food</th>
<th>Maximum treatment level in food (percent)</th>
<th>Functional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baked goods and baking mixes, § 170.3(n)(1) of this chapter.</td>
<td>0.04</td>
<td>Antimicrobial agent, § 170.3(o)(5) of this chapter; antioxidant, § 170.3(o)(6) of this chapter.</td>
</tr>
<tr>
<td>Beverages, alcoholic, § 170.3(n)(2) of this chapter.</td>
<td>0.003</td>
<td>Antimicrobial agent, § 170.3(o)(5) of this chapter; antioxidant, § 170.3(o)(6) of this chapter.</td>
</tr>
<tr>
<td>Gravies and sauces, § 170.3(n)(24) of this chapter.</td>
<td>0.016</td>
<td>Antioxidant, § 170.3(o)(23) of this chapter.</td>
</tr>
<tr>
<td>Sweet sauces, toppings, and syrups, § 170.3(n)(42) of this chapter.</td>
<td>0.15</td>
<td>Do.</td>
</tr>
</tbody>
</table>

d. By adding new § 184.3862 to read as follows:

§ 184.3862 Sulfur dioxide.

(a) Sulfur dioxide (SO₂, CAS
Reg. No. 007446-09-5) is also referred to as
sulfurous anhydride. It is prepared by
burning elemental sulfur in air, by
roasting pyrites, or by reducing calcium
sulfate with coke.

(b) The ingredient meets the
specifications of the U.S. Pharmacopeia
(USP), XIX, 1975, p. 577, which is
incorporated by reference. Copies are
available from the U.S. Pharmacopeial
Convention, Inc., 12801 Twinbrook
Parkway, Rockville, MD 20852, or
available for inspection at the Office of
the Federal Register, 1100 L St. NW.,
Washington, DC 20008.

(c) In accordance with § 184.1(b)(2),
the ingredient is used to treat food,
except food recognized as a source of vitamin B₆, only within the following specific limitations:

<table>
<thead>
<tr>
<th>Category of food</th>
<th>Maximum treatment level in food (per cent)</th>
<th>Functional use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beverages, alcoholic, § 170.3(o)(2) of this chapter, Gelatinos, puddings, and fillings, § 170.3(o)(23) of this chapter, Processed fruits and fruit juices, § 170.3(o)(25) of this chapter, Sugar, white, granulated, § 170.3(o)(41) of this chapter,</td>
<td>0.025 Antimicrobial agent, § 170.3(o)(2) of this chapter; antioxidant, § 170.3(o)(3) of this chapter; pH control agent, § 170.3(o)(20) of this chapter.</td>
<td>Antimicrobial agent, § 170.3(o)(2) of this chapter.</td>
</tr>
<tr>
<td></td>
<td>0.05 Antimicrobial agent, § 170.3(o)(2) of this chapter.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.4 Antimicrobial agent, § 170.3(o)(2) of this chapter.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.001 Antimicrobial agent, § 170.3(o)(2) of this chapter; antioxidant, § 170.3(o)(3) of this chapter.</td>
<td></td>
</tr>
</tbody>
</table>

Dated: June 18, 1982.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-19442 Filed 7-8-82; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 182

[Docket No. 80N-0108]

Ethyl Acrylate and Methyl Acrylate; Proposed Removal From GRAS Status as Indirect Human Food Ingredients

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing not to affirm ethyl acrylate and methyl acrylate as generally recognized as safe (GRAS) as indirect food ingredients and to remove them from the list of substances that are GRAS for use in the manufacture of paper and paperboard products. The safety of these ingredients has been evaluated under a comprehensive safety review conducted by the agency. The agency is proposing not to affirm ethyl acrylate and methyl acrylate as GRAS because there is no evidence the ethyl acrylate monomer and methyl acrylate monomer are used in the manufacture of paper and paperboard products except as components of polymers which are covered under food additive regulations and prior-sanctioned listings.

DATE: Comments by September 7, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Lawrence Lin, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-372-4750.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive safety review of human food ingredients classified as GRAS or subject to a prior sanction. The agency has issued several notices and proposed regulations (see the Federal Register of July 26, 1973 (38 FR 20340)) initiating this review, under which the safety of ethyl acrylate and methyl acrylate, including monomers and polymers, has been evaluated. In accordance with the provisions of § 170.35 (21 CFR 170.35), the agency proposes not to affirm the GRAS status of ethyl acrylate and methyl acrylate and to remove them from the GRAS list because the monomers are not used in the manufacture of paper and paperboard products except as components of polymers that are covered under food additive regulations and prior-sanctioned listings.

Ethyl acrylate and methyl acrylate are both colorless, volatile, lacrimatory liquids. They easily polymerize on standing but are stable when stored below 10° C. Ethyl acrylate and methyl acrylate are miscible with alcohol and ether and are slightly soluble in water. Ethyl acrylate occurs in such fruits as pineapples and raspberries and has an intense, penetrating, fruity odor. Methyl acrylate has an unpleasant, acrid odor, and it is not known to occur naturally. Both compounds can be synthesized from ethylene chlorohydrin with sulfuric acid and ethanol or methanol and from acetylene, carbon monoxide, and ethanol or methanol in the presence of suitable catalysts.

Ethyl acrylate and methyl acrylate are listed in § 182.90 (21 CFR 182.90) as substances migrating to food from paper and paperboard products used in food packaging under regulations published in the Federal Register of June 17, 1961 (26 FR 5421). Films made from ethyl acrylate resin and methyl acrylate resin were prior-sanctioned by the U.S. Department of Agriculture for use in contact with federally inspected meat food products. Methyl acrylate polymer and ethyl acrylate and methyl methacrylate copolymers of itaconic acid or methacrylic acid are listed as prior-sanctioned in § 181.30 (21 CFR 181.30) for use in the manufacture of paper and paperboard that is waxed.

Ethyl acrylate polymer and methyl acrylate polymer are listed in § 175.105 (21 CFR 175.105) as components of adhesives; in § 175.300 (21 CFR 175.300) as components of resins and polymeric coatings; in § 175.320 (21 CFR 175.320) as components of resins and polymeric coatings for polyolefin films; in § 175.380 (21 CFR 175.380) as components of xylene-formaldehyde resins condensed with 4,4'-isopropylidene-diphenol-epichlorohydrin epoxy resins; in § 175.390 (21 CFR 175.390) as components of acrylic and modified acrylic plastics, semirigid and rigid; and in § 177.1210 (21 CFR 177.1210) as components of closures with sealing gaskets for food containers.

Ethyl acrylate copolymer and methyl acrylate copolymer are regulated in § 175.390 (21 CFR 175.390) as components of vinylidene chloride...
copolymer coatings for nylon film; in § 176.170 (21 CFR 176.170) as components of paper and paperboard in contact with aqueous and fatty foods; in § 177.1630 (21 CFR 177.1630) as components of polyethylene phthalate polymers; and in § 177.2420 (21 CFR 177.2420) as components of polyester resins, cross-linked.


Methyl acrylate copolymer is regulated in § 173.25 (21 CFR 173.25) as a component of ion-exchange resins; in § 175.365 (21 CFR 175.365) as a component of vinylidene chloride copolymer coatings for polycarbonate film; in § 177.1340 (21 CFR 177.1340) as a component of ethylene-methyl acrylate copolymer resins; and in § 177.1600 (21 CFR 177.1600) as a component of carboxyl modified polyethylene resins.

Ethyl acrylate, methyl acrylate and their polymers have been the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity or mutagenicity, (7) dose response, (8) reproductive effects, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 65 abstracts was reviewed and 36 particularly pertinent reports from the literature survey have been summarized in a scientific literature review.

Information from the scientific literature review has been summarized in a report to FDA by the Select Committee on GRAS substances (Select Committee), which is composed of qualified scientists chosen by the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (FASEB). The members of the Select Committee have carefully evaluated all the available safety information on ethyl acrylate, methyl acrylate, and their polymers.1 In the Select Committee’s opinion:

The amounts of monomeric and polymeric methyl and ethyl acrylates that may migrate to foods from paper and paperboard used in food packaging are limited by regulation.

Measurements made under severest conditions of extraction, show that human exposure to these substances from food packaged in materials containing them is less than 1 mg per kg body weight per day, and is probably considerably less than this figure under usual conditions.

While it has been shown that both monomers are absorbed from the gastrointestinal and respiratory tracts and from the skin, no absorption studies of the polymers have been made and the metabolic fate of the monomers and polymers has not been elucidated. However, no adverse effects have been observed and no pathological changes encountered in animals consuming up to 23 mg per kg of the methyl monomer for 33 days, or up to 280 mg per kg of the ethyl monomer for two years. Polyethyl acrylate, but not polymethyl acrylate, has been fed for eight weeks at a dose of 5.5 g per kg body weight and a formulation containing both polyethyl acrylate and polymethylacrylate has been fed for six months at a dose of 2.5 g per kg body weight without appearance of toxic or pathological effects.

The biological data on the monomers and on polylethyl acrylate, when related to estimates of human exposure that might occur due to migration of these substances from packaging materials, raise no concern about the safety of current practices. However, no biological studies upon which evaluation of the methyl polymer can be based have been reported.1

The Select Committee concludes that there is no evidence in the available information on monomeric ethyl acrylate, monomeric methyl acrylate, or polymeric ethyl acrylate that demonstrates or suggests reasonable grounds to suspect, a hazard to the public when they are used in paper and paperboard food-packaging materials as now practiced, or as they might be expected to be used for such purposes in the future.

In view of the deficiency of relevant biological studies, the Select Committee has insufficient data upon which to base an evaluation of polymeric methyl acrylate when it is used as an ingredient of food packaging materials.2

Based on own evaluation of the available information on monomeric ethyl acrylate and methyl acrylate, FDA concurs with the conclusions for these compounds. However, based on the greater volatility and reactivity of the monomers compared to the polymers, the agency concludes that any hazard to the public resulting from the use of polymeric ethyl acrylate and methyl acrylate in paper and paperboard food-packaging materials is a consequence of the migration of the respective monomers to food. Therefore, the agency concludes that the Select Committee’s conclusion regarding the safety of the use of monomers in paper and paperboard food-packaging materials applies also to the use of polymers in these materials.

In addition, FDA has no information indicating that ethyl acrylate monomer and methyl acrylate monomer have been used in paper and paperboard food-packaging materials except as components of polymers. The monomers are volatile, and, to be functional as an ingredient of paper and paperboard products, they must be polymerized to some extent before use in the manufacture of such products.

Therefore, the agency finds that because the monomers are not themselves useful and functional in the manufacture of paper products and have not been used as such in those products, it is inappropriate to affirm the GRAS status of the monomers. The agency also finds that it is unnecessary to address the GRAS status of ethyl acrylate and methyl acrylate polymers because all known uses of these substances are covered under the existing food additive regulations and prior-sanctioned listings. Consequently, the agency is proposing not to affirm the GRAS status of ethyl acrylate, methyl acrylate, and their polymers as indirect human food ingredients.

This proposal does not affect the uses of acrylate polymers permitted by other regulations or the use of ethyl acrylate as a synthetic flavoring substance.

1Ibid., p. 8.

2Ibid., p. 9.
This proposal does not affect the current use of ethyl acrylate, methylacrylate or their polymers in pet food or animal feed.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71746) that the action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In accordance with the Regulatory Flexibility Act, FDA has considered the effect that this proposal would have on small entities including small businesses and has determined that the effect of this proposal is to maintain current known uses of the substances as components of polymers that are covered under food additive regulations and prior-sanctioned listings. FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal, and the agency has determined that it will not result in a major rule as defined by that Order.

List of Subjects in 21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients; Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1786 as amended [21 U.S.C. 321(s), 348, 371(a)]) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is proposed that Part 182 be amended in § 182.90 Substances migrating to food from paper and to remove it from the list of substances that are GRAS. The safety of this ingredient is being evaluated under a comprehensive safety review being conducted by FDA. Because of the absence of sufficient safety information, it is not possible to affirm the safety of the ingredient for GRAS use. The proposed action does not affect the present food additive regulated use of Japan wax.

DATE: Comments by September 9, 1982.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 15, 1982; 4–42, 5600 Fishers Lane, Rockville, MD 20857.


SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive review of human food ingredients classified as GRAS or subject to a prior sanction. The agency has issued several notices and proposed regulations (see the Federal Register of July 29, 1973 [38 FR 20040]), initiating this review. Under this review, the safety of Japan wax has been evaluated. In accordance with the provisions of § 170.35 (21 CFR 170.35), the agency proposes to delete this ingredient from the GRAS list. The use of Japan wax as an indirect food ingredient will continue under existing food additive regulations.

Japan wax is a tallow obtained from the fruits of the oriental sumac, Rhus succedanea (Japan, Taiwan, and Indo-China), R. vernicifera (Japan) and R. trichocarpa (China, Indo-China, India, and Japan). Japan wax is prepared mostly from the mesocarp by hot pressing the immature fruit. Depending upon the method of preparation, the commercial tallow may contain more or less of the kernel fat that alters its melting range. Japan wax may be bleached by exposing flakes to sunlight for some days or weeks. The wax is unusual in that it contains glycerides of the C16-C18 dibasic acids and also has a particularly high content of tripalmitin. The forms are credited with giving Japan wax its characteristic properties of toughness and ability to be kneaded without crumbling.

Japan wax is used in the manufacture of candles, wax matches, pomades, creams, polishes, textile finishes, and sizing. It is also used as a lubricant for cordage and leather dressing.

Japan wax is currently listed in § 182.70 (21 CFR 182.70) as a GRAS substance migrating from cotton and
cotton fabrics used in dry food packaging, under a regulation published in the *Federal Register* of June 10, 1961 (26 FR 5224). As a regulated substance, Japan wax is listed in § 73.1(b)(2) (21 CFR 73.1(b)(2)) for use in diluents in color additive mixtures for coloring shell eggs, in § 175.105 (21 CFR 175.105) for use in adhesives, in § 175.350 (21 CFR 175.350) for use as an optional substance in vinyl acetate/crotonic acid copolymers, in § 176.170 (21 CFR 176.170) for use as a component of paper and paperboard in contact with aqueous and fatty foods.

No information was requested on Japan wax during the National Academy of Sciences/National Research Council (NAS/NRC) survey of food manufacturers on the use of GRAS ingredients in food, and none was submitted. However, information from other sources indicates that in recent years total annual imports have varied from 321,000 pounds in 1968 to 97,000 pounds in 1972. From the largest annual import it may be calculated, assuming a population of 205 million, that about 2 milligrams are available per person per day. Most domestic consumption is apparently in nonfood uses. Thus, the quantity used in cotton packaging materials for dry foods is likely to be a fraction of a milligram per person per day. No data are available on the extent of migration of Japan wax from packaging material to food, but it is reasonable to assume that only a small percentage of the Japan wax that is present will migrate. It is probable, therefore, that exposure from this source is not more than a small fraction of a milligram per person per day.

Japan wax was the subject of a search of the scientific literature from 1920 to the present. The criteria used in the search were chosen to discover any articles that considered (1) chemical toxicity, (2) occupational hazards, (3) metabolism, (4) reaction products, (5) degradation products, (6) carcinogenicity, teratogenicity, or mutagenicity, (7) dose response, (8) reproductive toxicity, (9) histology, (10) embryology, (11) behavioral effects, (12) detection, and (13) processing. A total of 129 abstracts on beeswax and Japan wax was reviewed, and 11 particularly pertinent reports from the literature survey have been summarized in a scientific literature review. Of the abstracts, six dealt specifically with Japan wax, and one particularly pertinent report was summarized in the review. In addition, eight other sources containing data on Japan wax or its constituents were consulted.

The select Committee on GRAS Substances (the Select Committee), composed of qualified scientists chosen by the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB), has examined the available information on Japan wax. The scientific literature review shows the following information, as summarized in the report of the Select Committee:

Only one early study, involving the feeding of Japan wax to four rats, was available to the Select Committee. Four rachitic rats were fed Japan wax at a 2 percent level (about 2 g per kg of body weight) in their rations. Two animals gained weight over 8 to 16 days and one lost weight; the fourth lost weight and died after 22 days. No anirrachitic effect was produced by feeding the wax.

Digestibility of tripalmitin (M.P. 66.5°C), the major constituent of Japan wax, was determined in adult female rats fed rations containing 15 percent of the triglyceride (about 10 g per kg of body weight). Coefficient of digestibility was 12.8% for rations containing 7 percent of the Osborne-Mendal salt mixture (6.1 mg calcium and 0.9 mg magnesium per gram ration) and 27.9% for rations in which the calcium and magnesium salts had been omitted from the salt mixture.

Digestibility of tripalmitin as a component of a diet containing unsaturated fats may be higher since increasing the fluidity of saturated fats by the addition of unsaturated fat markedly increases the digestibility.

In vitro mutagenic evaluation of Japan wax using *Saccharomyces cerevisiae*, strain D4 and *Salmonella typhimurium*, strains TA-1530, TA-1537, and TA-1538, with and without metabolic activation with liver, lung, kidney or testis homogenates from mice, rats, or monkeys revealed that it exhibits no genetic activity. Dimethylsulfoxide was used as the solvent; dose levels of the wax were 0.015 to 0.060 percent in the *Salmonella* tests and 0.125 to 0.500 percent in the tests with *Saccharomyces*.

No reports were available to the Select Committee on the acute toxicity, long-term feeding carcinogenicity or teratogenicity of Japan wax.

All of the available safety information on Japan wax has been carefully evaluated by the Select Committee. It is the opinion of the Select Committee that: Japan wax is a substance of plant origin which is [listed as] generally recognized as safe (GRAS) as a substance migrating to food from cotton and cotton fabrics used in dry food packaging. However, the Select Committee found no information on the acute toxicity of this substance, or reports of long-term feeding studies, or studies of its carcinogenicity or teratogenicity.

The Select Committee concludes that, in view of the nearly complete lack of biological studies, it has insufficient data upon which to evaluate the safety of Japan wax as a substance migrating to food from cotton and cotton fabrics used in dry food packaging. After considering all available data, including the Select Committee's report, FDA agrees with the conclusion of the Select Committee. However, before deciding on a course of regulatory action, the agency approached a wax trade association to determine whether any of its members could supply additional safety data on Japan wax. The association's response was that there were no additional safety data available. FDA also inquired whether any of the association's members would be willing to conduct or sponsor an LD₅₀ study on the ingredient. The association responded that because the quantity of Japan wax used for food purposes is small, there is no interest in sponsoring this study. FDA concludes, therefore, that Japan wax must be removed from the GRAS list as an ingredient migrating to food from cotton and cotton fabrics because there is insufficient information to affirm it as GRAS. If, however, during the comment period, information is presented that supports the safe use of Japan wax in cotton and cotton fabrics for use in dry food packaging, FDA will reconsider its proposal to remove this ingredient from the GRAS list.

Alternatively, FDA approval for this use of Japan wax may be sought through the GRAS or food additive petition procedures as outlined in § 170.35 (21 CFR 170.35) or § 171.1 (21 CFR 171.1).

FDA has reviewed the regulated uses of Japan wax as a diluent in color additive mixtures for shell eggs, as a component of adhesives, as an optional substance in vinyl acetate/crotonic acid copolymers, and as a component of paper and paperboard in contact with aqueous and fatty foods. The agency concludes that these regulated uses of Japan wax may continue pending their evaluation under the safety review of regulated food additives.

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Copies of the scientific literature review of Japan wax, the mutagenic screening test for the ingredient, and the report of the Select Committee are available for review at the Dockets Management Branch (address above), and may be purchased from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, as follows:

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<th>Order No.</th>
<th>Price code</th>
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<td>Beeswax and Japan wax (scientific literature review)</td>
<td>PB-233-854/AS</td>
<td>A03</td>
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<tr>
<td>Japan wax (Select Committee report)</td>
<td>PB-262-657/AS</td>
<td>A02</td>
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<tr>
<td>Japan wax (mutagenic evaluation, tier I, microbial test)</td>
<td>PB-254-513/AS</td>
<td>A03</td>
<td>6.00</td>
</tr>
</tbody>
</table>

¹ Price subject to change.

This proposed action does not affect the present use of Japan wax in pet food or animal food.

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1978; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and has concluded that the removal of Japan wax from the GRAS list will not cause measurable economic effect. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal and the agency has determined that the proposal will not result in a major rule as defined by the Order.

List of Subjects in 21 CFR Part 182

- Generally recognized as safe (GRAS) food ingredients; Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1786 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), it is proposed that Part 182 be amended in §182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging by removing the entry for “Japan wax”.

The agency hereby gives notice that it is unaware of any prior sanction for the use of this ingredient in food under conditions different from those identified in this document. Any person who intends to assert or rely on such a sanction shall submit proof of its existence in response to this proposal.

The regulation proposed above will constitute a determination that excluded prior-sanctioned uses would result in adulteration of the food in violation of section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), and the failure of any person to come forward with proof of an applicable prior sanction in response to this proposal constitutes a waiver of the right to assert or rely on it later. Should any person submit proof of the existence of a prior sanction, the agency hereby proposes to recognize such use by issuing an appropriate regulation under Part 181 (21 CFR Part 181) or affirming it as GRAS under Part 184 or 186 (21 CFR Part 184, 186), as appropriate.

Interested persons may, on or before September 7, 1982 submit to the Docket Management Branch (address above), written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 14, 1982.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[BFR Doc. 82-21443 Filed 7-6-82; 8:45 am]
BILLING CODE 4160-01-M
Part III

Department of Labor

Employment Standards Administration,
Wage and Hour Division

Minimum Wages for Federal and
Federally Assisted Construction; General
Wage Determination Decisions
DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 308 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, 'Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 12-71 and 15-71 (36 FR 8735, 8736). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and Supersedeas Decisions to General Wage Determination Decisions

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

*The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 308 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, 'Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 12-71 and 15-71 (36 FR 8735, 8736). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the Federal Register without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Office of Government Contract Wage Standards, Division of Government Contract Wage Determinations, Washington, D.C. 20210.

The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

Modifications 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.

Maryland: DCB1-3040 .................................................. June 5, 1981.
Virginia: DCB1-3040 .................................................. June 5, 1981.
Georgia: GA82-2041 ............................................. June 25, 1982.
South Carolina: GA82-2041 ............................................. June 25, 1982.

KS82-4017 .................................................. Apr. 16, 1982.

California: CA82-5143 ............................................ Aug. 21, 1981.

CTB1-3032 .................................................. Feb. 15, 1981.

Oregon: OR82-5109 ............................................. Mar. 12, 1982.

Texas: TX82-4033 .................................................. June 18, 1982.
New York: NY81-3000 ............................................. May 1, 1981.

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. Supersedeas decision numbers are in parentheses following the numbers of the decisions being superseded.

Arkansas:
ARB1-3042 (ARB2-4036) .......................................... June 19, 1981.
ARB1-4003 (ARB2-4037) .......................................... June 19, 1981.


Virginia:
VA81-3083 (VA82-3023) .......................................... Nov. 27, 1981.
VA81-3084 (VA82-3022) .......................................... Nov. 27, 1981.
Please note that we are changing the format for Federal Register wage decisions to coincide with the provisions of All Agency Memorandum No. 132 dated January 29, 1980 which provides that the Department will discontinue identifying fringe benefits separately. Rather, they will be stated as a composite figure which is the total hourly equivalent value of fringe benefits found to be prevailing. Fringe benefits which can not be stated in monetary terms will be shown in footnotes. This procedure is being phased in gradually.

Signed at Washington, D.C., this 2nd day of July 1982.
Dorothy P. Come,
Assistant Administrator, Wage and Hour Division.

BILLING CODE 4510-27-M
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<th>Basic Hourly Rates</th>
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<td>16.44</td>
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<tr>
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<td>Dredge Plant; Fireman</td>
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<td>MWD. #3</td>
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<td>(46 FR 74850 - May 1, 1981)</td>
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<td>CATTARAUGUS, CHAUTAUCA &amp; ERIE COUNTIES, NEW YORK</td>
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<tr>
<td>CARPENTERS:</td>
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<td>Carpenters, Building Millwrights &amp; Pile drivers</td>
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<td><strong>LABORERS, HEAVY &amp; HIGHWAY</strong></td>
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<td>MAY 4, 1982</td>
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<tr>
<td><strong>DESCRIPTION OF WORK:</strong></td>
<td>Building Projects (excluding single family homes and apartments up to and including four stories).</td>
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<tr>
<td><strong>Asbestos workers</strong></td>
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<tr>
<td><strong>Roofers</strong></td>
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<tr>
<td><strong>Boilermakers</strong></td>
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<td><strong>Bricklayers-Stonemasons</strong></td>
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<tr>
<td><strong>Group I</strong></td>
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</tr>
<tr>
<td><strong>Group II</strong></td>
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<td><strong>Group III</strong></td>
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<tr>
<td><strong>Group IV</strong></td>
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<td><strong>Framers</strong></td>
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<td>** basic hourly rate**</td>
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<tr>
<td><strong>plus seven paid holidays</strong></td>
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<tr>
<td>A. 6 mos. to 5 yrs. - 6%</td>
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<tr>
<td>B. 5 yrs. to 8 yrs. - 8%</td>
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</tr>
<tr>
<td>C. 8 yrs. to 10 yrs. - 10%</td>
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</tr>
<tr>
<td>D. 10 yrs. to 12 yrs. - 12%</td>
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<tr>
<td>E. 12 yrs. to 15 yrs. - 15%</td>
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<tr>
<td>F. 15 yrs. to 20 yrs. - 20%</td>
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<tr>
<td>G. 20 yrs. to 25 yrs. - 25%</td>
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<tr>
<td>H. 25 yrs. &amp; over - 30%</td>
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<td><strong>Glaziers</strong></td>
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<td><strong>Welders</strong></td>
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<td><strong>basic hourly rate</strong></td>
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<td><strong>Group IV</strong></td>
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<td><strong>Group V</strong></td>
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<tr>
<td><strong>Group VI</strong></td>
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<td><strong>Group VII</strong></td>
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<td><strong>LINE CONSTRUCTION:</strong></td>
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<tr>
<td><strong>Linemen-Operators</strong></td>
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<td><strong>Cable splicers</strong></td>
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<td><strong>Groundmen</strong></td>
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<td><strong>basic hourly rate</strong></td>
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<tr>
<td><strong>basic hourly rate</strong></td>
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<td><strong>UNLISTED classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contracts (29 CFR, 5.5 (a)(1)(I)).</strong></td>
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</table>
LABORERS LABORERS CLASSIFICATION DEFINITIONS

GROUP I - Construction laborer-concrete, wrecking, carpenters, drywall, mechanics, excavating, plumbers and electricians laborers, iron cutter, bricopipe, and crete pump hose placer.

GROUP II - Semi-skilled labor - pipelayers, concrete, clay, and mechanical tool, cement mixer, wet or dry finishers and plasterers, mason tenders, mortar mixers, asphalt rakers and shovellers, crosscut wood handlers, chuck tender.

GROUP III - Skilled "A" - Steelform setters, curb and gutters, grout, and cement muckers

GROUP IV - Skilled "B" - Swinging scaffold, baro, 90lb pavement breaker and burners.

GROUP V - Nozelman (gruite, grout, and sandblasters); concrete pump (moatle placer).

GROUP VI - Powderman and blaster

GROUP VII - Wagon drill

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP I - Cranes, draglines, shovels and pipelayers with a lifting capacity of 50 tons or over, and operators of all towers, climbing cranes, and derricks required to work 25 feet or over from the ground, blacksmith, mechanics.

GROUP II - Hydraulic cranes, cherry pickers, backhoes and all derricks with a lifting capacity less than 50 tons, as specified by the manufacturers, all backhoes, tractor or truck type, all over- and traveling cranes, or operators with swining boom attachments, graddies, all above equipment irrespective of motive power, leverman (engineer), hydraulic or bucket dredges, ir stories of size.

GROUP III - HEAVY EQUIPMENT OPERATORS: All bulldozers, all front end loaders, all sidebooms, skytracks, all push tractors, all pull scrapers, all motor graders, all trenching machines, regardless of size or motive power, all back fillers all mixing plants, 100 and larger, finishing machines, all boiler firemen high or low pressure, all asphalt spreaders, hydraulic truck crane, multiple drum hoist, irrespective of motive power, all rotary, all cable core drill or churn drill, water well and foundation drilling machines regardless of size, regardless of motive power and dredge tender operator.

GROUP IV - LIGHT EQUIPMENT OPERATORS: Oilideriver motor crane, single drum hoists, winches and air tuggers, irrespective of motive power, winch or A-frame trucks, forklifts, rollers of all types and pull tractors, regardless of size, elevator operators inside and outside when used for carrying workmen from floor to floor & handling building material, Lod-A-Vator, conveyor, batch plant, and motor or concrete mixers, below 100, and dump Euclid, pumperete, spray drill or churn drill, water well and foundation drilling machines regardless of size, all equipment, welding machines light plants, pumps, all well point system dw-watering and portable pumps, space heater, irrespective of size, and motive power, equipment greaser, oiler, asphalt distributor, and like equipment, safety boat operator and deckhand.

SUPERSEDES DECISION

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<th>COUNTY: JEFFERSON</th>
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<tr>
<td>SUPERSEDES DECISION AR81-4043 dated June 19, 1981 in 46FR12175</td>
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<td>DESCRIPTION OF WORK: Building Projects (including single family homes and apartments up to and including four stories).</td>
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<th>Basic Fringe Hourly Benefits</th>
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Asbestos workers $11.25 2.05 Roofers $11.81 .10
Boilermakers 16.35 2.415 Sheet metal workers 12.96 1.65
Bricklayers-Stonemasons 12.00 1.44 Sprinkler fitters 14.57 1.83
Carpenters: Group I 11.40 1.06 Power equipment operators 13.22 1.25
Millwrights-Piledrivermen, Cement masons 11.50 1.06 Group II 11.97 1.25
ELECTRICIANS: Group III 12.40 1.25 Group IV 9.38 1.25
Electricians 14.20 3%+2.15
Cable splicers 18.25 3%+2.15
ELEVATOR CONSTRUCTORS:
Journeymen 12.04 2.33A
Helpers 70KJR 2.33A
Probability helpers 50KJR .25
Glaziers 10.48 .25
Ironworkers 12.80 1.91
LABORERS:
Group I 8.30 1.15
Group II 8.55 1.15
Group III 8.70 1.15
Group IV 8.80 1.15
Group V 8.95 1.15
Group VI 9.20 1.15
Group VII 9.10 1.15
LINE CONSTRUCTION:
Lineman-Operators 13.75 3-7/8
Cable splicers 13.875 3-7/8
Groundmen 65KJR 3-7/8
Winch equipment 73KJR 3-7/8
Marble, tile & terrazzo workers 10.95 .40
PAINTERS:
Painters, paperhangers, steam cleaners, sheetrock finishers and wall coverers 10.45 .53
Spray gun operators and sandblasters 11.05 .53
All skeleton steel & all work on stages, structural steel over 30 ft. machine & pressure grout machine, air compressors, regardless of size, all equipment, welding machines light plants, pumps, all well point system dw-watering and portable pumps, space heater, irrespective of size, and motive power, equipment greaser, oiler, asphalt distributor, and like equipment, safety boat operator and deckhand.

FOOTNOTES:
A. 6 mos. to 5 yrs. - 6% over 5 yrs. - 8% of basic hourly rate; plus seven paid holiday days.

PAID HOLIDAYS:
A-New Year's Day
B-Memorial Day
C-Independence Day
D-Labor Day
E-Thanksgiving Day
F-Day after Thanksgiving
G-Christmas Day

WELDERS--receive rate prescribed for craft performing operation to which welding is incidental.

UNLISTED classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR. 5.5 (a)(1)(ii).
DECISION NO. AM82-4037

LABORERS LABORERS CLASSIFICATION DEFINITIONS

GROUP I - Construction laborer-concrete, wrecking, carpenters, dry-wall, mechanics, excavating, plumbers and electricians laborers, green cutter, bimpipe, and crane pump hose placer

GROUP II - Semi-skilled labor - pipelayers, concrete, clay, and mechanical tool, cement mixer, wet or dry finishers and plasterers, mason tenders, mortar mixers, asphalt rakers and shovellers, creosote wood handlers, chuck tender

GROUP III - Skilled "A" - Steelform setters, curb and gutters, grout and cement muckers

GROUP IV - Skilled "B" - Swinging scaffold, barco, 90lb pavement breaker and burners

GROUP V - Nailsman (guitte, swinging, and sandblasters); concrete pump (noseel placer)

GROUP VI - Powderman and blaster

GROUP VII - Wagon drill

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP I - Cranes, draglines, shovels and pile drivers with a lifting capacity of 50 tons or over, and operators of all towers, climbing cranes, and derricks required to work 25 feet or over from the ground, blacksmith, mechanics

GROUP II - Hydraulic cranes, cherry pickers, backhoes and all derricks with a lifting capacity less than 50 tons, as specified by the manufacturer, all backhoes, tractor or truck type, all over-head and traveling cranes, or tractors with swinging boom attachments, gradalls, all above equipment irrespective of motive power, leverman (engineer), hydraulic or bucket dredges, irrespective of size

GROUP III - HEAVY EQUIPMENT OPERATORS: All bulldozers, all front end loaders, all sidehoes, skylifts, all push tractors, all pull scrapers, all motor graders, all trenching machines, regardless of size or motive power, all back fillers all central mixing plants, 105 and larger, finishing machines; all boiler firemen high or low pressure, all asphalt spreaders, hydro truck crane, multiple drum hoist, irrespective of motive power, all rotary, cable tool core drill or churn drill, water well and foundation drilling machines, regardless of size, regardless of motive power and dredge tender operator
group iv - LIGHT EQUIPMENT OPERATORS: Oilfield motor crane, single drum hoists, winches and air tuggers, irrespective of motive power, winch or A-frame trucks, forklifts, rollers of all types and pull tractors, regardless of size, elevator operators inside and outside when used for carrying workmen from floor to floor & handling building material. Lad-A-ATOR, conveyer, batch plant, and mortar or concrete mixers, below 105, end dump Euclid, pumpercre, spray equipment, aching a pressure grout machine, all compressors, regardless of size, all equipment, welding machines light plants, pumps, all well point system de-watering and portable pumps, space hoater, irrespective of size, and motive power, equipment greaser, oiler, asphalt distributor, and like equipment, safety boat operator and deckhand.
<table>
<thead>
<tr>
<th>ZONE 1 - WAYNE, OAKLAND &amp; MACOMB COS.</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLASS 1</td>
<td>10.01 3.94</td>
<td></td>
<td>CLASS 5</td>
<td>11.09 2.19</td>
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<tr>
<td>CLASS 2</td>
<td>10.45 2.19</td>
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<td></td>
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<tr>
<td>CLASS 3</td>
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<tr>
<td>CLASS 4</td>
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</table>

<table>
<thead>
<tr>
<th>LABORERS: HIGHWAY, AIRPORT &amp; BRIDGE CONSTRUCTION</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
<th>Basic Hourly Rates</th>
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<tbody>
<tr>
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<td>CLASS B</td>
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<td>11.41 11.23</td>
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<td>CLASS C</td>
<td>12.22 11.63</td>
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<td>CLASS D</td>
<td>12.41 11.73</td>
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<td>CLASS E</td>
<td>12.60 12.09</td>
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<td>CLASS F</td>
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<td>CLASS G</td>
<td>13.00 11.77</td>
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<td>CLASS H</td>
<td>13.20 12.07</td>
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<td>11.01 10.81</td>
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<table>
<thead>
<tr>
<th>ZONE 7 - SAGINAW, BAY, MIDLAND, GRATIOT, TUSCOLA, ISABELLA, HURON, CLARE, CLAYTON, ARENSBURG, ROGERSBORO, OCEANA COS.</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
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<td>11.16 2.19</td>
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<table>
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<tr>
<th>ZONE 8 - BARRY, CALDWELL, BURNET, BELL, CARROLL, RALPH, HENRY, HENRY, TUSCOLA, RUSA, MICHIGAN CO., OCEANA CO., LIVINGSTON CO.</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
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<table>
<thead>
<tr>
<th>ZONE 9 - SAGINAW, BAY, MIDLAND, GRATIOT, TUSCOLA, ISABELLA, HURON, CLARE, CLAYTON, ARENSBURG, ROGERSBORO, OCEANA COS.</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLASS 1</td>
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<td>8.95 2.19</td>
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<tr>
<td>CLASS 3</td>
<td>8.95 2.19</td>
<td></td>
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</tr>
<tr>
<td>CLASS 5</td>
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<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ZONE 10 - MANISTEE, MASON, HANET, CHEBOYGAN, ARTHUR, CHARLEVOIX, OMAH, HANET, GRAND TRAVERSE, KALASKA</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
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<td>CLASS 2</td>
<td>6.70 2.19</td>
</tr>
<tr>
<td>CLASS 2</td>
<td>6.70 2.19</td>
<td></td>
<td>CLASS 3</td>
<td>6.80 2.19</td>
</tr>
<tr>
<td>CLASS 3</td>
<td>6.80 2.19</td>
<td></td>
<td>CLASS 4</td>
<td>6.85 2.19</td>
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<tr>
<td>CLASS 4</td>
<td>6.85 2.19</td>
<td></td>
<td>CLASS 5</td>
<td>6.95 2.19</td>
</tr>
</tbody>
</table>

FRINGE BENEFITS: Health & Welfare, Pension, Vacation, and Holiday Apprenticeship Training Total $2.44
### Page 4

**ZONE 11 - ENTIRE UPPER PENINSULA**

<table>
<thead>
<tr>
<th>Laborers: Open Cut Construction (Cont'd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1</td>
</tr>
<tr>
<td>Basic Hourly Rates</td>
</tr>
<tr>
<td>Fringe Benefits</td>
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<td>9.79</td>
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<td>Class 3</td>
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<td>10.04</td>
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<tr>
<td>Class 5</td>
</tr>
<tr>
<td>10.09</td>
</tr>
<tr>
<td>2.19</td>
</tr>
</tbody>
</table>

**LINE CONSTRUCTION:**

ZONE 1 - HURON, LAPER, MACOMB, ST. CLAIR, SANILAC, TUSCOLA & WAYNE CO.; INDIAN (Type of Leroy, Locke, Wheatfield, White Oak & Williamson), LENAWEE (Type of Clinton & Macon), LIVINGTON (All but the Type of Tyrone, Cohoctah, Deerfield and Unadilla), MONROE (All but the Type of Bedford, Errie, Lasalle and Whiteford), WASHTENAW (All but the Types of Lyndon, Manchester, Sharon, & Sylvan), OAKLAND (All but the Type of Holly).

- Lineman Technician: 17.38, 1.70, +114%
- Cable Splicer: 18.12, 1.70, +114%

**ZONE 2 - REMAINDER OF STATE**

### Page 5

**DECISION NO. M182-2042**

**LINE CONSTRUCTION (Cont'd)**

<table>
<thead>
<tr>
<th>Combination Truck Driver - Groundman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Hourly Rates</td>
</tr>
<tr>
<td>Fringe Benefits</td>
</tr>
<tr>
<td>7.82</td>
</tr>
<tr>
<td>+.65</td>
</tr>
</tbody>
</table>

**POWER EQUIPMENT OPERATORS:**

ZONE 1 - WAYNE, MONROE, LIVINGTON, WASHINGTON, MACOMB & GENESSEE

- Class 1: 12.73, 4.00, +133%
- Class 2: 12.25, 4.00, +133%
- Class 3: 11.81, 4.00, +133%
- Class 4: 11.67, 4.00, +133%

**ZONE 2 - REMAINDER OF STATE**

- Class 1: 12.73, 4.00, +133%
- Class 2: 12.13, 4.00, +133%
- Class 3: 11.69, 4.00, +133%
- Class 4: 11.44, 4.00, +133%

**POWER EQUIPMENT OPERATORS:**

- Underground Construction

ZONE 1 - WAYNE, OAKLAND, MACOMB, MONROE, LENAWEE, HILLSIDE, BRANCH, CALHOUN, JACKSON, WASHTENAW, LIVINGTON, INGHAM, EATON, CLINTON, SANILAC, TUSCOLA, SAGINAW, GRATIOT, MIDLAND, BAY & HURON CO.

Class 1: 13.73, 3.35+, +133%

Class 2: 13.44, 3.35+, +133%

Class 3: 12.80, 3.35+, +133%

Class 4: 12.29, 3.35+, +133%

### Class A - Landscape Specialist, including air, gas, diesel, electric tool and/or equipment

ZONE 1: 8.60
ZONE 2: 8.18
## DECISION NO. M182-2042

**LOWER EQUIPMENT OPERATORS: STEEL ERECTION (CONT'D)**

<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class A</strong></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>16.55</td>
</tr>
</tbody>
</table>

---

**ZONE 1 - Wayne, Oakland, Macomb, Washtenaw, Monroe, St. Clair, Genesee, Huron, Sanilac & Livingston (Eastern 4 of Co.)**

**Class A**
- Performs all necessary labor uses all tools required to construct & set concrete forms required in the installation of highway & street signs

<table>
<thead>
<tr>
<th><strong>Class B</strong></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.52</td>
<td>12.87</td>
<td></td>
</tr>
</tbody>
</table>

---

**ZONE 2 - Remainder of State**

**Class A**
- Performs all miscellaneous labor, uses all hand & power tools, operates all other equipment, moves or otherwise, required for the installation of highway & street signs

<table>
<thead>
<tr>
<th><strong>Class B</strong></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.70</td>
<td>11.44</td>
<td></td>
</tr>
</tbody>
</table>

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**ZONE 3 - All Counties in Upper Peninsula**

**Class 1**
- 12.04 & 3.35 & 11.42 |

**Class 2**
- 10.72 & 3.35 & 11.42 |

**Class 3**
- 9.61 & 3.35 & 11.42 |

---

**CLASSIFICATION: (Zone 3 only)**

**Class 1** - Operator
**Class 2** - Compressor & Welder
**Class 3** - Oiler & Fireman

**NOTES:**
- 1-Cranes with Boom & Jib of 220' or longer, Tower Cranes & Derrick -- $5.75 per hour more than Class 1
- 2-Cranes with Boom & Jib of 140' or longer -- $5.50 per hour more than Class 1
- 3-Cranes with Boom & Jib of 120' or longer -- $5.25 per hour more than Class 1

---

**DECISION NO. M182-2042**

**TRUCK DRIVERS UNDERGROUND CONSTRUCTION**

**ZONE 1 - Wayne, Oakland, Macomb, Washtenaw, Monroe, St. Clair, Genesee, Huron, Sanilac & Livingston (Eastern 4 of Co.)**

<table>
<thead>
<tr>
<th><strong>Class 1</strong></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.37</td>
<td>12.50</td>
<td>12.70</td>
</tr>
</tbody>
</table>

---

**ZONE 2 - Lapeer & Shiawassee Cos.**

<table>
<thead>
<tr>
<th><strong>Class 1</strong></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.27</td>
<td>12.40</td>
<td>12.60</td>
</tr>
</tbody>
</table>

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**ZONE 3 - Jackson, Lenawee & Hillsdale Cos.**

<table>
<thead>
<tr>
<th><strong>Class 1</strong></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.86</td>
<td>10.92</td>
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**ZONE 4 - Branch, Calhoun & Eaton (Southern 4 of Co.)**

<table>
<thead>
<tr>
<th><strong>Class 1</strong></th>
<th>Basic Hourly Rates</th>
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<tbody>
<tr>
<td>11.35</td>
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</tbody>
</table>

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**ZONE 5 - Benzie, Manistee, Mason, Lake, Oceana, Newaygo & Muskegon Cos.**

<table>
<thead>
<tr>
<th><strong>Class 1</strong></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.14</td>
<td>13.27</td>
<td>13.40</td>
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</tbody>
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---

**ZONE 6 - Clinton, Ingham, Ionia (Eastern 4), Eaton (Northern 4) & Livingston (Western 4) Cos.**

<table>
<thead>
<tr>
<th><strong>Class 1</strong></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.16</td>
<td>10.26</td>
<td>10.36</td>
</tr>
</tbody>
</table>

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**ZONE 7 - Emmet, Charlevoix, Missaukee, Mecosta, Muskegon, Montcalm, Kent, Ottawa & Ionia (Western 4) Cos.**

<table>
<thead>
<tr>
<th><strong>Class 1</strong></th>
<th>Basic Hourly Rates</th>
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</tr>
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<tbody>
<tr>
<td>11.50</td>
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<td>11.70</td>
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**FOOTNOTES:**
- b. $99.50 per week, per employee
### Decision No. M182-2042

#### Truck Drivers (Cont')

<table>
<thead>
<tr>
<th>Class</th>
<th>Basic</th>
<th>Fringe</th>
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<tbody>
<tr>
<td>3</td>
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<tr>
<td>4</td>
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</tbody>
</table>

**Footnote:** £ 200.00 per week, per employee

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**Classification Definitions**

**Laborers: Highway, Airport & Bridge Construction**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1 - Lineman or Lineman Helper</td>
<td>Lineman or Lineman Helper</td>
</tr>
<tr>
<td>Class 2 - Paving Crew Member</td>
<td>Paving Crew Member</td>
</tr>
<tr>
<td>Class 3 - Tunnel Operator</td>
<td>Tunnel Operator</td>
</tr>
<tr>
<td>Class 4 - Pipe Layer</td>
<td>Pipe Layer</td>
</tr>
</tbody>
</table>

**Footnote:**

- **Footnote:** Only for a limited period of time.
- **Footnote:** Adjusted for inflation.

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**Classification Definitions**

**Laborers: Open Cut Construction**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Class 1 - Construction Laborers</td>
<td>Construction Laborers</td>
</tr>
<tr>
<td>Class 2 - Mortar and Material Mixer</td>
<td>Mortar and Material Mixer</td>
</tr>
<tr>
<td>Class 3 - Air, Gasoline and Electric Tool Operator</td>
<td>Air, Gasoline and Electric Tool Operator</td>
</tr>
</tbody>
</table>

**Footnote:**

- **Footnote:** Only for a limited period of time.
- **Footnote:** Adjusted for inflation.
POWER EQUIPMENT OPERATORS: HIGHWAY, AIRPORT & BRIDGE CONSTRUCTION

CLASSIFICATIONS:

CLASS 1 - Asphalt Plan Operator, Crane Operator, Dredline, Shovel Operator, Locomotive Operator, Paver (5 bags or more), Elevating Grader Operator, Pile Driving Operator, Roller (asphalt), Blade Grader Operator, Trenching Machine (ladder or wheel type), Auto-Grader, Slip Form Paver, Self-Propelled or tractor drawn Scraper, Conveyor Loader Operator (eucild type), End Loader Operator (1 yd. capacity or over), Bulldozer, Concrete Pump (13" and over), Diving Boom Truck (over 12 ton capacity), Hoisting Engineer, Tractor Operator, Finishing Machine (asphalt), Mechanic, Pump Operator (6" discharge or over, gas, diesel powered or generator of 300 amp or over), Shoulder or Gravel Distributing Machine Operator (self-propelled), Backhoe (with over 3/8 yard bucket), Side Boom Tractor (type D-4 or equivalent or larger), Tube Finisher (slip form paving), Gradall (and similar type machines), Asphalt Paver (self-propelled), Asphalt Planer (self-propelled), Batch Plant (Concrete-central mix, transit mix, shrink mix), Slurry Machine (asphalt), Roto Mill.
CLASS 2 - Sweeper (Wayne type & similar equipment), Screening Plant Operator, Washing Plant Operator, Crusher, Backhoe (with 3/8 yard bucket or less), Side Boom Tractor (smaller than D-4 type or equivalent), Batch Plant (Concrete - dry mix).
CLASS 3 - Air Compressor Operator (600 cfm or more), Air Compressor (2 or more - less than 600 cfm), Wagon Drill Operator, Concrete Breaker, Tractor Operator (Farm type w/ attachments).
CLASS 4 - Boiler Fireman, Gilder, Fireman, Mechanic's Helper, Trencher (service), Fireplane Operator, Clefplane Operator, Grader (Self-propelled Fine-Grade or Fin (concrete)), Finishing Machine (concrete), Boom or Winch Hoist Truck Operator, Concrete Pump (under 3"), Mesh Installer (self-propelled), End Loader (under 1 yard capacity), Roller Operator (other than asphalt), Curing Equipment (self-propelled), Concrete Saw Operator (40 h.p. or over), Power Bin Operator, Plant Drier (asphalt), Vibratory Compaction Equipment (6 ft. wide or over), Guard Post Driver (Power driven), All Mulching Equipment, Stump Remover, Farm Type Tractor Operator.

CLASSIFICATIONS: (POWER 1 & 2 only)
CLASS I - Rockfiller Tamper, Backhoe, Batch Plant Operator (concrete), Clamshell, Concrete Paver (two drums or larger), Conveyor Loader (eucild type), Crane (crawler, truck type or pile driving), Dozer (9 ft. blade and over), Dredline, Elevating Grader, End Loader (over 1 cubic yds. capacity), Gradall (and similar type equipment), Mechanic, Power Shoe, Roller (asphalt), Scraper (self-propelled or tractor drawn), Side Boom Tractor (type D-4 or equivalent and larger), Slip Form Paver, Slope Paver, Trencher (over 8 ft. digging capacity), Wall Drilling Rig.
CLASS II - Boom Truck (power swing type boom), Crusher, Dozer (less than 9 ft. blade), End Loader (1½ cubic yds. capacity and smaller), Hoist, Pump (one or more-8 in. discharge or larger—gas or diesel powered or powered by generator of 300 amp or more—inclusive of generator), Side Boom Tractor (smaller than type D-4 or equivalent), Sweeper (Wayne type and similar equipment), Tractor (poultired, other than backhoe or front end loader), Trencher (8 ft. digging capacity).
CLASS III - Air Compressors (600 cfm or larger), Air Compressors (two or more—less than 600 cfm), Boom Truck (non-swinging, non-powered type boom), Concrete Breaker (self-propelled or truck mounted—included compressor), Concrete Paver (one drum—1½ yd. or larger), Elevator (other than passenger), Maintenance Man, Mechanic Help, Pump (two or more-4 in. up to 6 in. discharge—gas or diesel), powered—excluding submersible pumps), Pumppr. Concrete Machine (and similar equipment), Wagon Drill (multiple), Welding Machine or Generator (two or more 100 amp. or larger—gas or diesel powered).
CLASS IV - Boiler, Concrete Saw (40 h.p. or over), Curing Machine (self-propelled), Farm Tractor (with attachment), Finishing Machine (concrete), Fireman, Hydraulic Pipe Pushing Machine, Mulching Equipment, Gilder, Pumps (two or more up to 4 in. discharge if used three hours or more & day—gas diesel powered—excluding submersible pumps), Roller (other than asphalt), Stump Remover, Trencher (service), Vibrating Compaction Equipment (self-propelled, 6 ft. wide or over)

CLASSIFICATIONS: (POWER 3 only)
CLASS A - Regular Equipment Operators, Crane, Dozer, Front End Loader, Pumppr, Squeeze Crete, Job Mechanic & Welder.
CLASS B - Air Track Drill, Boom Truck (non-swing), Concrete Mixers, Fork Truck, Natural Hoist and Tugger, Pumps (6" and over), Belt Crete, Sweeping Machine, Trencher, Head Grease Man, Winches, Well Points and Freeze Systems.
CLASS C - Air Compressor, Conveyor, Concrete Saw, Farm Tractor (without attachments), Generator, Guard Post Driver, Mulching Machines, Pumps (under 6"), Welding Machines, Grease Man.
CLASS D - Gilder, Fireman, Heater Operator.
DECISION NO. MI82-2042
CLASSIFICATION DEFINITIONS

POWER EQUIPMENT OPERATORS: STEEL ERECTION

CLASSIFICATIONS: (ZONE 1 only)
CLASS 1 - Crane Operator when operating combination of Boom and Jib 220' or longer.
CLASS 2 - Crane Operator when operating combination of Boom and Jib 220' or longer on a Crane that requires an Oiler.
CLASS 3 - Crane Operator when operating combination of Boom and Jib 140' or longer.
CLASS 4 - Crane Operator when operating combination of Boom and Jib 140' or longer on a Crane that requires an Oiler.
CLASS 5 - Crane Operator when operating combination of Boom and Jib 120' or longer.
CLASS 6 - Crane Operator on a Crane that requires an Oiler.
CLASS 7 - Crane Operator and/or Mechanic.
CLASS 8 - Crane Operator on a Crane that requires an Oiler.
CLASS 9 - Hoisting Operator.
CLASS 10 - Compressor and/or Welder Operator.
CLASS 11 - Oiler.

POWER EQUIPMENT OPERATORS: STEEL ERECTION (cont'd)

CLASSIFICATIONS: (ZONE 2 only)
CLASS 1 - Crane Operator with main Boom & Jib 220' or longer.
CLASS 2 - Crane Operator with main Boom & Jib 240' or longer, Tower Cranes.
CLASS 3 - Regular Equipment Operator, Crane, Dozer, Loader, Hoist, Straddle Wagon, Job Mechanic.
CLASS 4 - Air Tugger (single drum), Material Hoist, Pump 16' or over.
CLASS 5 - Air Compressor, Welder, Generators, Conveyors.
CLASS 6 - Oiler and Fireman.

TRUCK DRIVERS: FUTUY, AIRPORT & REFUEL CONSTRUCTION

CLASSIFICATIONS:
CLASS 1 - Truck Drivers (less than 8 cu yd capacity).
CLASS 2 - Truck Drivers (8 cu yd Capacity & over).
CLASS 3 - Truck Drivers (8 cu yd Capacity & over).

UNLISTED CLASSIFICATIONS needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses 129 CFR, 5.5(a)(11)(ii)).
<table>
<thead>
<tr>
<th>SUPERSEDES DECISION</th>
<th>LOCATION: The Cities of Chesapeake, Portsmouth and Virginia Beach</th>
</tr>
</thead>
<tbody>
<tr>
<td>DECISION NO.: VA82-3023</td>
<td>Dated November 27, 1981 in 46 FR 58029</td>
</tr>
<tr>
<td>DESCRIPTION:</td>
<td>Building construction (does not include single family homes and apartments up to and including 4 stories).</td>
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<table>
<thead>
<tr>
<th>CLASSIFICATION</th>
<th>BARGAIN</th>
<th>FRINGE</th>
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<tbody>
<tr>
<td>ABSESTOS WORKERS</td>
<td>12.55</td>
<td>1.91</td>
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<tr>
<td>BOILERS</td>
<td>13.70</td>
<td>2.15</td>
</tr>
<tr>
<td>BRICKLAYS AND STONE Masons</td>
<td>12.68</td>
<td>1.23</td>
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<tr>
<td>CARPENTERS</td>
<td>11.65</td>
<td>1.46</td>
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<tr>
<td>CEMENT MASON</td>
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<td>1.76</td>
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<td>CEMENT MASON</td>
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<td>ELEVATOR CONSTRUCTORS</td>
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<td>ELEVATOR CONSTRUCTORS HELPERS</td>
<td>7.75</td>
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<td>ELEVATOR CONSTRUCTORS</td>
<td>11.10</td>
<td>1.12</td>
</tr>
<tr>
<td>GLASSER</td>
<td>13.15</td>
<td>2.38</td>
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<tr>
<td>IRONWORKER</td>
<td>7.50</td>
<td>0.66</td>
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<td>IRONWORKER</td>
<td>13.60</td>
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<tr>
<td>MORTAR MIXERS</td>
<td>7.75</td>
<td>0.66</td>
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<tr>
<td>MORTAR MIXERS</td>
<td>7.85</td>
<td>0.66</td>
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<tr>
<td>MORTAR MIXERS</td>
<td>7.90</td>
<td>0.66</td>
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<tr>
<td>MORTAR MIXERS</td>
<td>8.00</td>
<td>0.66</td>
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<tr>
<td>POWDERMEN</td>
<td>10.75</td>
<td>0.66</td>
</tr>
<tr>
<td>LEAD BURNERS</td>
<td>10.75</td>
<td>0.66</td>
</tr>
<tr>
<td>LINE CONSTRUCTION: Linemen and Cable Splicers</td>
<td>12.50</td>
<td>1.76</td>
</tr>
</tbody>
</table>

**DECISION NO.** VA82-3023

**WELDERS** receive rate prescribed for craft performing operation for which welding is incidental.

**PAID HOLIDAYS:**
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

**FOOTNOTES:**

a. Workmen shall be allowed 2 hours with pay at the start or at the end of the work day on State and National Election days; Tuesday following the first Monday in November, provided they are qualified to and vote.

b. Employer contributes 4% basic hourly rate for 5 years or more of service or 6% basic hourly rate for 6 months to 5 years service as vacation pay credit.

c. Holidays: A through F; Washington's Birthday, Good Friday and Christmas Eve provided the employee has worked 30 full days during the 90 calendar days prior to the holiday and the regular scheduled work days immediately preceding and following the holiday.

**POWER EQUIPMENT OPERATOR CLASSIFICATIONS:**

**GROUP 1** - Tunnel machine, cranes, derricks, pile drivers, pavers, two or more drum hoist, finish motor grader, mechanized, batch plant, gradall, quad

**GROUP 2** - Cableways, tractors with attachments, combination front end loader and backhoe, front end loader, rubber tired scraper and pat, rough motor grader, 20-ton locomotive, bulldozers, pump crete, trenching machine, mixer larger than 165, fork lift

**GROUP 3** - Compressor over 125 cu. ft., bottom and end dumps, tractors without attachments, 1 drum hoist, rollers, welding machines (gas or diesel), locomotive under 20 tons, power plant, generator (1200 kW or larger), pumps (over 2 inches, including wellpoints), A-frame trucks, mechanic's helper

**GROUP 4** - Firemen

**GROUP 5** - Oilers

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR 5.5 (a)(1)(ii)).
### SUPERSEDING DECISION

**STATE:** Virginia  
**COUNTRIES:** Henrico and the Independent City of Richmond  
**DECISION NO.:** VA82-3022  
**DATE:** November 27, 1981  
**DESCRIPTION OF WORK:** Building Construction (does not include single family homes and apartments up to and including 4 stories).

<table>
<thead>
<tr>
<th></th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits</th>
</tr>
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<tbody>
<tr>
<td><strong>ASBESTOS WORKERS</strong></td>
<td>13.64</td>
<td>2.71</td>
<td>9.00</td>
<td>.66</td>
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<tr>
<td><strong>BOILERMANNERS</strong></td>
<td>10.40</td>
<td>1.37</td>
<td>8.00</td>
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<tr>
<td><strong>BRICKLAYERS AND STONE- MASON</strong></td>
<td>13.64</td>
<td>1.37</td>
<td>8.25</td>
<td>.66</td>
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<tr>
<td><strong>CARTERS AND SOFT FLOOR LAYERS</strong></td>
<td>10.75</td>
<td>1.46</td>
<td>9.39</td>
<td>.66</td>
</tr>
<tr>
<td><strong>CREDIT MASON</strong></td>
<td>10.85</td>
<td>1.46</td>
<td>10.75</td>
<td>.66</td>
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<tr>
<td><strong>CREDIT MASON MACHINE MAN</strong></td>
<td>10.85</td>
<td>1.46</td>
<td>10.75</td>
<td>.66</td>
</tr>
<tr>
<td><strong>ZONE I - within a 12 mile radius of Staples Mills Road and Broad Street in the City of Richmond</strong></td>
<td>13.64</td>
<td>1.46</td>
<td>12.35</td>
<td>1.235</td>
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<tr>
<td><strong>ZONE II - remainder of city of Richmond and Henrico County</strong></td>
<td>14.60</td>
<td>1.53</td>
<td>13.10</td>
<td>1.31</td>
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<tr>
<td><strong>ELEVATOR CONSTRUCTORS</strong></td>
<td>12.03</td>
<td>2.46</td>
<td>11.05</td>
<td>1.45</td>
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<tr>
<td><strong>ELEVATOR CONSTRUCTORS HELPERS</strong></td>
<td>8.42</td>
<td>2.46</td>
<td>11.05</td>
<td>1.45</td>
</tr>
<tr>
<td><strong>GLASSERS</strong></td>
<td>11.10</td>
<td>1.12</td>
<td>13.05</td>
<td>1.45</td>
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<tr>
<td><strong>GIRDERS-STRUCTURAL, REINFORCING AND ORNAMENTAL</strong></td>
<td>13.64</td>
<td>1.85</td>
<td>11.25</td>
<td>1.35</td>
</tr>
<tr>
<td><strong>ZONE I - up to 10 miles from Capital Square</strong></td>
<td>13.64</td>
<td>1.85</td>
<td>11.25</td>
<td>1.35</td>
</tr>
<tr>
<td><strong>ZONE II - from 10 miles to 30 miles radius</strong></td>
<td>13.87</td>
<td>1.85</td>
<td>11.25</td>
<td>1.35</td>
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<tr>
<td><strong>ZONE III - from 30 miles and beyond</strong></td>
<td>14.12</td>
<td>1.85</td>
<td>11.25</td>
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<td><strong>UNSKILLED WORKERS</strong></td>
<td>7.50</td>
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<td><strong>ROADS COMPLIANCE</strong></td>
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<td><strong>FIREMEN</strong></td>
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<td>.66</td>
<td>8.10</td>
<td>.66</td>
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<tr>
<td><strong>LINESMEN AND CABLERS</strong></td>
<td>7.75</td>
<td>.66</td>
<td>8.10</td>
<td>.66</td>
</tr>
<tr>
<td><strong>WELDERS</strong></td>
<td>7.85</td>
<td>.66</td>
<td>8.10</td>
<td>.66</td>
</tr>
</tbody>
</table>

**SPEWELER FITTERS** | 13.47 | 2.83 | 12.40 | 1.775 |
| **POWER EQUIPMENT OPERATORS-BUILDING CONSTRUCTION** | 13.47 | 2.83 | 12.40 | 1.775 |
| **GROUP 1** | 12.40 | 1.775 | 12.40 | 1.775 |
| **GROUP 2** | 12.40 | 1.775 | 12.40 | 1.775 |
| **GROUP 3** | 12.40 | 1.775 | 12.40 | 1.775 |
| **GROUP 4** | 12.40 | 1.775 | 12.40 | 1.775 |
| **GROUP 5** | 12.40 | 1.775 | 12.40 | 1.775 |

**WELDERS** - Receive rate prescribed for craft performing operation to which welding is incidental.

**PAID HOLIDAYS:**  
- A-New Year's Day;  
- B-Memorial Day;  
- C-Independence Day;  
- D-Labor Day;  
- E-Thanksgiving Day;  
- F-Christmas Day

**FOOTNOTES:**
- a. Employer contributes 8% of basic hourly rate for 5 years or more of service or 6% of basic hourly rate for 6 months to 5 years of service as vacation pay credit.
- c. Paid Holidays: A through P, Washington's Birthday; Good Friday and Christmas Eve, provided the employee has worked 30 full days during the 90 calendar days prior to the holiday and the regular scheduled work days immediately preceding and following the holiday.

**PERS. DEFINITIONS:**

**GROUP 1**
- Tunnel machine, cranes, derricks, pile drivers, pavers, two or more drum hoist, finish motor grader, mechanic, batch plant, gradall, quadr and auxiliary equipment.

**GROUP 2**
- Cableway, tractors with attachments, combination front end loader and backhoe, front end loader, rubber tired scraper and pans, rough motor grader, 20-ton locomotive, bulldozers, pump crate, trenching machine, mixer larger than 160, fork lift.

**GROUP 3**
- Compressor over 125 cu. ft., bottom and end dumps, tractor without attachments, 1 drum hoist, rollers, welding machines (gas or diesel), locomotive under 20-ton, power plant, generator (1200 kW or larger), pumps (over 2 inches, including wellpoints), A-frame truck, mechanic's helpers.

**GROUP 4**
- Firemen

**GROUP 5**
- Oilers

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR 5.5(a)(1)(ii)).
Part IV

Department of Health and Human Services

Food and Drug Administration

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph
DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 76N-0482]

Topical Antimicrobial Drug Products
for Over-the-Counter Human Use;
Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) topical first-aid antibiotic drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Topical Antimicrobial II Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs on the proposed regulation by September 7, 1982. New data by July 11, 1983. Comments on the new data by September 9, 1983. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730).

Written comments on the agency's economic impact determination by November 8, 1982.

ADDRESS: Written comments, objections, or requests for oral hearing before the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 1, 1977 (42 FR 17642), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical antibiotic drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Antimicrobial II Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by June 30, 1977. Reply comments in response to comments filed in the initial comment period could be submitted by August 1, 1977.

In a notice published in the Federal Register of March 21, 1980 (45 FR 18400), the agency advised that it had reopened the administrative record for OTC topical antibiotic drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the date the administrative record previously had officially closed. The agency concluded that any new data and information filed prior to March 21, 1980 should be available to the agency in developing a proposed regulation in the form of a tentative final monograph.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information. Data and information received after the administrative record was reopened have also been put on display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the Federal Register of April 1, 1977 (42 FR 17642), was designated as a “proposed monograph” in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated in the OTC drug review regulations as a “tentative final monograph.” Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) the FDA states for the first time its position on the establishment of a monograph for OTC topical first-aid antibiotic drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC topical first-aid antibiotic drug products.

In response to the advance notice of proposed rulemaking, one drug manufacturer association, three drug manufacturers, two medical associations, nine physicians, one pharmacologist, one consumer, and one consumer group submitted comments. Copies of the comments received are also on public display in the Dockets Management Branch.

This proposal to establish new Subpart B of Part 333 constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC topical antibiotic drug products as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect any new information that has come to the agency's attention. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

The agency points out that the categories "skin wound protectant" and "skin wound antibiotic," as recommended by the Panel, have been replaced by the category "First aid antibiotic" and that a new Category I indication is proposed in this tentative final monograph. The details of these monograph modifications are explained in part I, paragraph B. 5. below—Comments on Product Categories and Labeling. The agency invites specific comment on these modifications.

In the Federal Register of September 13, 1984 (39 FR 33103), the agency published an advance notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products (21 CFR Part 333) in four subparts: Subpart A—General Provisions, Subpart B—Active Ingredients, Subpart C—Testing Procedures, and Subpart D—Labeling. In the Federal Register of January 6, 1978 (43 FR 1210), the agency published a tentative final monograph which contained the same subpart designations in Part 333 as described above. The agency is republishing Part 333 to delete the four subparts appearing in the tentative final monograph at 43 FR 1246. The sections appearing those subparts (§§ 333.1, 333.3, 333.20, 333.30, 333.40, 333.45, 333.50, 333.65, 333.80, 333.85, 333.87, 333.90, 333.92, 333.93, 333.97, 333.98) will now be combined under the designation "Subpart A—[Reserved].” The name of Subpart A has not yet been determined, but will be designated when that portion of Part 333 is republished as an amended tentative final monograph.

In the Federal Register of April 1, 1977 (42 FR 17642), the agency published an advance notice of proposed rulemaking to establish a monograph for OTC topical antibiotic drug products (21 CFR Part 342). The agency has determined that both antimicrobial and antibiotic drug products should be
combined into one monograph to be designated as "PART 333—Topical Antimicrobial Drug Products for OTC Human Use." Therefore, the proposed rulemaking for OTC Topical Antibiotic Drug Products (formerly designated as 21 CFR Part 342) will now be designated in this tentative final monograph as Subpart B of Part 333. FDA published the Federal Register of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in Cutler v. Kennedy, 475 F. Supp. 838 (D.D.C. 1979). The Court in Cutler held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they monograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call for data notice published in the Federal Register of September 7, 1973 (38 FR 24391) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Tentative Conclusions on the Comments and Reply Comments

A. General Comments

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the Federal Register of May 11, 1972 (37 FR 9484) and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the Federal Register of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., National Pharmaceutical Manufacturers v. Weinberger, 512 F. 2d 688, 699-98 (2d Cir. 1975) and National Association of Pharmaceutical Manufacturers v. FDA, 487 F. Supp. 412 (S.D.N.Y. 1980), aff'd, 637 F. 2d 897 (2d Cir. 1981).

2. One comment contended that Category III is illegal and that consumers should not be exposed to antibiotics which have not been proven safe and effective while manufacturers undertake tests.

As noted earlier in this document, the legality of Category III was the subject of litigation in Cutler v. Kennedy, 475 F. Supp. 838 (D.D.C. 1979). The Court in Cutler held that the OTC drug regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, FDA proposed in the Federal Register of May 13, 1980 (45 FR 31422) to delete this provision and provide that any testing necessary to resolve safety or effectiveness issues that formerly resulted in a Category III
classification, and the submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process, before the establishment of a final monograph.

The final rule on this proposal was published in the Federal Register of September 29, 1981 (46 FR 47730).

The agency points out that it has been FDA's policy to take regulatory action prior to a final monograph against products that present a potential health hazard or a significant and substantial question of effectiveness. The agency concludes that none of the topical antibiotics included in this document fit either of these criteria. Therefore, the agency sees no need for regulatory action on Category III conditions prior to the effective date of the final monograph for topical first aid antibiotic drug products.

Several comments supported the continued OTC availability of topical antibiotics for first aid of minor skin injuries. The comments stated that there is more evidence that topical antibiotics are safe and effective than for other topical antibacterial agents and that removing topical antibiotics from the OTC market would deprive the public of a safe and effective first aid product.

The comments expressed concern that if OTC topical antibiotics were not available, the public would either switch to older, more toxic, and less effective OTC topical agents, such as ammoniated mercury, or delay proper first aid treatment until an infection developed and became severe enough to justify a visit to a physician.

Because the agency is not proposing to remove the entire topical antibiotic drug class from the OTC market, it is unnecessary to respond to the comment on a hypothetical basis. All OTC agents, including ammoniated mercury for topical use, are being reviewed and evaluated for safety and effectiveness. At the conclusion of the OTC drug review, only those ingredients that are generally recognized as safe and effective for OTC use will be included in the OTC drug monographs.

One comment expressed concern over the Panel's statement "that the American Academy of Pediatrics recommendations to the Panel (on the safety and effectiveness of certain OTC topical antibiotics) were based on members' (Academy members) clinical impressions rather than on a comprehensive review of the extensive data which was reviewed by the Panel." (See 42 FR 17646.) The comment submitted a statement concerning the effectiveness of topical antibiotics from the Academy's Committee on Drugs and pointed out that this statement, which was published in the June 1977 issue of Pediatrics (Ref. 1), represented the official position of the Academy. In this statement, the Academy concluded that the use of topical antibiotics may prevent infection after minor cuts, abrasions, and burns and therefore may be appropriate as an adjunct to cleansing, but it pointed out that systemic therapy is the treatment of choice in established skin infection. The Academy cautioned that because persons who are sensitive to neomycin may also react to other aminoglycosides (e.g., gentamycin, kanamycin, paromomycin, and streptomycin), the systemic use of any of the aminoglycoside antibiotics should be avoided, if possible, in patients known to be sensitive to neomycin. The Academy also cautioned that, because of possible absorption and systemic toxicity, aminoglycosides should not be used topically on large denuded skin surfaces.

The Panel's conclusion that the Academy's recommendations on safety and effectiveness of certain topical antibiotics were based at that time on clinical impressions resulted from the appearance of a representative of the Academy at the Panel's meeting on July 24, 1975. The agency recognizes that the official statement of the Academy's Committee on Drugs was published in Pediatrics in June 1977 (Ref. 1) and was based on an extensive review of the literature. The agency has considered the Academy's official recommendations in reaching its conclusions on topical antibiotic drug products in this document.

Reference


B. Comments on Product Categories and Labeling

5. Numerous comments objected to the Panel's recommendation of two different drug product categories for topical antibiotic-containing drug products without labeling that indicates the product has antimicrobial activity. For this reason, the agency has concluded that the "skin wound protectant" category, as recommended by the Panel, is inappropriate for topical antibiotic-containing drug product without labeling that indicates the product has antimicrobial activity. This conclusion is based on the premise that the "skin wound protectant" as commonly understood by consumers, and reflects the intended OTC use of these products. In comparing the indications recommended by the Panel for skin wound protectants and skin wound antibiotics, the agency identified the phrase "first aid product" as common to both drug categories. "First aid" is also a term that is frequently included in the labeling of topical antibiotic drug products, is readily understood by consumers, and reflects the intended OTC use of these products. For these reasons, FDA proposes that the drug category and statement of identity for OTC topical drug products containing antibiotics should be "first aid antibiotic." The agency has also reviewed the available data to determine the acceptable Category I claims for this drug category. As discussed in comment 14 below, the agency concludes that the application of topical antibiotics may
help prevent infection in minor skin injuries. The agency has therefore determined that the Category I indication for a first aid antibiotic drug product should be as follows: “First aid to help prevent infection in minor cuts, scrapes, and burns.” In order to improve clarity and to simplify OTC labeling, the agency has used the word “scrapes” instead of “abrasions” in the indication. The agency believes that this statement will clearly inform consumers of the function of these products.

In addition, the agency has reviewed the labeling recommended by the Panel in § 342.52(a) and proposes that those statements, with slight modifications or deletions made for clarity or to eliminate redundancy, may be used in addition to the required indication stated above. The revised labeling appears in § 333.150(b)(2) of this tentative final monograph as follows:

(1) [Select one of the following: “Decreases” or “Helps reduce”) “the number of bacteria on the treated area.”
(2) “Helps” [select one of the following: “prevent,” “guard against,” or “protect against”] “skin infection.”
(3) “Helps reduce the” [select one of the following: “risk” or “chance”) “skin infection.”
(4) “Helps prevent bacterial contamination in minor cuts, scrapes, and burns.”

In addition to the required indications the labeling may contain one or both of the following statements: “First aid product” or “Antibiotic medication for minor cuts, scrapes, and burns,” provided such statements are neither stated in direct conjunction with deletions made for clarity or to eliminate redundancy, may be used in addition to the required indication stated above. The revised labeling appears in § 333.150(b)(2) of this tentative final monograph as follows:

(1) [Select one of the following: “Decreases” or “Helps reduce”) “the number of bacteria on the treated area.”
(2) “Helps” [select one of the following: “prevent,” “guard against,” or “protect against”] “skin infection.”
(3) “Helps reduce the” [select one of the following: “risk” or “chance”) “of skin infection.”
(4) “Helps prevent bacterial contamination in minor cuts, scrapes, and burns.”

Also, as discussed in comment 13 below, the agency proposes that treatment of infections is not an OTC indication, and such claims have been placed in Category II in this document.

The agency recognizes that the vehicles of topical antibiotic preparations contain many of the same ingredients that were reviewed as skin protectants by the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (hereafter referred to as the Topical Analgesic Panel). The agency believes that any protection-type claims would be attributable to these ingredients and not to the antibiotic ingredients. The agency is also aware of substantial comment to the Topical Analgesic Panel’s report on Skin Protectant Drug Products for Over-the-Counter Human Use, published in the Federal Register of August 4, 1978 (43 FR 34629), stating that skin protectants should not be considered drugs.

Because the subject of this document is topical first aid antibiotics and not protectants, the agency has deferred discussion of protective claims to the skin protectant rulemaking. Depending upon the agency’s conclusions with regard to the advance notice of proposed rulemaking to establish a monograph for OTC skin protectant drug products, the agency will consider the suitability of a combination first aid antibiotic/skin protectant product and will amend the first aid antibiotic monograph at that time if necessary.

8. One comment believed that the Panel’s distinction between antiseptics (which are often synthetic chemicals having antimicrobial activity when used in fairly high concentration) and antibiotics (chemicals which are derived from microorganisms and which have antimicrobial activity in low concentration) presents a problem because some antibiotics are now synthesized in commercial quantities.

The agency points out that the terms “antibiotic” and “antiseptic” are defined in the Federal Food, Drug, and Cosmetic Act (hereafter referred to as the act). An antibiotic drug is defined in section 507(a) of the act (21 U.S.C. 357(a)) as “any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).”

Antisepic is defined in section 201(o) of the act (21 U.S.C. 321(o)) as “a germicide except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.” The agency believes that the Panel was attempting to distinguish the antibiotic class of drugs from other (nonantibiotic) antimicrobial drugs. Antibiotics are all produced by or derived from living microorganisms even though, as the comment states and the act recognizes, some are now being commercially synthesized. Nonantibiotic antimicrobial drugs are chemically synthesized and are usually used in higher concentration.

The agency believes that the term “antiseptic” is most often associated with the nonantibiotic group of antimicrobial drugs and that allowing this term to be used on antibiotic products would be misleading and confusing to consumers. For this reason, the agency agrees with the Panel that the term “antiseptic” is a Category II claim for topical antibiotic drug products. The agency further believes that the term “first aid antibiotic,” discussed in comment 5 above, adequately identifies this class of OTC drug products and distinguishes it from other antimicrobial products.

7. One comment contended that FDA does not have the authority to legislate the exact wording of OTC labeling claims to the exclusion of what the comment described as other equally truthful claims for the products. The comment objected to the labeling recommended by the Panel as being overly restrictive and recommended that more flexibility in labeling be permitted by adding the following statement to each list of approved claims: “* * * or similar indication statements which are in keeping with the Panel’s report.” The comment further contended that some of the wording recommended by the Panel is meaningless to consumers and suggested that manufacturers be permitted to use those words that experience indicates are best understood by consumers. Specifically, the comment questioned what meaning the terms “hand eczema,” “wound contamination,” “protectant,” and “microorganisms” would have to the consumer.

Since the inception of the OTC drug review, the agency has maintained that a monograph describing the conditions under which an OTC drug will be generally recognized as safe and effective and not misbranded must include both specific active ingredients and specific labeling. (This policy has become known as the “exclusivity rule.”) The agency’s position has been that it is necessary to allow the acceptable labeling language to that developed and approved through the OTC drug review process in order to ensure the proper and safe use of OTC drugs. The agency has never contended, however, that any list of terms developed during the course of the review literally exhausts all the possibilities of terms that appropriately can be used in OTC drug labeling. Suggestions for additional terms or for other labeling changes may be submitted as comments to proposed or tentative final monographs within the specified time periods or through petitions to amend monographs under 21 CFR 330.10(a)(12). For example, the labeling proposed in this tentative final monograph has been expanded and revised in response to comments received.

During the course of the review, FDA’s position on the “exclusivity rule”
has been questioned many times in comments and objections filed in response to particular proceedings and in correspondence with the agency. The agency has also been asked by the Proprietary Association to reconsider its position. To assist the agency in resolving this issue, FDA plans to conduct an open public forum on September 29, 1982 where all interested parties can present their views. The forum will be a legislative type administrative hearing under 21 CFR Part 15 that will be held in response to a request for a hearing on the tentative final monograph for nighttime sleep aids (published in the Federal Register of June 13, 1978; 43 FR 25544). Details of the hearing were announced in a notice published in the Federal Register of July 2, 1982 (47 FR 29002). In proposed and tentative final monographs issued in the meantime, the agency will continue to state its longstanding policy. Accordingly, the agency at this time does not accept the comment's recommendation to add to the monograph the statement "‘* * * or similar indications statements which are in keeping with the Panel's report.”

FDA believes that the labeling of OTC antibiotic drug products has been made clearer and more meaningful to the consumer by the changes reflected in this document. These changes include the deletion of the terms: "microorganisms," "protectant," and "hand eczema," three of the four terms which the comment contended consumers would not understand. (See comment 8 below for discussion of "hand eczema.") "Wound contamination," the fourth term, has been revised to "bacterial contamination in minor cuts, scrapes, and burns" in the following allowable statement in § 333.150(b)(2)(iv): "Helps prevent bacterial contamination in minor cuts, scrapes, and burns." As discussed above, labeling terminology in addition to that specified in the monograph can still be considered when a final monograph is issued.

8. One comment questioned whether most consumers would know what the term "hand eczema" means. The term appears in the Panel's warning. "Do not use on long-standing skin conditions such as leg ulcers, diaper rash or hand eczema," in §§ 342.50(b)(5) and 342.52(b)(5).

The agency agrees that most consumers probably would not know what the term "hand eczema" means. The agency believes that the use of this term in the above warning is confusing because it implies that an OTC topical antibiotic may be used on eczema that occurs on areas of the body other than the hands. The agency concludes that it was the Panel's intent to prohibit the use of OTC topical antibiotics on any chronic skin condition, including eczema on any part of the body. The agency believes that the revised indication for use, "first aid to help prevent infection in minor cuts, scrapes, and burns," and the 1-week use limitation warning are sufficient to warn the consumer that topical antibiotics are not to be used on long-standing skin conditions. Therefore, the Panel's warnings in §§ 342.50(b)(5) and 342.52(b)(5) have been deleted from the monograph. The agency recognizes, however, that a physician may prescribe an OTC topical antibiotic to be used for longer than 1 week. For this reason, the 1-week use limitation warning has been revised to read as follows: "Do not use longer than 1 week unless directed by a doctor." The agency believes that the revised indication for use of OTC topical antibiotics may be use for longer than 1 week. The agency has added "animal bites" to this warning; although such injuries might be included under "puncture wounds." However, the agency believes that many consumers may not consider animal bites as puncture wounds. In order to assure that the warning is clear, the term "animal bites" has been added because it is understood by all consumers. Animal bites often become infected, and consumers should be alerted to get proper medical care.

The agency has combined and revised the warnings in § 342.50(b)(2) and (3) to read as follows: "Stop use and consult a doctor if the condition persists or gets worse. Do not use this product longer than 1 week unless directed by a doctor." The agency believes that the warning recommended by the Panel in § 342.50(b)(3) could confuse consumers because it states that the user should stop using the product if itching, redness, swelling, or pain develops or increases. These are the same symptoms that often occur after a minor skin injury, the condition for which topical first aid products are indicated. The agency believes that the above revision will be more informative and less confusing to consumers.

The agency has also slightly revised the directions for use to make them clearer. (See comments 7 and 8 above for other specific labeling changes.)

10. One comment suggested deletion of the Panel's recommended warning in § 342.52(b)(2), "Do not use longer than 1 week." The comment claimed that the desired effect of the warning could be achieved by adding the words "for not longer than 1 week" to the last sentence in the directions for use in §§ 342.50(c) and 342.52(c), to read as follows: "May be applied one to three times daily for not longer than 1 week."

The agency disagrees with the comments. The purpose of a period-of-use statement on a product is to warn the consumer of the product's limitations. In the case of OTC topical antibiotics, the indications are for minor cuts, scrapes, and burns, which normally heal within 1 week. If the 1-week limitation statement were incorporated into the directions for use, it would lose its intended effect of alerting consumers that an unhealed lesion could indicate a more serious skin disease or a proliferating infection. Therefore, the agency proposes that the 1-week limitation, as modified in comment 8 above, be retained as part of the warnings.

11. One comment objected to the Panel's Category II classification of wounds, animal bites, or serious burns, consult a doctor." The agency has added "animal bites" to this warning; although such injuries might be included under "puncture wounds." However, the agency believes that the term "animal bites" has been added because it is understood by all consumers. Animal bites often become infected, and consumers should be alerted to get proper medical care.
labeling terms that suggest decreased healing time. The comment maintained that the Panel's statement that the rate of wound healing may vary, depending on how many and what types of bacteria are present in the wound, and the Panel's conclusion that there is little evidence to support the claim of shortened healing time are inconsistent. The comment also pointed out that the Panel should not have been concerned with wound-healing claims because under § 369.21 (21 CFR 369.21) topical antibiotic drug products containing the bacitracin-polymyxin-neomycin combination may be labeled only for the prevention of infection in minor cuts and abrasions. The comment stated that § 369.21 would prevent claims dealing with wound healing from being used in the labeling of these products; therefore, the Panel's statement that manufacturers had made such claims was incorrect.

The agency agrees with the Panel that the rate of healing is variable, depending on the number and types of bacteria present in the wound. However, the Panel placed wound-healing claims in Category II because it had no evidence to show that applying topical antibiotics to minor wounds would alter the healing rate. The agency agrees that additional evidence is necessary to support such claims. Although § 369.21 indicates that any bacitracin-containing preparation is to be labeled only for the prevention of infection in minor cuts and abrasions, several marketed products submitted to the Panel for review (Ref. 1 through 6) included the indications "aids in healing" or "as an aid to healing." It was for this reason that the Panel categorized these claims. The agency points out that the current regulations for labeling topical antibiotics in § 369.21 will be revoked on the effective date of the final monograph for OTC first aid antibiotics.

References

(1) OTC Volume 190001.
(2) OTC Volume 190003.
(3) OTC Volume 190004.
(4) OTC Volume 190005.
(5) OTC Volume 190006.
(6) OTC Volume 190012.

12 Two comments objected to the Panel's Category II classification of the phrase "helps kill bacteria." One comment noted that the Panel acknowledged in its discussion on potencies that each antibiotic ingredient is present in products in sufficient amounts to either destroy susceptible bacteria or inhibit their development. The other comment questioned the logic of prohibiting the phrase "kills bacteria" but permitting the phrase "decreases bacteria," when the mechanism by which the bacteria are "decreased" is by "killing" them.

The agency agrees with the Panel's Category II classification of the phrase "helps kill bacteria," although for different reasons than those stated by the Panel. According to the definition in section 507(a) of the act (21 U.S.C. 357(a)), antibiotics have the capacity to inhibit or destroy microorganisms. However, the agency believes that the claim "helps kill bacteria" is misleading to the average consumer because the word "kill" implies elimination of all bacteria on the skin when, in fact, topical antibiotics only decrease the number of certain bacteria on the skin. For this reason, the agency believes that the term "decreases the number of bacteria" would not be misleading and is an allowable Category I labeling claim. (See comment 5 above.) The phrase "helps kill bacteria" will remain in Category II.

13. One comment objected to the Panel's conclusion that the claim "treats infection" would be acceptable for OTC labeling of topical antibiotics provided that the effectiveness of this claim was established in controlled studies. The comment pointed out that OTC topical antibiotic drug products are now labeled principally for prevention of infection on the premise that lay users could properly use a topical antibiotic only for prevention of infection.

The agency agrees with the comment that treatment of bacterial skin infection is not an OTC indication. Lay persons do not have adequate medical background or training and should consult a physician for diagnosis and appropriate therapy of the different types of skin infections. Also, the treatment of bacterial infections usually involves systemic therapy. Therefore, the agency concludes that the claim "treats infection" or any similar claim is inappropriate for OTC first aid antibiotic drug labeling and is classified Category II. However, the agency would consider including claims for treatment of skin infection in professional labeling if data are submitted to demonstrate the effectiveness of topical first aid antibiotics for this use.

C. Comments on Effectiveness of Topical Antibiotics

14. One comment, opposed to the availability of OTC topical antibiotics, asserted that consumers should not be exposed to any topical antibiotic for the prevention of minor skin infections. The common statement that there is little chance of minor cuts and wounds becoming infected and that such infections are usually handled by the body's normal healing functions. The comment concluded that even if topically applied antibiotics are shown to be effective in preventing infection, the risks would outweigh the benefit. These risks include the possibility of sensitization of the skin, or the development of bacterial resistance to other antibacterial agents that might be important for treating serious disease.

A reply comment agreed that many minor skin injuries heal without treatment, but pointed out that some do not and that it is impossible to make a distinction at the time of injury. This comment stated that most people want to insure against the risk of infection by applying a safe and effective product for that purpose.

Other comments stated that OTC topical antibiotics can provide rational preventive therapy. Several comments objected to the Panel's not accepting controlled studies of prevention and treatment of infection in large wounds. The comments contended that if an antibacterial preparation is effective in reducing the incidence of infection in a variety of large wounds, there is no reason to believe that the same activity would not be exerted in smaller wounds.

One comment, noting that FDA has provided for a waiver from the requirement of controlled clinical trials for OTC drugs [21 CFR 330.10(a)(4)(iii)], objected to the Panel's unwillingness to apply this waiver to the topical antibiotic ingredients (42 FR 17647). The comment concluded that topical antibiotics have been used for 25 years, and that this experience is sufficient to support the continued use of these products in the prevention and treatment of minor skin injuries.

The agency has determined that OTC topical antibiotic drug products can be used safely and effectively to help prevent infection in minor skin injuries. The agency concludes that this use of the OTC topical antibiotics is rational and does not pose undue risks to the consumer.

The agency agrees with the comments that many minor skin injuries, such as cuts and scrapes, are self-healing and that the body's healing mechanisms can handle some infections that might develop in these injuries. However, as the reply comment pointed out, some minor skin injuries do not heal without treatment and it is impossible to make this distinction at the time of injury.

The agency believes that reducing the number of bacteria on the skin may help prevent infection in minor skin injuries. It is well documented in the medical literature that applying topical antibiotics to skin wounds reduces the
number of bacteria at the site of application and serves as an adjunct to cleansing wounds (Refs. 1 through 4). The agency also agrees with the Panel that studies in which topical antibiotics were used in major wounds under supervised conditions in hospitals or physicians' offices (Refs. 5 through 9) were insufficient to establish the prophylactic effectiveness of topical antibiotics in minor skin injuries, and that a well-controlled study of the prophylactic effectiveness of these drug products on minor skin injuries was needed.

The agency has reviewed a well-controlled study, published after the Panel had completed its review, in which the effectiveness of an antibiotic ointment was compared with a placebo in preventing infection in minor skin injuries and insect bites (Ref. 10). This 15-week study was conducted in a rural day-care center in 59 subjects ranging in age from 2 through 5 years. Health aides examined the children daily for minor skin injuries or insect bites, and a placebo ointment or an ointment containing neomycin sulfate, zinc bacitracin, and polymyxin B sulfate was applied three times daily to any minor skin injury or insect bite. Minor skin injuries and insect bites occurred with similar frequency in both treatment groups.

The study investigators examined the children twice weekly and cultured lesions that were present at either or both of these examinations. Epidermal cultures were done weekly. Fifteen (47 percent) of the 32 children in the placebo group and 3 (15 percent) of the 27 children in the antibiotic group developed streptococcal infection. Infections recurred in five of the placebo group but none of the antibiotic group. Twelve children in the placebo group and one child in the antibiotic group required oral therapy for the skin infection. The authors stated that the lower incidence of streptococcal skin infection in the antibiotic group was statistically significant (p < 0.01).

The agency considers this study, along with the other data cited above, as sufficient evidence to support the claim "first aid to help prevent infection in minor cuts, scrapes, and burns" for all OTC topical antibiotics. Treatment of infection is not appropriate as an indication for OTC topical antibiotics. (See comment 13 above.)

References

15. Two comments stated that OTC topical antibiotics applied to an insect bite or a wound are capable of killing the bacteria that would go on to produce impetigo in susceptible populations. One comment stated that application of topical antibiotics to impetigo lesions serves as an adjunct of systemic therapy by minimizing the shedding of virulent organisms into the environment because systemic antibiotics do not reach the outer surfaces of skin lesions. The comment cited a published article (Ref. 1) to support this statement.

The agency has reviewed the article cited by the comment. The authors of the article discussed the potential use of topical antibiotics as adjuncts to systemic therapy by reducing the shedding of virulent organisms into the environment. The study was not designed to evaluate this indication, but rather to evaluate the effectiveness of antibiotic combinations in experimentally induced infections. In addition, the authors concluded that a final judgment on the usefulness of topical antibiotics in prevention the shedding of virulent organisms into the environment would depend upon evidence of clinical efficacy. The agency concurs with the authors' conclusions. (For a discussion of the effectiveness of topical antibiotics in preventing infection in minor skin injuries, see comment 14 above.)

Reference

16. Several comments suggested using a human model study as an alternative to the Panel's recommendation of a double-blind, controlled clinical study to substantiate claims for prevention and treatment of infection for topical antibiotics. The comments stated that the following difficulties are likely to occur in performing a clinical study using patients with spontaneously occurring wounds: (1) Variability of the extent and depth of spontaneous lesions; (2) differences in the age of the lesion at the time the treatment is started; (3) differences in the number and type of organisms causing the infection; (4) differences from one patient to another in response to infection, personal habits, and living environment. The comments concluded that these difficulties could be avoided by using a human model study in which these factors are more exactly controlled.

Several comments considered it unethical to withhold antibacterial treatment from patients randomly selected for a clinical trial because of the potential for septiciemia or acute poststreptococcal glomerulonephritis developing. One comment stated that a human model study on healthy young adult volunteers would use accurately determined numbers of known pathogenic staphylococci and streptococci, and care would be taken to avoid using strains of streptococci that can cause poststreptococcal glomerulonephritis to develop.

One comment stated that the Panel's report contained several substantive errors regarding published work, unpublished material, and testimony to the Panel concerning human model studies. The comment resubmitted a protocol for a human model study (Ref. 1) and stated that this particular model had used *Staphylococcus aureus* and a pathogenic strain of *Escherichia coli*, and not normal skin bacteria as the Panel stated. The comment contended...
that the Panel's recommended requirement that "effectiveness must necessarily be demonstrated in clinical trials because this model system uses normal skin bacteria" is not a valid conclusion. (See 42 FR 17656.)

The comments concluded that well-controlled human model studies, using volunteers, were submitted to the Panel to show that bacitracin and polymyxin, alone and in combination, are effective in preventing infection in experimentally induced wounds. The comments objected to the Panel's Category III classification of the claim "prevents infection" for the combination of bacitracin and polymyxin B sulfate.

The agency disagrees with the comments that the performance of clinical trials to study prevention and treatment claims is unethical. Although septicemia can develop from minor cuts or scrapes, it is extremely rare. Testimony presented to the Panel during its deliberations showed that treatment probably cannot be administered soon enough to prevent glomerulonephritis when a nephritogenic strain is present in an infection. (A nephritogenic strain of streptococci is one that can cause inflammation of the kidney.) Therefore, the risk of poststreptococcal glomerulonephritis would not differ between the treated and the control groups in the clinical trial.

As discussed previously, claims of preventing bacterial infection are Category I (see comments 5 and 14 above); claims of treating bacterial infections are Category II (see comment 13 above). The agency points out that the combination of bacitracin and polymyxin B sulfate is Category I for the indication "first aid to help prevent infection in minor cuts, scrapes, and minor burns," and needs no further study. (See § 333.110 and § 333.120 in this tentative final monograph.)

The agency believes that human model studies have a place in the testing of topical antibiotics. For example, they can be used as a screening mechanism to determine the possible effectiveness of new ingredients or to demonstrate bioavailability of the Category I ingredients from new formulations. However, because the agency has reclassified most of the submitted antibiotics into Category I, there is no need to discuss model studies in great detail in this document.

Reference

17. One comment contended that the Panel's conclusion that topical antibiotics have not been shown to prevent or treat infections was influenced by the results of a study performed in 1971 (Ref. 1), and this study has since been discredited. This study compared the effectiveness of a combination antibiotic preparation, and another lesion was treated only with the base, on the assumption that each person would serve as his or her own control. Although treated and untreated lesions showed some improvement, no significant differences were reported between the effects of the antibiotic and the placebo.

- The comment argued that the phenomenon of translocation (the spread of a drug from the site of application to other areas of the skin) operated to produce an antibiotic effect on both lesions of each subject because the lesions were deliberately left uncovered after the ointments were applied. The comment contended that because this study met the Panel's recommendations for control, it influenced the Panel's final conclusions, even though a report on translocation (Ref. 2) was included in a submission to the Panel in 1975 (Ref. 3).

- The agency notes that the summary of data and conclusions in this submission has since been published (Ref. 4). The agency agrees with the comment that the phenomenon of translocation could explain the results of the 1971 study cited by the Panel. However, a more involved discussion of this issue is not necessary because FDA has placed prevention claims in Category I and treatment claims in Category II. (See comments 5, 13, and 14 above.) Also, according to § 333.120, the combination of bacitracin, polymyxin, and neomycin is Category I.

References
(3) OTC Volumes 190019 through 190025.

18. One comment objected to the Panel's recommendation that animal and human model studies be used to test the effectiveness of the submitted antibiotic ingredients because of the large volume of clinical experience already at hand. The comment pointed out that such studies are suitable for screening new ingredients before clinical trials, but are unnecessary and wasteful for widely used ingredients. As stated in comment 16 above, the agency agrees that animal and human model studies are useful as a screening mechanism; however, they will not be required for establishing proof of effectiveness of the submitted antibiotic ingredients. Because gramicidin is the only submitted ingredient that remains to be tested, and because it will not be necessary to test this ingredient using animal or human model studies, it is not necessary to discuss the use of these models any further in this document. Because no comments were received regarding gramicidin, the agency will address the testing of gramicidin in response to any future comments as provided in the policy statement published in the Federal Register on September 29, 1981 (46 FR 47740).

D. Comments on Safety of Topical Antibiotics

19. Several comments objected to the Panel's concern over potential misuse of OTC topical antibiotics because the Panel had no evidence that these products had ever been misused. The comments contended that theoretical possibilities should not be made a part of a scientific report and that it was improper for any scientific Panel to assume "misuse" of the drugs under its purview.

FDA agrees that the Panel cited no specific evidence of misuse of OTC topical antibiotic ingredients. However, the agency does not agree that concerns about potential misuse should not be a part of a scientific report. Theoretical concerns of misuse or potential misuse may be taken into account by panels in determining general recognition of safety and in developing labeling for an OTC drug product. The Panel's main concern in considering this potential problem was to recommend labeling that would, through clear and accurate directions for use and warnings against misuse, prevent misuse or abuse of these products.

20. Several comments stated that preparations that are merely occlusive barriers (and do not contain an antibiotic) may be dangerous for the public to use on minor skin injuries because such products would be ineffective in preventing multiplication of bacteria and could even favor the proliferation of bacteria. These comments supported the continued availability of topical antibiotic drug products and stated that there is no justification for a skin wound protectant without antimicrobial action.
As stated in comment 14 above, the agency has concluded that topical antibiotics will continue to be available as OTC first aid preparations to be applied to minor cuts, scrapes, and burns to help prevent infection. The comments and statements that there is no justification for skin wound protectants without antimicrobial activity concerns a class of products that does not fall within the scope of this tentative final monograph. Products of this type were discussed by the Topical Analgesic Panel in the advance notice of proposed rulemaking for skin protectant drug products, which was published in the Federal Register of August 4, 1978 (43 FR 34628). The agency will address the issue of skin wound protectants without antimicrobial activity in a future issue of the Federal Register.

21. One comment objected to the following statement by the Panel concerning the data necessary to establish the safety of all topical antibiotics: "Studies should be conducted to determine the highest blood levels achievable in man from maximum exposure to topical application." (See 42 FR 17652.) The comment contended that such a study was conducted and presented to the Panel in May 1975 (Refs. 1 and 2), but the results of the study apparently were not taken into account in the Panel's conclusions.

The agency points out that the statement to which the comment objected is part of the Panel's general discussion of the rationale for determination of the safety factors of topical antibiotics and is not part of the Panel's recommended testing guidelines. Although the study cited by the comment was not specifically cited by the Panel in its report, the agency does not agree that its results were not taken into account. The agency points out that the Panel concluded that it had been presented with enough data on all ingredients except gramicidin to make a determination concerning systemic toxicity. The agency concurs with the Panel that no further systemic toxicologic data are needed for any of the submitted OTC topical antibiotics other than gramicidin. The agency encourages manufacturers to use the Panel's recommendations for guidance in the development of the toxicologic data necessary for establishing the safety of gramicidin when used topically. (See 42 FR 17678.)

References

(1) OTC Volumes 190019 through 190025.

22. One comment urged FDA to ban the prophylactic use of all topical antibiotics because such unnecessary exposure to antibiotics increases the chances of bacterial resistance to antibiotics that are useful or essential for the systemic treatment of serious infections. The comment contended that FDA has proposed to ban the use of certain antibiotics in animal feed because of the potential for promoting bacterial resistance, and that antibiotics for prevention of minor skin infections should be banned for the same reason.

The agency's proposal, published in the Federal Register of January 20, 1978 (43 FR 3023), was not intended to ban the use of all antibiotics in animal feed, but to limit the routine subtherapeutic use of certain antibiotics in animal feed. The proposal was based on the concern that chronic exposure to animal feeds containing antibiotics could lead to the development of antibiotic-resistant bacteria. However, the proposal was limited to those antibiotics that are also used systemically in humans to treat infections.

The agency points out that, for the most part, the antibiotics used in OTC topical first aid products are not used systemically. The agency recognizes that the use of topical antibiotics in closed environments, such as hospitals, or in chronic conditions for extended periods of time may lead to the development of resistant strains. However, the agency is unaware of any evidence indicating that the occasional use of OTC topical antibiotics has led to an increase in infection in the general population because of resistant organisms. Therefore, the agency concludes that concerns regarding the development of resistant organisms from occasional use of OTC topical antibiotics should not prevent these ingredients from being classified in Category I.

E. Comments on Bacitracin

23. One comment contended that products containing antibiotics effective only for gram-positive bacteria, such as bacitracin, may promote the uncontrolled growth of gram-negative bacteria and that the Panel failed to address this potential problem in its report. A reply comment maintained that the Panel recognized the potential for bacterial overgrowth and made recommendations in those cases where there was a problem, e.g., in recommending that polymyxin B sulfate should not be used as a single active ingredient in OTC antibiotic drug products.

The agency agrees with the reply comment that the Panel recognized the limited spectra of the various antibiotic ingredients (e.g., polymyxin B sulfate and bacitracin) and considered the potential for bacterial overgrowth if those ingredients were used alone. Polymyxin B sulfate is active against certain gram-negative bacteria, but is not active against gram-positive bacteria. Because most infections of minor skin wounds are caused by gram-positive bacteria, applying polymyxin B sulfate alone could allow for uncontrolled growth of these gram-positive bacteria. The Panel determined, and the agency agrees, that it is rational to require polymyxin B sulfate to be used only in combination with antibiotics that have activity against gram-positive bacteria. Conversely, because bacitracin is active against gram-positive bacteria, which are the most frequent cause of minor skin wound infections, the Panel determined that it is acceptable to use this ingredient alone as a first aid antibiotic. The agency also agrees with this conclusion.

F. Comments on Neomycin.

24. One comment contended that neomycin should be removed from the market immediately until it is proven safe and effective. The comment stated that the National Academy of Sciences-National Research Council Drug Efficacy Study concluded that topical applications of neomycin have not been proven effective. (See 37 FR 12857.) A reply comment stated that this study did not make that conclusion, but instead stated that no well-controlled trials comparing topical neomycin with the cream or ointment vehicle alone in minor skin infections have been reported.

The agency agrees with the reply comment that the Drug Efficacy Study concluded that neomycin preparations were possibly effective for their labeled indications, not that they were ineffective. The Drug Efficacy Study stated that many studies support the fact that superficial skin injuries and infections improve after the use of topical neomycin preparation; however, in searching the literature of 1952 to 1967, no double-blind, controlled studies comparing neomycin ointment or cream with the vehicle alone were found. The agency points out that any final conclusions on certain OTC topical preparations containing neomycin sulfate were deferred to the OTC drug review. A notice of this deferment was published in the Federal Register on
June 29, 1972 (37 FR 12857). As discussed below (see comments 25 through 28), the agency has reclassified neomycin sulfate from Category III to Category I.

25. Several comments objected to the Panel’s classification of neomycin in Category III because the use of neomycin may promote the development of resistant organisms or cross-resistance to other aminoglycoside antibiotics. The comments stated that although cases of neomycin resistance and cross-resistance in closed environments, such as hospitals, have been reported, there is no evidence that the use of neomycin in the general population has led to any increase in infection due to neomycin-resistant strains. One comment stated that the Panel used a “double standard” in evaluating bacterial resistance of neomycin and the tetracyclines when it classified these topical antibiotics. The comment stated that bacterial resistance to tetracyclines has been demonstrated in hospitalized patients, but this did not prevent the Panel from classifying the tetracyclines in Category I.

The agency recognizes that the use of topical antibiotics in closed environments, such as hospitals, or in chronic conditions for extended periods of time has led to the emergence of resistant strains of bacteria. These closed environments are particularly prone to the development of resistant strains. However, the agency is unaware of any evidence indicating that the occasional use of OTC topical antibiotics, including neomycin, has led to an increase in infection in the general population because of resistant organisms. OTC topical antibiotics have been marketed for a number of years, some for more than 25 years. The agency believes that if the development of resistance were a problem from the OTC use of these ingredients it would have been evident by now. As noted in comment 22 above, the agency concludes that concerns regarding the development of resistant organisms for occasional use of OTC topical antibiotics should not prevent these ingredients from being classified in Category I.

26. One comment stated that until the Panel’s questions concerning percutaneous absorption of neomycin are answered, it must be assumed that topical use of this ingredient presents the same risks of deafness and kidney damage that are seen from systemic use of the drug. Other comments objected to the Panel’s statement that toxic blood levels can be reached if neomycin sulfate preparations are placed on large areas of broken skin (42 FR 17862), and that the amount of neomycin that may be absorbed into the bloodstream after topical application to diseased skin is unknown (42 FR 17861). One comment contended that the Panel’s statements are imprecise because a study submitted to the Panel in May 1975, a summary of which has since been published (Ref. 1), showed that the use of neomycin in patients with widespread psoriasis and atopic dermatitis produced no detectable blood levels of neomycin despite the patients’ broken skin barrier. Another comment pointed out that systemic toxicity has occurred only when neomycin has been applied to large areas of denuded skin, and that there is no risk of toxicity from the application of neomycin to minor cuts and burns.

Although FDA agrees with the comments that the Panel’s statements regarding “broken” and “diseased” skin are imprecise, the agency believes that it was the Panel’s intent to make it clear that the topical use of neomycin can be potentially hazardous if the drug is used improperly. After reviewing the Panel’s report and the comments, the agency concludes that the short-term use of neomycin in minor cuts and burns would not present a toxicologic risk. The agency concurs with the Panel’s conclusion that no further toxicologic testing is needed for neomycin for OTC topical use.

Reference

27. Several comments objected to the Panel’s placement of neomycin sulfate in Category III because of questions concerning this ingredient’s sensitization potential. The comments contended that the symptoms of sensitization are not serious and that they subside and leave no lasting effect when the treatment is stopped. One of the comments submitted two articles (Refs. 1 and 2), which were published after the Panel had completed its deliberations. These articles show that the incidence of sensitivity is much lower than previously believed and that the topical use of neomycin products on minor cuts or abrasions presents little risk to the user. Another comment suggested that a precautionary statement on the label would be more appropriate than the testing recommended by the Panel to determine the sensitization rate of neomycin in the general population, because the frequency of clinical hypersensitivity to neomycin is probably quite low and because the reactions are not serious. Another comment stated that neomycin sulfate should not be available OTC because it can cause allergic sensitization and can sensitize the skin to structurally related, potentially lifesaving drugs.

After evaluating the comments and other information, the agency believes that little would be gained by requiring further study to determine the actual prevalence or incidence of neomycin sensitization in the general population. Therefore, no further testing to determine a sensitization rate will be required.

Among the studies reviewed by the agency was one by Leyden and Kligman (Ref. 1), in which 2,175 subjects were patch tested with 20 percent neomycin sulfate ointment. The researchers reported that only two subjects (0.09 percent of the total population) had a clear-cut reaction to neomycin. Both of these subjects had a history of frequent use of neomycin-containing products.

Leyden and Kligman (Ref. 1) also reviewed the results of patch testing with 20 percent neomycin in 653 children who had chronic dermatoses and had been referred for diagnostic patch testing. Only one child (0.15 percent) had an allergic response to neomycin. The authors stated that this sensitization rate is much lower than that seen when adults with chronic dermatoses are patch tested with neomycin. The authors stated that because topical antibiotics are mainly used on minor cuts and wounds, which are more common in children, the periodic use of topical antibiotics is unlikely to pose a sensitization problem. They also noted that when sensitization to neomycin did occur, the reactions were mild and self-limiting.

Prystowsky et al. (Ref. 2) reported that in a general population of 1,158 subjects who were patch tested with 20 percent neomycin sulfate, 12 subjects (1.1 percent) showed sensitivity to neomycin. Ten of these 12 subjects had used neomycin for 1 week or longer on an inflammatory dermatosis. Use tests, in which commercial products containing neomycin 0.5 percent were applied three times a day for 7 days, were then conducted on these subjects. Three of the 12 subjects with positive patch tests had negative use tests. The authors concluded that these persons could possibly use neomycin-containing products for several days on minor cuts, wounds, and abrasions without experiencing persistent dermatitis. In patients who had positive reactions to the use test, the reactions were mild, self-limiting dermatoses. Prystowsky et al. concluded that the use of neomycin-containing products presents little risk.
to the user. However, they emphasized that labeling should limit the use of such products to not more than 7 days because the use of such products for more than a week increases the chance of an allergic reaction.

The agency is aware of a study in which the estimated prevalence of positive neomycin patch test results was 0 percent in 50 “normal” subjects (Ref. 3). In another study the prevalence of positive neomycin patch tests was 3 percent in 100 “normal” subjects (Ref. 4). The agency is also aware that the rate of contact sensitivity to neomycin in patch test studies of dermatologic clinic populations was reported to be between 5 and 6 percent (Refs. 5, 6, and 7).

The data discussed above are sufficient to show that the general population is at a much lower risk of developing sensitization than persons who have chronic dermatitis or who have used neomycin-containing products for extended periods of time. Children, because of their play activities, are more likely than adults to have minor skin injuries and would be the more frequent users of topical antibiotics. Moreover, among persons with chronic dermatitis, neomycin sensitization appears to be much less prevalent in children than in adults. Even when sensitization does occur, the symptoms are not severe and are localized and self-limiting. Also, the labeling on products containing neomycin includes warnings not to use the product for longer than 1 week and to discontinue use and consult a doctor if the condition persists or gets worse. For these reasons, the agency believes that concerns regarding sensitization should not prevent placing neomycin in Category I as a first aid antibiotic.

28. One comment contended that neomycin can sensitize the skin to agents such as the sun and cosmetics. A reply comment disagreed with the statement that neomycin can cause sensitization to the sun and cosmetics and pointed out that allergens sensitize only to themselves or very closely related chemical entities.

The agency acknowledges that a variety of drugs can, theoretically, be altered by sunlight to form allergenic or irritating compounds, and that some drugs may interact with cosmetics to produce sensitivity. However, the comment submitted no data to show that neomycin caused such reactions, and a search of the literature revealed no information that neomycin is altered in this way.

G. Comments on Combinations and Dosage Forms

29. One comment requested that the proposed monograph be amended to provide for combinations of Category I antibiotics with Category I corticosteroids or Category I anesthetics. The comment contended that the Panel recognized the rationality of combining antibiotics with corticosteroids (42 FR 17671). The comment further stated that the Panel’s concern that anesthetics in combination with antibiotics would mask signs of worsening infection was applicable only to products that were used to treat an existing infection. These concerns, the comment added, are not applicable to products that by definition are excluded from making anti-infective claims. The comment pointed out that the Topical Analgesic Panel approved a number of topical anesthetics for use on minor cuts and burns (42 FR 69864), and because the “combined attributes of such ingredients are indicated for simultaneous use in first aid type products,” it would be inappropriate and against the public interest for FDA to ban topical antibiotic-anesthetic combinations.

Although the Panel stated that “it is entirely conceivable” to combine “certain” nonantibiotic ingredients, such as Category I corticosteroids, with antibiotics for reducing inflammation, the Panel believed that any such combination would have to be “properly evaluated.” (See 42 FR 17671.) The agency points out that when the Topical Analgesic Panel evaluated corticosteroids in its report on OTC External Analgesic Drug Products (44 FR 69768), it considered hydrocortisone to be Category I as a topical analgesic, but only for use in single active ingredient drug products and not for use in combination drug products (44 FR 69797 and 69813).

Furthermore, the agency points out that no data on any antibiotic-nonantibiotic combination were submitted to the Antimicrobial II Panel for review, nor were any submitted in the comments. Although it may be “conceivable” that antibiotic and “certain” nonantibiotic ingredients could provide rational therapy for OTC use, this possibility is theoretical at present. In view of the Panel’s concern that combinations of antibiotics with anesthetic ingredients could pose safety problems by masking signs of infection (42 FR 17672), the agency concludes that more information is needed to show that the population who would use antibiotic-nonantibiotic combinations on skin wounds would not be at risk. Until information is submitted to show that antibiotic-nonantibiotic combinations meet the criteria in 21 CFR 330.10(a)[4][iv], such combinations will not be included in the monograph.

30. One comment objected to the Panel’s restriction in §342.10(a), (b), and (c) of the dosage form of topical antibiotics to “topical ointment dosages” only. The comment stated that the term “ointment” is vague and unnecessarily restrictive. Referring to the definitions of cream and ointment in the United States Pharmacopoeia (Ref. 1), the comment stated that “apparently one cannot readily distinguish ointments from creams since both dosage forms can be either water-in-oil or oil-in-water emulsions.” The comment added that the Panel intended to include more than one dosage form in the monograph. To support this opinion, the comment cited several statements in the Panel’s report, such as “ointment or any other topical dosage form” (42 FR 17675) and “ointment, powder or any other topical dosage form” (42 FR 17678). The comment requested that the term “ointment” be replaced in the monograph by the term “semi-solid dosage form,” which would provide for more flexibility in the formulation of these products.

Several comments supported the recommended restriction to the ointment dosage form only. One comment theorized that a petrolatum (ointment) base may actually be more effective than a cream base because the occlusive effect of the ointment allows transepidermal moisture to solubilize the antibiotic, producing a higher concentration of the drug at the site of action than the concentration that would be delivered by a cream at the same labeled potency. Another comment argued that ointment bases are

References

preferable because they rarely produce allergic sensitization; whereas creams, which contain potential allergens, such as preservatives, emulsifiers, antioxidants, lanolin, wood alcohols, and perfumes, often produce allergic sensitization. Another comment stated that these added ingredients could delay wound healing.

The agency points out that manufacturers of OTC topical antibiotics must comply not only with the OTC drug regulations, but also with the antibiotic drug regulations in Subparts F of Parts 444, 446, and 448 (21 CFR Parts 444, 446, and 448), which establish standards of identity, strength, quality, and purity. In the Federal Register of October 29, 1980 (45 FR 71354), FDA published a final rule amending the antibiotic drug regulations (21 CFR 433.1) to exempt dermatologic antibiotic drug products, including those subject to the OTC drug review, from batch certification. The agency recognizes that the acceptable dosage forms for the various topical antibiotics are characterized in the antibiotic monographs and therefore sees no need to specify particular dosage forms in this OTC drug monograph. Manufacturers are restricted to using only those dosage forms that are contained in the antibiotic regulations.

The agency agrees that the traditional cream bases have been shown to produce allergic sensitization more often than petrolatum-type ointment bases, but recognizes that creams can be formulated to omit many of the potential allergens. Almost any preparation can produce an allergic reaction in some individuals. However, such reactions are usually not severe, and the agency believes that the labeling of topical antibiotic drug products adequately warns the user to consult a doctor if the condition worsens. Because no data were presented to support the contentsions that ointments are more effective or that ingredients in cream preparations delay wound healing, these comments are not being adopted.

Reference


II. The Agency's Tentative Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of ingredient categories. The agency has reviewed all claimed active ingredients submitted to the Panel, as well as other data and information available at this time, and has proposed the recategorization of neomycin sulfate from Category III to Category I as well as a change in the designation of the drug product categories from skin wound antibiotic and skin wound protectant to topical first aid antibiotic. For the convenience of the reader, the following table is included as a summary of the categorization of topical antibiotic ingredients by the agency.

<table>
<thead>
<tr>
<th>First aid antibiotic active ingredients</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacitracin</td>
<td>I.</td>
</tr>
<tr>
<td>Bacitracin zinc</td>
<td>I.</td>
</tr>
<tr>
<td>Chlortetracycline hydrochloride</td>
<td>III.</td>
</tr>
<tr>
<td>Gramicidin</td>
<td>I.</td>
</tr>
<tr>
<td>Neomycin sulfate</td>
<td>I.</td>
</tr>
<tr>
<td>Oxytetracycline hydrochloride</td>
<td>II.</td>
</tr>
<tr>
<td>Polymyxin B sulfate (in combination only)</td>
<td>I.</td>
</tr>
<tr>
<td>Tetracycline hydrochloride</td>
<td>I.</td>
</tr>
</tbody>
</table>

2. Testing of Category II and Category III conditions. The Panel recommended testing guidelines for topical antibiotic drug products (42 FR 17678). The agency is offering these guidelines as the Panel’s recommendations without adopting them or making any formal comment on them except as otherwise noted in this document. (See comments 16 and 18 above.) Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any antibiotic drug product ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the Federal Register of September 29, 1981 (46 FR 47740). This policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel’s report and recommended monograph with the changes described in FDA’s response to the comments above and with other changes described in the summary below. A summary of the changes made in the Panel’s recommendations and conclusions follows.

1. Part 342—Topical Antibiotic Drug Products For OTC Human Use has been renumbered as follows: Part 333—Topical Antimicrobial Drug Products For OTC Human Use—Subpart B—Topical First Aid Antibiotic Drug Products. (See Supplementary Information above.)

2. The two topical antibiotic drug product categories, skin wound protectant and skin wound antibiotic, have been combined and renamed "first aid antibiotic." The definition for first aid antibiotic is "an antibiotic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns." (See comments 5 above.)

3. The required indication for the first aid antibiotic drug product category is: "First aid to help prevent infection in minor cuts, scrapes, and burns." Certain allowable phrases may be used in addition to this indication. (See proposed § 333.150(b) (2) and (3).) Protectant claims have been deferred to the rulemaking for skin protectant drug products. (See comment 5 above.)

The indication "treats infection" is in Category II because it is not suitable for OTC first aid antibiotic labeling. (See comment 13 above.)

4. The agency has included bacitracin zinc in addition to bacitracin as a Category I first aid antibiotic ingredient in this tentative final monograph. Both bacitracin and bacitracin zinc were included in products submitted to the OTC drug review. Although both ingredients were discussed in the Panel's report, bacitracin zinc was inadvertently omitted from the Panel's recommended monograph. The agency has corrected this oversight by including bacitracin zinc in this tentative final monograph.

5. The Panel's recommended monograph stated the concentration of antibiotic ingredients as "not less than x amount per gram," but did not specify an upper limit. The agency has clarified these ingredient concentrations by stating the labeled amounts of each antibiotic consistent with the requirements of the applicable antibiotic drug monographs (Subparts F of Parts 444, 446, and 448). Bacitracin concentration has been restated from not less than 500 units per gram (units/g) to 500 units/g. The concentration for all three of the tetracyclines has been set at 30 milligrams per gram (mg/g). The Panel's recommended monograph set oxytetracycline hydrochloride at not less than 30 mg/g, tetracycline hydrochloride at not less than 15 mg/g, and chlorotetracycline hydrochloride at not less than 1 mg/g. The agency notes that various products containing the three tetracyclines reviewed by the Panel all contained 30 mg/g. Polymyxin B sulfate concentration has been revised to between 5,000 to 10,000 units/g instead of 4,000 to 5,000 units/g as recommended by the Panel. The agency notes that various polymyxin
combination products reviewed by the Panel contained polymyxin 5,000, 8,000, and 10,000 units/g. The Panel recommended a neomycin sulfate concentration of not less than 5 mg/g of finished ointment dosage form. This could be interpreted as requiring a specific 5-mg weight of neomycin sulfate to be contained in each gram of suitable vehicle. Because the antibiotic activity in a milligram of neomycin sulfate can vary depending on the purity of the material, it is better to designate the neomycin content on an activity basis. (See 21 CFR 430.6(b)(20).) Therefore, the neomycin sulfate concentration has been revised to an amount of neomycin sulfate equivalent to the antibiotic activity of 3.5 mg neomycin per gram of vehicle. (See 21 CFR 444.542(a).)

6. Neomycin sulfate was listed in Category III in the Panel’s report because of safety concerns about the potential of this ingredient to cause sensitization or antibiotic-resistant staphylococci. Neomycin sulfate has been classified as a Category I first aid antibiotic in this tentative final monograph. (See comments 24 through 28 above.)

7. In its recommended monograph, the Panel specifically listed acceptable combinations if they met the Panel’s criteria for combinations and if a monograph existed for the combination in the antibiotic drug regulations. Similarly, the monograph provided only for those dermatologic dosage forms that were contained in the antibiotic drug regulations for OTC topical antibiotics.

The tentative final monograph has been revised to state that OTC topical antibiotic drug products must conforms not only to the OTC drug regulations, but also to the antibiotic drug regulations (Subpart F of Parts 444, 446, and 448), thus obviating reference to specific antibiotic monographs.

The Panel concluded that to qualify as a Category I combination product, each of the following conditions must be met:

a. Each active antibiotic and claim in the combination product is Category I.

b. The active antibiotic ingredients are combined on the basis of broadening the relevant antimicrobial spectrum.

c. The total number of ingredients does not exceed three.

The agency concurs with the Panel’s criteria for combinations and has proposed in the tentative final monograph a combination policy consistent with these criteria as follows:

The Category I antibiotic active ingredients are grouped according to antibacterial activity.

Group A. Broad-spectrum antibiotics:

- Chlorotetracycline hydrochloride
- Neomycin sulfate
- Oxytetracycline hydrochloride
- Tetracycline hydrochloride

Group B. Antibiotics with primarily gram-positive activity:

- Bacitracin
- Bacitracin zinc

Group C. Antibiotics with primarily gram-negative activity:

- Polymyxin B sulfate

First aid antibiotic drug products may contain a single antibiotic ingredient chosen from either Group A or Group B. Antibiotic ingredients in Group C must be used in combination with at least one other antibiotic from Group A or B. Any combination of up to three antibiotic ingredients may be marketed provided only one antibiotic is chosen from each group.

The agency points out that, because OTC first aid antibiotics are subject to both an OTC final monograph and the antibiotic drug regulations, only those combinations for which an antibiotic certification monograph exists in Subparts F of Parts 444, 446, and 448 may be legally marketed.

8. The agency has combined and revised the warnings in §342.50(b)(1), (4), and (5) and §342.52(b)(1), (4), and (5) for clarity and to eliminate duplicative words. The agency has also added “animal bites” to the revised warnings, which appear in §333.150(a)(1) in this tentative final monograph as follows: “For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor.”

9. The agency has revised the Panel’s recommended directions for use in §342.50(c) and §342.52(c) to make them clearer and simpler. This information appears in §333.150(d) in this tentative final monograph as follows: “Clean the affected area. Apply a small amount of this product one to three times daily. May be covered with a sterile bandage.”

To eliminate inconsistencies and duplication, the warning and caution statements for OTC topical antibiotic-containing drugs included in 21 CFR 389.20 and 389.21 will be revoked when the final monograph becomes effective.

10. In several of its warnings, the Panel recommended the phrase, “see a physician,” which has often been used in OTC drug labeling as advice to the consumer in case of symptoms that indicate a condition that cannot be self-treated. Believing that the word “doctor” is more commonly used and better understood by consumers, the agency proposes to substitute “doctor” for “physician” in the warnings appearing in the tentative final monograph. This change is part of a continuing effort to achieve OTC drug labeling language that is simple, clear, and accurate, in keeping with §330.10(a)(4)(v), which states in part, “Labeling shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.” If the word “doctor” is adopted in the final monograph, the agency will use this language in other final monographs and other applicable OTC drug regulations and will propose amendments to those regulations accordingly. Public comment on this proposed change in labeling language is invited.

The agency has examined the economic consequences of this proposed rulemaking and has determined that it does not require either a Regulatory Impact Analysis, as specified in Executive Order 12291, or a Regulatory Flexibility Analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). Specifically, the proposal would necessitate some relabeling, resulting in minimal costs. Manufacturers may wish to test the one ingredient that is in Category III, but testing costs would be voluntary because products containing this ingredient may also be reformulated. Costs associated with reformulation include stability testing. Therefore, the agency concludes that the proposed rule is not a major rule as defined in Executive Order 12291.

Further, the agency certifies that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC topical first aid antibiotic drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC topical first aid antibiotic drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comments on the economic impact of the OTC drug review on topical first aid antibiotic drug products, a period of 120 days from the date of publication of this proposed rulemaking in the Federal Register will be provided for comments on this subject to be developed and transmitted.
generally recognized as safe and suitable for topical administration is 919 and 333.150 Labeling of first aid antibiotic drug products.

§ 333.103 Definitions.

As used in this subpart:
(a) Antibiotic drug. In accordance with section 507(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357(a)), "any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance)."
(b) First aid antibiotic. An antibiotic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns.

§ 333.110 First aid antibiotic active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient:

(a) Broad-spectrum antibiotics.
   (1) Chlorotetracycline hydrochloride 30 milligrams per gram.
   (2) Neomycin sulfate equivalent to the antibiotic activity of 3.5 milligrams neomycin per gram.
   (3) Oxytetracycline hydrochloride 30 milligrams per gram.
   (4) Tetracycline hydrochloride 30 milligrams per gram.
   (b) Antibiotics with primarily gram-positive activity.
      (1) Bacitracin 500 units per gram.
      (2) Bacitracin zinc 500 units per gram.
      (c) Antibiotic with primarily gram-negative activity. Polymyxin B sulfate 5,000 to 10,000 units per gram for use only in combination as provided in § 333.120.

§ 333.120 Permitted combinations of active ingredients.

Two or three ingredients identified in § 333.110 may be combined provided the combination contains only one ingredient from each class of antibiotics identified in § 333.110(a), (b), and (c), and provided the combination meets the conditions in § 433.1 and in the applicable sections of Subparts F of Parts 444, 446, and 448.

§ 333.150 Labeling of first aid antibiotic drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "first aid antibiotic." (b) Indications. (1) The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the phrase, "First aid to help prevent infection in minor cuts, scrapes, and burns." (2) Other allowable indications. In addition to the required indication identified in § 333.150(b)(1), the labeling of the product may contain additional indications under the heading "Indications" that are limited to any of the following phrases:
   (i) "Select one of the following: "Decreases" or "Helps reduce"") the number of bacteria on the treated area." (ii) "Helps" (select one of the following: "prevent," "guard against," or "protect against") "skin infection." (iii) "Helps reduce the" (select one of the following: "risk" or "chance") "of skin infection." (iv) "Helps prevent bacterial contamination in minor cuts, scrapes, and burns." (3) Other allowable statements. In addition to the required information specified in § 333.150(a), (b)(1), (c), and (d), the labeling of the product may contain any of the following statements, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence of conspicuousness than the required information.
   (i) "First aid product." (ii) "Antibiotic medication for minor cuts, scrapes, and burns." (c) Warnings. The labeling of the product contains the following warnings under the heading "Warning":
      (1) "For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor." (2) "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by a doctor." (d) Directions. The labeling of the product contains the following information under the heading "Directions":
         (1) "Clean the affected area. May be covered with a sterile bandage." (2) "Directions.

References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

List of Subjects in 21 CFR Part 333

OTC drugs: Topical antibiotics.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982) it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in proposed Part 333 by adding new Subpart B, to read as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart B—Topical First Aid Antibiotic Drug Products

Sec.

333.101 Scope.

333.103 Definitions.

333.110 First aid antibiotic active ingredients.

333.120 Permitted combinations of active ingredients.

333.150 Labeling of first aid antibiotic drug products.


§ 333.101 Scope.

(a) An over-the-counter first aid antibiotic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it satisfies each of the conditions in this subpart, each of the general conditions established in § 330.1, the exemptions established in § 433.1, and the applicable sections of Subpart F of Parts 444, 446, and 448.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 333.103 Definitions.

As used in this subpart:
(a) Antibiotic drug. In accordance with section 507(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357(a)), "any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance)."
(b) First aid antibiotic. An antibiotic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns.

§ 333.110 First aid antibiotic active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient:

(a) Broad-spectrum antibiotics.
   (1) Chlorotetracycline hydrochloride 30 milligrams per gram.
   (2) Neomycin sulfate equivalent to the antibiotic activity of 3.5 milligrams neomycin per gram.
   (3) Oxytetracycline hydrochloride 30 milligrams per gram.
   (4) Tetracycline hydrochloride 30 milligrams per gram.
   (b) Antibiotics with primarily gram-positive activity.
      (1) Bacitracin 500 units per gram.
      (2) Bacitracin zinc 500 units per gram.
      (c) Antibiotic with primarily gram-negative activity. Polymyxin B sulfate 5,000 to 10,000 units per gram for use only in combination as provided in § 333.120.

§ 333.120 Permitted combinations of active ingredients.

Two or three ingredients identified in § 333.110 may be combined provided the combination contains only one ingredient from each class of antibiotics identified in § 333.110(a), (b), and (c), and provided the combination meets the conditions in § 433.1 and in the applicable sections of Subparts F of Parts 444, 446, and 448.

§ 333.150 Labeling of first aid antibiotic drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "first aid antibiotic." (b) Indications. (1) The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the phrase, "First aid to help prevent infection in minor cuts, scrapes, and burns." (2) Other allowable indications. In addition to the required indication identified in § 333.150(b)(1), the labeling of the product may contain additional indications under the heading "Indications" that are limited to any of the following phrases:
   (i) "Select one of the following: "Decreases" or "Helps reduce"") the number of bacteria on the treated area." (ii) "Helps" (select one of the following: "prevent," "guard against," or "protect against") "skin infection." (iii) "Helps reduce the" (select one of the following: "risk" or "chance") "of skin infection." (iv) "Helps prevent bacterial contamination in minor cuts, scrapes, and burns." (3) Other allowable statements. In addition to the required information specified in § 333.150(a), (b)(1), (c), and (d), the labeling of the product may contain any of the following statements, provided such statements are neither placed in direct conjunction with information required to appear in the labeling nor occupy labeling space with greater prominence of conspicuousness than the required information.
   (i) "First aid product." (ii) "Antibiotic medication for minor cuts, scrapes, and burns." (c) Warnings. The labeling of the product contains the following warnings under the heading "Warning":
      (1) "For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor." (2) "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by a doctor." (d) Directions. The labeling of the product contains the following information under the heading "Directions":
         (1) "Clean the affected area. May be covered with a sterile bandage." (2) "Directions.

Interested persons may, on or before September 17, 1982 submit to the Dockets Management Branch (HFA—305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on
the agency's economic impact determination may be submitted on or before November 8, 1982. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, 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.

Interested persons, on or before July 11, 1983 may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before September 9, 1983. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA-305) (address above). Received data and comments may also be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on September 9, 1983. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the Federal Register unless the Commissioner finds good cause has been shown that warrants earlier consideration.

Arthur Hull Hayes, Jr.,
Commissioner of Food and Drugs.

Dated: June 7, 1982.
Richard S. Schweiker,
Secretary of Health and Human Services.
Part V

Department of Health and Human Services

Food and Drug Administration

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Over-the-Counter Anticholinergic Drug Products and Expectorant Drug Products
Cold, Cough, Allergy, Bronchodilator, and Antisthomatic Drug Products for Over-the-Counter Use; Tentative Final Monograph for Over-the-Counter Anticholinergic Drug Products and Expectorant Drug Products

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) anticholinergic drug products and expectorant drug products are generally recognized as safe and effective and not misbranded. Anticholinergics are drugs used in cough-cold products for the relief of excessive secretions of the nose and eyes, symptoms which are commonly associated with hay fever, allergy, rhinitis, and the "common cold" (cold); expectorants are drugs used to promote or facilitate the removal of secretions from the respiratory airways. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antisthomatic Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal deals only with anticholinergic drug products and expectorant drug products and is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs on the proposed regulation by September 7, 1982. New data by July 11, 1983. Comments on the new data by September 9, 1983. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Written comments on the agency's economic impact determination by November 8, 1982.

ADDRESS: Written comments, objections, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5000 Fishers Lane, Rockville, MD 20857. New data and comments on new data should also be addressed to the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, 5000 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 9, 1976 (41 FR 38312), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC cold, cough, allergy, bronchodilator, and antisthomatic drug products, together with the recommendations of the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antisthomatic Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in these drug classes. Interested persons were invited to submit comments by December 8, 1976. Reply comments in response to comments filed in the initial comment period could be submitted by January 7, 1977.

In a notice published in the Federal Register of March 21, 1980 (45 FR 18400), the agency advised that it had reopened the administrative record for OTC cold, cough, allergy, bronchodilator, and antisthomatic drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the date the administrative record previously had officially closed. The agency concluded that any new data and information filed prior to March 21, 1980 should be available to the agency in developing a proposed regulation in the form of a tentative final monograph.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information. Data and information received after the administrative record was reopened have also been put on display in the Dockets Management Branch.

FDA is issuing the tentative final monograph for OTC cold, cough, allergy, bronchodilator, and antisthomatic drug products in segments. This document on anticholinergic drug products and expectorant drug products is the first segment. Subsequent segments on antitussives, bronchodilators, antihistamines, nasal decongestants, combinations, etc., will be published in future issues of the Federal Register.

The advance notice of proposed rulemaking, which was published in the Federal Register on September 9, 1976 (41 FR 38312), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated in the OTC drug review regulations as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) the FDA states for the first time its position on the establishment of a monograph for OTC anticholinergic drug products and expectorant drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC anticholinergic drug products and expectorant drug products.

In response to the advance notice of proposed rulemaking, two drug manufacturers, one consumer group, and one health professional submitted comments on anticholinergics. Two drug manufacturers, two health care professionals, and two consumer groups submitted comments on expectorants. Copies of the comments received are also on public display in the Dockets Management Branch.

This proposal to establish Part 341 (21 CFR Part 341) constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC anticholinergic drug products and expectorant drug products as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them. The agency emphasizes that no anticholinergic active ingredients and no expectorant active ingredients have been determined to be generally recognized as safe and effective and not misbranded. However, the agency is proposing Category I labeling in this document in the event that data are submitted which result in the upgrading of any ingredients to monograph status in the final rule.

FDA published in the Federal Register of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in...
The Court in Cutler v. Kennedy, 475 F. Supp. 638 (D.D.C. 1979), held that the OTC drug review regulations (21 CFR 200.31(a)) are unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph (46 FR 47736).

Although it was not required to do so under Cutler, FDA will no longer use the terms “Category I,” “Category II,” and “Category III” at the final monograph stage in favor of the terms “monograph conditions” (old Category I and nonmonograph conditions” (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved new drug application. Further, any OTC drug products subject to this monograph that are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products (published in the Federal Register of September 9, 1976 [41 FR 38312]), the agency suggested that the conditions included in the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the Federal Register and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use.

In the case of anticholinergic drug products and expectorant drug products, there are currently no Category I conditions. The agency is aware that at least one expectorant ingredient is being tested and that data relating to that ingredient may be submitted before the final monograph is issued. Thus, the agency cannot at this time determine whether all expectorant drug products, or only some, may have to be reformulated. The agency is not aware that any anticholinergic ingredients are being tested. Thus, it appears that products containing anticholinergic ingredients will have to be reformulated to comply with the monograph.

Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

In addition to reformulation, relabeling of products will be necessary in order for manufacturers to comply with the final regulation. New labels complying with the regulation have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final regulation. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss but also interfere with consumers’ access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the Federal Register. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling or reformulate their products and have them in compliance in the marketplace. However, if the agency determines that any labeling for a condition included in the final monograph should be implemented sooner, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All “OTC Volumes” cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the Federal Register of August 9, 1972 (37 FR 16029) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Tentative Conclusions on the Comments

A. General Comments on Anticholinergic Drug Products

1. One comment contended that the amount of belladonna alkaloids contained in a particular OTC timed-release cough-cold product is too high for safe use, and another comment questioned whether this same product might be unsafe because the time-release dosage form could release its ingredients inconsistently or all at once.

The product mentioned in the comments contains 0.2 milligrams (mg) belladonna alkaloids, 50 mg phenylpropanolamine hydrochloride, and 4 mg chlorpheniramine maleate in a 12-hour timed-release dosage form. The Panel concluded that the dosage of belladonna alkaloids in this timed-release dosage form is probably safe in OTC cough-cold products for anticholinergic use, but that further testing is needed to establish their effectiveness. The agency concurs with the finding, and points out that the product is the subject of a new drug application (NDA), approved on September 1, 1961 on the basis of safety. FDA is unaware of any data that would change the conclusion that the specific product subject to the NDA is safe.

However, timed-release products are subject to the regulation in § 200.31(a) (21 CFR 200.31(a)), which requires that any timed-release dosage form that contains per dosage unit (e.g., capsule or tablet) a quantity of active drug ingredient that is not generally recognized as safe for administration as a single dose under the conditions suggested in its labeling is regarded as a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)). This requirement is grounded on the agency's recognition that there is a possibility of overdosage if products that are designed
to release the active ingredient over a prolonged period are improperly made and the active ingredient is released all at once or over too short a time interval. An NDA for a timed-release product must contain bioavailability data that demonstrate that the active ingredient is released uniformly over the dosage duration of the product and not over too short or too long a time interval. Thus, timed-release products containing a quantity of active ingredient that is not generally recognized as safe for administration as a single dose may not be introduced into interstate commerce unless an NDA has been approved for the product. Because the Panel reviewed no data on belladonna alkaloids apart from the timed-release formulation, it made no recommendations as to a single dose amount that would be generally recognized as safe and effective. The agency is unaware of any data that would establish a generally recognized safe and effective single dose of belladonna alkaloids for use in non-timed-release cough-cold products.

2. One comment objected to FDA's permitting the marketing of the timed-release product containing belladonna alkaloids until FDA has evaluated data on the belladonna component and has found the ingredient to be effective for use in OTC cough-cold products. It has been the agency's policy, since the initiation of the OTC drug review, to take regulatory action prior to a final monograph against only those products that present a potential health hazard or a significant and substantial effectiveness question. The product which the comment refers to has been marketed OTC since 1961 with an approved NDA for safety. FDA believes that with additional testing the belladonna alkaloids may be shown to be effective. Therefore, the agency sees no need for regulatory action toward this ingredient prior to public release of a final rule.

3. A comment objected to the Panel's not having required studies of belladonna alkaloids for "long-term" effects. The Panel stated that "clinical experience has confirmed that belladonna alkaloids are safe in the dosage ranges used as anticholinergics." [41 FR 36373]. Section 330.10(a)(4)[1] of the OTC drug regulations states that proof of safety "shall include results of significant human experience during marketing." Because belladonna alkaloids have been marketed in this and other products, and have been widely used for many years, the Panel did not believe it necessary to recommend studies for long-term effects. The agency agrees with the Panel and concludes that studies for long-term effects are not needed.

4. One comment requested that a dosage be established for belladonna alkaloids when they are used in combination drug products which are not time-released. The comment pointed out that the Panel recommended only an adult oral dose for belladonna alkaloids of 0.2 mg two times a day, based on review of a timed-release dosage form. Based on this timed-release dose, the comment requested that a dose of 0.067 mg every 4 hours or 0.1 mg every 6 hours also be allowed.

The Panel did not recommend a dosage for belladonna alkaloids to be administered every 4 to 6 hours because no data on such dosage forms were submitted for review. Because the comment submitted no new data, and because FDA is unaware of any such data, a generally recognized safe and effective dosage for belladonna alkaloids administered every 4 to 6 hours in cold, cough, and allergy products has not been established. Therefore, the agency denies this request.

5. Two comments expressed concern that belladonna alkaloids might cause urinary retention in males. The comments cited personal experiences where urinary retention has occurred after taking an OTC combination cough-cold product containing belladonna alkaloids.

It is well known that belladonna alkaloids and related drugs, particularly atropine, contribute to retention of urine (Ref. 1). The Panel recognized that urinary retention might become a problem in a male with an enlarged prostate. Such persons might develop urinary obstruction. For this reason, the Panel recommended an appropriate label warning which states in part "Caution: Do not take this product if you have * * * difficulty in urination due to enlargement of the prostate gland except under the advice and supervision of a physician." FDA concurs that this warning will adequately alert men who have an enlarged prostate gland and who may experience urinary retention problems following use of a product containing belladonna alkaloids. FDA has incorporated this warning into the tentative final monograph with two minor revisions, i.e., deletion of the signal word "Caution" and substitution of the word "doctor" for "physician." (See § 341.70(c)[3] below)

Historically there has not been a consistent usage of the signal words "warning" and "caution" in OTC drug labeling. For example, in §§ 369.20 and 369.21 [21 CFR 369.20 and 369.21], which list "warning" and "caution" statements for drugs, the signal words "warning" and "caution" are both used. In some instances, either of these signal words is used to convey the same or similar precautionary information.

FDA has considered which of these signal words would be most likely to attract consumers' attention to that information describing conditions under which the drug product should not be used or its should be discontinued. The agency concludes that the signal word "warning" is more likely to flag potential dangers so that consumers will read the information being conveyed. Therefore, FDA has determined that the signal word "warning," rather than the word "caution," will be used routinely in OTC drug labeling that is intended to alert consumers to potential safety problems. Accordingly, the signal word "caution" has been deleted from § 341.70(b)[3] (redesignated as § 341.70(c)[3] in the tentative final monograph).

The agency believes that the word "doctor" is more commonly used and better understood by consumers and, therefore, is substituting "doctor" for "physician" in the warnings appearing in the tentative final monograph. This change is being made as part of a continuing effort to achieve OTC drug labeling that is simple, clear, and accurate, in keeping with § 330.10(a)[4][v]. (21 CFR 330.10(a)[4][v]), which states in part:

Labeling * * * shall state the intended uses and results of the product; adequate directions for proper use; and warnings against unsafe use, side effects, and adverse reactions in such terms as to render them likely to be read and understood by the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use.

Public comment on these proposed changes in labeling language is invited. The agency also invites public comment on ways to define the terms "anticholinergic" and "expectorant" in lay language.

Reference

excessive dryness of the mouth, insomnia, excitement, confusion, and rapid pulse are side effects, which can occur with the use of belladonna alkaloids. The Panel recommended in § 341.70(b)[2] that the labeling of these products bear a warning that consumers should stop taking the product if any of these side effects occur. The Panel did not, however, specifically include dizziness as a possible side effect. Because the agency previously recognized dizziness as a possible side effect of belladonna alkaloid products, dizziness was included in the recommended warning statement set forth for belladonna preparations in § 368.20. Therefore, the agency agrees with the comment and has added dizziness to the warning in § 341.70(c)[2]. Further, in the interest of clarity, the agency is changing the Panel’s recommended wording “do not continue to take” to “stop taking.” Thus, § 341.70(b)[2] which is redesignated as § 341.70(c)[2] in the tentative final monograph, reads as follows: “Stop taking this product if constipation, excessive dryness of the mouth, insomnia, excitement, confusion, dizziness, rapid pulse, or blurring of vision occurs.”

7. One comment questioned the Panel’s classification of an antihistamine and an anticholinergic combination drug product in Category III for safety. The comment contends that information presented to the Panel at its December 3, 1974 meeting showed that combining an anticholinergic with an antihistamine does not increase the nature or severity of the potential side effects of each ingredient. The comment requested elimination of the requirement of additional safety studies for such a combination.

The agency disagrees with the comment. The agency concludes that the data cited by the comment cannot be used to establish general recognition of the safety of OTC anticholinergic/antihistamine combinations because different antihistamines and anticholinergics have varying degrees of side effects. Moreover, because antihistamines have anticholinergic effects in varying degrees, when drugs from each class are combined it may be necessary to adjust the dose of each to prevent cumulative side effects. The agency therefore considers it important to require a measure of the side effects of any proposed antihistamine/anticholinergic combination. Effectiveness testing will be required for any such combinations that are proposed because there are no Category I anticholinergics, and the two anticholinergic ingredients in Category III were placed there because of a lack of effectiveness data. Measurement of side effects could be done in conjunction with this effectiveness testing in order to determine the overall benefit-to-risk ratio of the addition of the anticholinergic to the combination, as well as a safe dosage for the combination.

B. General Comments on Expectorant Drug Products

8. One comment agreed with the Panel’s conclusion that oral expectorants lack proven effectiveness and that some of them are potentially dangerous as OTC drugs. The comment suggested, however, that wild cherry syrup or tea and honey preparations should be labeled as placebos and marketed for the treatment of mild, self-limited cough.

The Panel suggested that a number of currently marketed expectorant active ingredients required further testing to establish their effectiveness. A number of other expectorants reviewed by the Panel were placed in Category II because they were considered safe. The agency appreciates the comment’s agreement with the Panel’s conclusions. As for the comment’s suggestion that certain ingredients be labeled as placebos and marketed for the treatment of mild self-limited cough, in order for a product to be marked with OTC drug labeling it must be shown to be generally recognized as safe and effective for its labeled indication. There are no data available to the agency to demonstrate that tea and honey or wild cherry syrup are effective for the treatment of mild, self-limited cough. Therefore FDA disagrees with the comment.

9. One comment submitted a new clinical study (Protocol 14) in support of the effectiveness of guaifenesin (glyceryl guaiacolate). The comment also questioned specific statements made by the Panel and presented a reevaluation of previous studies (Protocols 06 and 08) discussed in the Panel’s report at 41 FR 38362–38363. The data, rebuttal of the Panel’s statements, and the reevaluation were submitted to establish the effectiveness (Category I status) of guaifenesin as an expectorant for OTC use (Ref. 1).

The agency has reviewed the new data (Protocol 14) and all of the data on guaifenesin which the Panel had previously reviewed. In summary, the studies performed under Protocol 08 were judged unacceptable by the Panel (41 FR 38363), and the agency concurs with the Panel’s conclusions. Because the studies performed under Protocol 08 were essentially identical to Protocol 08, the agency finds that these studies are also unacceptable. The Protocol 14 study was inadequate for several reasons: (a) The lack of comparability between placebo and treatment groups with respect to age and characteristics of disease (i.e., the placebo group was older and produced more and thicker sputum), (b) the small sample of patients studied, and (c) the inadequate period of drug administration. Additionally, although the Panel required only subjective tests for determining the effectiveness of expectorants, the agency believes that objective measurements of sputum volume and sputum viscosity should be done. The data submitted were inadequate to establish whether the subjective improvement produced was the result of an expectorant-action, i.e., reduced thickness or increased quantity of secretions. The agency concludes that the data do not support the reclassification of guaifenesin as an expectorant from Category III to Category I.

The agency’s detailed comments and evaluations on the data and its recommendations for additional studies are on file in the Dockets Management Branch (Refs. 2, 3, and 4).

References

(1) Comment Nos. SUP013 and SUP014, Docket No. 76N-0052, Dockets Management Branch.
(2) Letter from William E. Gilbertson, FDA, to Frederick A. Clark, Jr., A. H. Robins Co.,
coded ANS and 81/01/14 to SUP013 and SUP014, Docket No. 76N-0052, Dockets Management Branch.
(3) Memoranda of meetings, coded MM0004, MM0005, and MM0006, Docket No. 76N-0052C, Dockets Management Branch.
(4) Letter from William E. Gilbertson, FDA, to Frederick A. Clark, Jr., A. H. Robins Co., coded LET078, Docket No. 76N-0052C, Dockets Management Branch.

10. One comment stated that several references concerning research on guaifenesin, which was conducted by the correspondent and his colleagues, were inappropriately used by the Panel in reaching its conclusions. The comment contended that, because the cited studies were performed in patients with chronic lung secretion problems and employed larger-than-usual doses, they should not have been used in drawing conclusions about the effectiveness of guaifenesin in acute conditions, for which guaifenesin is generally used as an OTC drug. The comment stated that it would have been more reasonable for the Panel to have distinguished the use of guaifenesin in acute illnesses from its use in chronic
illnesses, even though this distinction would not have resulted in a change in the Panel's recommendations. The Panel's recommendations apply only to the use of guaifenesin in acute, self-limited conditions which are suited to OTC treatment. The agency notes that the data cited above were not the sole determining factor in the Panel's decision to place guaifenesin in Category III. The Panel recognized that the available data showed conflicting results regarding guaifenesin's effectiveness and that there is considerable dispute among experts as to the appropriate dosage for OTC use. The Panel therefore placed guaifenesin in Category III for further study. The agency concurs with this classification.

11. One comment objected to the Panel's review of ipecac fluidextract. The comment contends that ipecac fluidextract is not contained in any OTC preparation and that any reference to this ingredient in the OTC drug review is unnecessary.

The agency disagrees. The Panel received data on the use of ipecac fluidextract as a source of ipecac in an OTC preparation intended for use as an expectorant. These data comprise OTC Volume 040011 (Ref. 1). Therefore, it was necessary for the Panel to review this ingredient.

Reference
(1) OTC Volume 040011.

12. One comment questioned the omission of an article by Boyd, Palmer, and Pearson (Ref. 1) in the Panel's discussion of ipecac syrup as an expectorant at 41 FR 38363. The comment stated that this article is an excellent short paper showing favorable results of the use of ipecac syrup as an expectorant. The Boyd, Palmer, and Pearson article reports a study concerning testing of a cough mixture containing theophylline ethylendiamine, potassium citrate, wine of ipecac, and chloroform in a syrup. The article reports the results of testing the expectorant action of this cough mixture in animals and humans, testing the effects of the separate ingredients in animals, investigating the mechanism of action of the cough mixture in animals, and measuring the effect of the cough mixture on volume output of respiratory tract fluid in animals. The agency notes that the Panel was aware of this article and cited it as a reference in its discussion of sodium citrate as an expectorant at 41 FR 38367 but not in the ipecac syrup section of the report.

The agency has reviewed the Boyd, Palmer, and Pearson article. Ipecac as a single expectorant ingredient was studied only in albino rats. The wine of ipecac was tested in a group of 11 albino rats at a dose of 0.4 milliliters per kilogram of body weight. Each of the active ingredients of the cough mixture when tested separately had an expectorant effect measured as a percentage increase in respiratory tract fluid output. The agency notes, however, that the Boyd, Palmer, and Pearson article does not provide the amount of ipecac contained in the wine of ipecac administered to the animals in the study. The data from the study are of little value in supporting a safe and effective single dose of ipecac for use as an expectorant in humans.

The only human data presented were on the whole cough mixture combining the four active ingredients. In this part of the study, the combination was tested in 43 patients for antitussive and not for expectorant properties.

The agency concludes that because of the lack of testing of ipecac as a single ingredient in humans the Boyd, Palmer, and Pearson article provides no additional significant data to establish general recognition of the effectiveness of ipecac syrup as an OTC expectorant.

Reference

13. One comment noted that, in the Panel's discussion on the effectiveness of ipecac syrup as an expectorant, the Panel referred to several references (Refs. 1, 2, and 3 below—cited as Refs. 8, 9, and 10 in the Panel's report on page 38564 (41 FR 38364)) as "* * * controlled studies in humans with chronic cough * * *" as though they meet the Panel's criteria for controlled studies. The comment suggested that the Panel erred in referring to these studies as "controlled studies." Further, the comment stated that "none of the references cited to support the proposition of controlled studies showing no efficacy actually support that proposition."

Even though the Panel referred to these studies as "controlled," the agency believes that the Panel did not intend to mean that the studies met the Panel's testing criteria for establishing effectiveness of expectorants.

The Panel concluded that the available data were insufficient to make a determination that ipecac is effective. The agency has reviewed these studies and concurs with the Panel that they do not demonstrate that ipecac is effective as an expectorant and that further study is needed.

References

14. One comment submitted individual patient data sheets for two studies previously submitted to the Panel (Ref. 1). The comment believed that these additional data would support the classification of ipecac as a Category I expectorant. One study was a single dose study in 72 subjects—24 received the comment's product (a liquid combination drug product containing ipecac as one of its ingredients), 24 received a product containing guaifenesin as its active ingredient, and 24 received placebo. The purpose of the study was to investigate the single-dose effect of the combination drug product in the relief of symptoms of upper respiratory congestion associated with the common cold. The study was conducted under double-blind conditions. Results were reported in terms of a decrease in nasal-airway resistance, relief of runny nose, relief of stuffy nose, reduction in sneezing, relief of coughing, and reduction of a number of other symptoms for which there were insufficient positive responses to carry out statistical evaluations. The second study assessed the effectiveness of a single-and multi-dose schedule of the combination drug product in 26 patients with chronic cough. The study was carried out as a double-blind, placebo-controlled trial with the random allocation of 13 patients to test drug treatment and 12 patients to placebo: Frequency, intensity, and distress of cough were evaluated subjectively by the patients, and reduction in the number of coughs was measured objectively.

The agency has reviewed the studies submitted by the comment and concludes that they were improperly designed and thus could not demonstrate the effectiveness of ipecac as an expectorant. The combination drug product contains ipecac, beechwood creosote, cascaria, menthol, white pine, wild cherry, and alcohol. Ipecac, white pine, and beechwood creosote were classified by the Panel as Category III expectorants. Menthol and beechwood creosote were classified as Category III antitussives and as Category III nasal decongestants. The wild cherry and alcohol are considered inactive ingredients. Guaifenesin, used
as a comparative drug in the first study, was classified as Category III expectorant by the Panel. As the combination drug product contains a number of ingredients with various pharmacological actions (expectorant/antitussive/nasal decongestant), it is impossible to determine from the studies, as conducted, which of the active ingredients were contributing to or producing the pharmacological actions that resulted in relief of the symptoms evaluated. Because the ingredients of the combination drug product were not studied individually, the agency cannot ascertain which ingredient(s) in the product were responsible for any of the effects obtained.

In addition, an expectorant drug product was defined by the Panel in §341.3(j) as “a drug used to promote or facilitate the removal of secretions from the respiratory airways.” The studies submitted by the comment did not include any objective measurements of the quality or thickness of sputum. The agency believes that such measurements (an increase in sputum volume and a decrease in viscosity) are necessary to establish the effectiveness of an expectorant ingredient (see comment 9 above). In order to establish the effectiveness of ipecac as an expectorant, it should be studied alone against a placebo (not guaifenesin) with the appropriate parameters being objectively evaluated. The agency concludes that the studies as conducted by the comments do not establish the effectiveness of ipecac as an expectorant active ingredient.

Reference
(1) OTC Volume 040289.

15. A comment disagreed with limiting the OTC use of ipecac syrup as an expectorant to Children 6 years of age and older. The comment contended that there is no basis in the literature for such a limitation. Furthermore, according to the comment, ipecac syrup has a long history of safe usage in children between 2 and 6 years of age, and there is no basis to require the advice and supervision of a physician for its OTC use in children in this age range.

A committee composed of experts in pediatric drug therapy served as advisors to the Panel in determining pediatric dosages for OTC cough-cold drug ingredients. These experts reviewed the available data and recommended that ipecac syrup, as an OTC expectorant, be used only in children 6 years of age and over. The Panel also reviewed the available data and noted that there were no clinical studies substantiating the effectiveness of ipecac syrup as an expectorant and no data on the toxicity of ipecac syrup as a single ingredient for expectorant use in children under 6 years of age. Because of this lack of data, the Panel adopted the pediatric committee’s recommendation limiting ipecac syrup as an expectorant to use in children 6 years of age and over. The comment provides no new information which would lead the agency to alter the Panel’s recommendation.

16. One comment states that because of the very unusual pharmacological properties of noscapine the Panel should have considered it as an expectorant as well as an antitussive. The comment pointed out that noscapine has been shown to have the significant advantage of facilitating expectoration and stimulating the production of bronchial mucus while suppressing non-productive cough in certain disease states such as asthma. An early study was referenced in support of this activity (Ref. 1). The comment requested that noscapine be considered as an expectorant or, alternatively, be placed in Category III so that further studies can confirm its unique qualities.

The agency has reviewed the reference cited in the comment in which noscapine hydrochloride was administered intravenously to 50 surgical patients in a dosage of 3 milligrams per kilogram of body weight. Doses were administered before the induction of anesthesia or at the end of anesthesia. The cough reflex was not completely removed but foreign matter in the laryngeal or bronchial areas was coughed up. Loder (Ref. 1) concluded that “it appears that this drug should be given an extended trial in any situation where a reduction of the cough reflex is desirable.”

The agency concludes that the study only assessed the intravenous use of noscapine in surgical patients as an antitussive and was not designed to measure the expectorant activity of the drug. Data and information submitted to the Panel contained studies which were designed primarily to assess antitussive effectiveness (Ref. 2) but also contained unsupported statements that implied the effectiveness of noscapine as an expectorant. The agency has reviewed the Panel’s statement on the Category III status of noscapine as an antitussive. (See 41 FR 38352.) The Panel concluded that “There are no well-controlled studies documenting the effectiveness of noscapine as an antitussive. Effectiveness has not been established by objective, controlled clinical trials.” Because the comment provides no additional data and because the data and information reviewed by the Panel do not support the effectiveness of noscapine as an expectorant, the agency concludes that noscapine is Category II for OTC use as an expectorant.

References

(2) OTC Volumes 040001, 040002, 040003, 040004, and 040204.

17. Two comments objected to the Panel’s recommendation that chloroform be permitted for use as a flavoring agent in cough-cold products. Both comments stated that the Panel’s recommendation conflicts with the National Cancer Institute’s finding that chloroform is an animal carcinogen having the potential for carcinogenesis in humans. The comments concluded that chloroform should not be allowed to be used as a flavoring agent.

This issue is addressed in this document because the Panel discussed the safety of chloroform as a flavoring agent as part of its evaluation of chloroform as an expectorant agent. One of the documents which the Panel reviewed pertaining to the possible carcinogenicity of chloroform was a preliminary report from the National Cancer Institute (NCI) entitled “Report on Carcinogenesis Bioassay of Chloroform” dated February 1976 (Ref. 1). After considering the dosage of chloroform administered in the study described in the NCI report, the Panel stated that it was unable to determine from the available data whether chloroform at a maximum allowable concentration of 0.4 percent proposed for use as a flavoring agent was safe.

The Panel’s report was adopted and submitted to FDA during its last meeting on March 2 and 3, 1976. On March 1, 1976, the agency received the NCI’s “Report On The Carcinogenesis Bioassay of Chloroform.” FDA reviewed this report and, prior to publication of the Panel’s report, published a proposal in the Federal Register of April 9, 1976 (41 FR 15026) and a final regulation in the Federal Register of June 29, 1976 (41 FR 26842), which has been codified in §310.513 (21 CFR 310.513), stating that any human drug product containing chloroform as an ingredient is a new drug and is misbranded. The Panel’s report was subsequently published in the Federal Register on September 9, 1976 (41 FR 38312), and was not changed to reflect the above regulation because it was not an agency proposal. The chloroform ban in §310.513 is, of course, applicable to chloroform used as an
and information to demonstrate the
safety or effectiveness of any
anticholinergic or expectorant ingredient
or condition included in the review by
following the procedures outlined in the
agency's policy statement published in the
Federal Register of September 29, 1981 (46 FR 47740). This policy statement
includes procedures for the submission
and review of proposed protocols,
agency meetings with industry or other
interested persons, and agency
communications on submitted test data
and other information.

A. Summary of Ingredient Categories
and Testing of Category II and Category
III Conditions

1. Summary of ingredient categories.

The agency has reviewed all claimed
active ingredients submitted to the
Panel, as well as other data and
information available at this time, and
has made no changes at this time in the
Panel's categorization of ingredients. For
the convenience of the reader, the
following tables are included as
summaries of the categorization of
anticholinergic and expectorant active
ingredients.

<table>
<thead>
<tr>
<th>Category</th>
<th>Anticholinergic Active Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Atropine sulfate</td>
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<tr>
<td></td>
<td>Belladonna alkaloids</td>
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<tr>
<td></td>
<td>Belladonna alkaloids as contained in atropa belladonna and datura stramonium (inhalant).</td>
</tr>
<tr>
<td></td>
<td>Expectorant Active Ingredients</td>
</tr>
<tr>
<td></td>
<td>Ammonium chloride</td>
</tr>
<tr>
<td></td>
<td>Antimony potassium tartrate</td>
</tr>
<tr>
<td></td>
<td>Beechwood resorcinol</td>
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<tr>
<td></td>
<td>Benzoin preparations (inhalant) (compound tincture of benzoin, tincture of benzoin).</td>
</tr>
<tr>
<td></td>
<td>Camphor (topical/inhalant)</td>
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<tr>
<td></td>
<td>Chloroform</td>
</tr>
<tr>
<td></td>
<td>Eucalyptus oil/eucalyptus elixir (topical/inhalant).</td>
</tr>
<tr>
<td></td>
<td>Guaifenesin (glyceryl guaiacolate)</td>
</tr>
<tr>
<td></td>
<td>Iodide (calcium iodide, anhydrous; hydriodic acid; sodium iodide, tincture of iodine; potassium iodide).</td>
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<tr>
<td></td>
<td>Ipecac (fluidextract).</td>
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<td></td>
<td>Ipecac syrup</td>
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<tr>
<td></td>
<td>Methyl/peppermint oil (topical/inhalant).</td>
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<tr>
<td></td>
<td>Pine tar preparations (extract white pine compound; pine tar, syrup of pine tar, compound white pine syrup, white pine).</td>
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<tr>
<td></td>
<td>Potassium guaiacolulonate</td>
</tr>
<tr>
<td></td>
<td>Sodium citrate</td>
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<tr>
<td></td>
<td>Squill preparations (squill, squill extract).</td>
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<tr>
<td></td>
<td>Tepin hydrodate preparations (tepin hydrodate, tepin hydrodate alcohol).</td>
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<tr>
<td></td>
<td>Tolu preparations (tolu, tolu balsam, tolu balsam tincture),</td>
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<tr>
<td></td>
<td>Turpentine oil (spirits of turpentine) (oral).</td>
</tr>
<tr>
<td></td>
<td>Turpentine oil (spirits of turpentine) (topical/inhalant).</td>
</tr>
</tbody>
</table>

2. Testing of Category II and Category III Conditions

The Panel recommended testing guidelines for anticholinergic drug products and expectorant drug products (41 FR 38329, 38369, and 38379). The agency is offering these guidelines as the Panel's recommendations without adopting them or making any formal comment on them. The agency has some reservations about the Panel's testing guidelines for expectorants and suggests that manufacturers discuss their proposed protocol(s) with the agency prior to performing studies. Interested persons may communicate with the agency about the submission of data

3. The agency has combined the
indications for anticholinergics that
were included under § 341.70(a)
(redesignated as § 341.70(b)). The
agency has also combined several
indications for expectorants that were
included under § 341.78(a) (redesignated as § 341.78(b)). The agency believes that combining these respective indications presents them to the consumer in a clearer and more concise manner. Therefore, the Panel's indications in § 341.70(b)(1) through (5) have been revised, combined, and redesignated as § 341.70(b). The Panel's indications in § 341.78(a)(1) through (4) have been combined, revised, and redesignated as new § 341.78(b)(1). Section 341.78(a)(5) has been redesignated as new § 341.78(b)(2).

4. The Panel's recommended warning in § 341.70(b)(2) has been redesignated as § 341.70(c)(2) and changed to include "dizziness" as described in comment 6 above.

5. In §§ 341.70(b)(3) and 341.78(b)(3)
the Panel recommended use of the signal
word "caution" in a section of the
labeling where the heading "Warning"

6. The Panel recommended use of the
word "physician" in several warnings.
Believing that the word "doctor" is more
commonly used and better understood
by consumers, the agency is substituting
the word "doctor" for "physician" in the
warnings appearing in the tentative final
monograph. FDA is proposing that the
term "doctor" be used instead of the
term "physician" in all OTC drug
monographs. (See comment 5 above).

The agency has examined the
economic consequences of this proposed
rulemaking and has determined that it
does not require either a Regulatory
Impact Analysis, as specified in
Executive Order 12291, or a Regulatory
Flexibility Analysis, as defined in the
Regulatory Flexibility Act (Pub. L. 96-
354). Specifically, the proposal would
necessitate some testing or
reformulation as there are currently no
Category I anticholinergic or
expectorant ingredients. The agency is
aware that one expectorant ingredient,
guaifenesin, is being tested and that the
data relating to that ingredient may be
submitted before the final monograph is
issued. If guaifenesin is placed in
Category I, some minor relabeling will
be necessary, resulting in minimal costs.
The agency knows of no anticholinergic
ingredients being tested, and it appears
that cough-cold products containing
these ingredients will have to be
reformulated after the final monograph is issued. Minimal impact is expected, however, as most of these products have already been reformulated voluntarily without the anticholinergic ingredient. Therefore, the agency concludes that the proposed rule is not a major rule as defined in Executive Order 12291.

Further, the agency certifies that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC anticholinergic drug products and expectorant drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding any substantial or significant economic impact that this rulemaking would have on OTC anticholinergic drug products and expectorant drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on anticholinergic drug products and expectorant drug products, a period of 120 days from the date of publication of this proposed rulemaking in the Federal Register will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has carefully considered the potential environmental effects of this proposal and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency’s findings of no significant impact and the evidence supporting this finding, contained in an environmental assessment (under 21 CFR 25.31, proposed in the Federal Register of December 11, 1979; 44 FR 71742), may be seen in the Dockets Management Branch, Food and Drug Administration.

List of Subjects in 21 CFR Part 341

OTC drugs: Anticholinergics, Expectorants.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 341, to read as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

341.1 Scope.

341.3 Definitions.

Subpart B—Active Ingredients [Reserved]

Subpart C—Labeling

341.70 Labeling of anticholinergic drug products.

341.78 Labeling of expectorant drug products.


Subpart A—General Provisions

§ 341.1 Scope.

(a) An over-the-counter cold, cough, allergy, bronchodilator, or antiasthmatic drug product in a form suitable for oral, inhalant, or topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 341.3 Definitions.

As used in this part:

(a) Anticholinergic drug. A drug used for the relief of excessive secretions of the nose and eyes, symptoms which are commonly associated with hay fever, allergy, rhinitis, and the "common cold" (cold).

(b) Expectorant drug. A drug used to promote or facilitate the removal of secretions from the respiratory Airways.

Subpart B—Active Ingredients [Reserved]

Subpart C—Labeling

§ 341.70 Labeling of anticholinergic drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any and identifies the product as an "anticholinergic."

(b) Indications. The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the following phrase: "Temporarily" (selected one of the following: "suppresses" or "relieves") (select one of the following: "watery nose," "excessive nasal secretions," or "running nose") "and watery eyes as may occur in certain allergic conditions and infections of the upper respiratory tract."

(c) Warnings. The labeling of the product contains the following warnings under the heading "Warnings":

(1) "Do not exceed recommended dosage unless directed by a doctor."

(2) "Stop taking this product if constipation, excessive dryness of the mouth, insomnia, excitement, confusion, dizziness, rapid pulse, or blurring of vision occurs."

(3) "Do not take this product if you have asthma, glaucoma, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor."

(4) "Do not give this product to children under 12 years of age unless directed by a doctor."

(d) Directions [Reserved]

§ 341.78 Labeling of expectorant drug products.

(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "expectorant."

(b) Indications. The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or both of the following phrases:

(1) "Helps" (select one of the following: "Loosen phlegm (sputum) and bronchial secretions and rid the bronchial passageways of bothersome mucus" or "Drain bronchial tubes by thinning mucus.").

(2) "Relieves irritated membranes in the respiratory passageways by preventing dryness through increased mucus flow."

(c) Warnings. The labeling of the product contains the following warnings, under the heading "Warnings":

(1) "Do not give this product to children under 2 years of age unless directed by a doctor."

(2) "Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or where cough is
accompanied by excessive secretions unless directed by a doctor."

(3) "A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor."

(d) Directions. [Reserved]

Interested persons may, on or before September 7, 1982 submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency’s economic impact determination may be submitted on or before November 8, 1982. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, 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.

Interested persons, on or before July 11, 1983 may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before September 9, 1983. These dates are consistent with the time periods specified in the agency’s final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA-305) (address above). Received data and comments may also be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on September 9, 1983. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the Federal Register, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

Arthur Hull Hayes, Jr.,
Commissioner of Food and Drugs.

Dated: June 7, 1982.
Richard S. Schweiker,
Secretary of Health and Human Services.

[FR Doc. 82-18540 Filed 7-8-82; 8:45 am]
BILLING CODE 4160-01-M
Part VI

Department of Health and Human Services

Food and Drug Administration

Topical Otic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 344
[Docket No. 77N-0334]

Topical Otic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) topical otic drug products (products for the ear) are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs on the proposed regulation by September 7, 1982. New data by July 11, 1983. Comments on the new data by September 9, 1983. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 9, 1983 (46 FR 47730). Written comments on the agency's economic impact determination by November 9, 1982.

ADDRESS: Written comments, objections, or requests for oral hearing to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. New data and comments on new data should also be addressed to the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HPD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 18, 1977 (42 FR 63556) FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical otic drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by March 16, 1978. Reply comments in response to comments filed in the initial comment period could be submitted by April 14, 1978.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

The advance notice of proposed rulemaking, which was published in the Federal Register on December 16, 1977 (42 FR 63556), was designated as a 'proposed monograph' in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated in the OTC drug review regulations as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) the FDA states for the first time its position on the establishment of a monograph for OTC topical otic drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC topical otic drug products.

In response to the advance notice of proposed rulemaking, two drug manufacturer associations, one drug manufacturer, one otolaryngologist, and one consumer group submitted comments. Copies of the comments received are also on public display in the Dockets Management Branch.

Recent rulemaking activities have been described in this issue of the Federal Register (330.10(a)(6) (21 CFR 330.10(a)(6)) and noted in the advance notice of proposed rulemaking for OTC topical otic drug products (published in the Federal Register of December 18, 1977 (42 FR 63556)(1)). The agency suggested that the
conditions included in the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the Federal Register and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss but also interfere with consumers access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the Federal Register. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace. However, if the agency determines that any labeling for a condition included in the final monograph should be implemented sooner, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

1. The Agency's Tentative Conclusions on the Comments

A. General Comments

1. Two comments urged the agency to recognize the legal status of the monographs issued under the OTC drug review as being interpretative rather than substantive regulations. This subject was dealt with in paragraph 85 through 91 of the preamble to the procedures for classification of OTC drug products published in the Federal Register of May 11, 1972 (37 FR 9464) and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the Federal Register of November 17, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., National Nutritional Foods Association v. Weinberger, 512 F. 2d 688, 696-98 [2d Cir. 1973]; National Association of Pharmaceutical Manufacturers v. FDA, 487 F. Supp. 412 (S.D.N.Y. 1980), aff'd, 637 F. 2d 885 (2d Cir. 1981).

2. One comment suggested that FDA should affirm its active support of the Federal Trade Commission (FTC) proposal to limit commercial advertising claims of OTC drugs to the labeling specified in the OTC drug monographs. The comment recommended several statements on OTC drug advertising for inclusion in the topical otic monograph. In a notice published in the Federal Register of May 1, 1981 (46 FR 24584), the FTC announced its decision to terminate the proposal to restrict the terms used in OTC drug advertising to those labeling terms specifically permitted by the OTC drug monographs. Instead of using this across-the-board approach, FTC will review advertising for OTC drugs on a case-by-case basis, taking into consideration the OTC drug review findings on safety and effectiveness in making its decisions. It is thus no longer relevant for FDA to take a position on the FTC proposal. Further, because OTC drug advertising is regulated primarily by the FTC, it would not be appropriate for FDA to include specific statements dealing with advertising in applicable OTC drug monographs.

3. One comment noted the Panel's statement that there is a great need for consumer education regarding ear care and topical otic therapy and expressed concern that the proposed regulations alone will do little to educate the public regarding ear care. The comment recommended that FDA develop a consumer education program on ear care to be released at the same time the final monograph is published.

The comment makes a sound recommendation. FDA has Consumer Affairs Officers who implement consumer education programs in all parts of the country. Information about the OTC drug review is provided in the consumer drug education program, and the agency will develop information for consumers on ear care and topical otic therapy which will be included in this program.

B. General Comments on Topical Otic Ingredients

4. One comment stated that the Panel supported its conclusions on the safety of carbamide peroxide in anhydrous glycerin as an earwax removal aid on clinical use and marketing experience and not on well-controlled studies. This comment contend that such an approach is in violation of regulations promulgated by FDA.

The agency does not believe that the process by which the Panel concluded that carbamide peroxide in anhydrous glycerin is safe for use as an earwax removal aid is in violation of FDA regulations. The regulations at 21 CFR 330.10(a)(4)(ii) state: "Proof of safety shall consist of adequate tests by methods reasonably applicable to show the drug is safe under the prescribed, recommended, or suggested conditions of use. This proof shall include results of significant human experience during marketing. General recognition of safety shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data."

The Panel's conclusion as to the safety of carbamide peroxide in anhydrous glycerin was arrived at in accordance with the above regulation. The Panel reviewed published studies, as cited in its report, and used clinical and marketing experience to corroborate these studies. The agency believes that the evidence in these studies and the Panel's expertise in evaluating the clinical and marketing experience of carbamide peroxide in anhydrous glycerin are sufficient to establish the safety of this ingredient under its recommended conditions of use as an earwax removal aid.

5. One comment stated that the Panel supported its conclusions on the effectiveness of carbamide peroxide in anhydrous glycerin as an earwax removal aid on clinical use and marketing experience and not on well-controlled studies. The comment argued that such an approach is inadequate, is in violation of FDA regulations, and sets a dangerous precedent with regard to establishing the required burden of proof for other Category I drugs.

Proof of effectiveness, as defined in 21 CFR 330.10(a)(4)(ii), "shall consist of controlled clinical investigations as
defined in §314.111(a)(5)(iii) of this chapter, 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.

Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing.

The agency agrees that the studies on which the Panel primarily based its conclusion that carbamide peroxide in anhydrous glycerin is effective as an earwax removal aid were not double-blinded or placebo-controlled. However, all patients participating in these studies were examined professionally and found to require removal of earwax. When carbamide peroxide was instilled in affected ears over periods ranging from 3 to 6 days, subsequent irrigation of the ears with lukewarm water was shown to remove earwax from a significant number of the ears tested.

The agency is aware of an additional study, not cited by the Panel, in which 26 patients were treated for bilateral excessive or impacted earwax (Ref. 1). Ten drops of 6.5 percent carbamide peroxide in anhydrous glycerin were instilled into each ear canal twice daily, upon arising and at bedtime, for 6 days followed by syringing the ear canals twice daily for 2 days with lukewarm water and a soft rubber ear syringe. The following day the ear canals were examined by a physician for any evidence of tissue reaction and for the degree of earwax removal. Complete removal of the earwax was achieved in 22 of the 26 patients. In two cases, additional syringing by the physician resulted in complete removal of the earwax. The remaining two patients required a second course of treatment, which resulted in complete removal of the earwax. The author concluded that carbamide peroxide in anhydrous glycerin was a safe, clinically effective, and easily administered agent for the lysis and removal of earwax, without the need for pressure syringing and instrumentation.

The agency believes that the methods of investigation employed in these studies and the results obtained, along with subsequent reports of significant human experience during marketing, justify a waiver of the well-controlled study requirements. Because an earwax removal aid achieves its intended therapeutic effect by means of a mechanical action whose results are readily ascertainable, these studies are sufficient to establish the effectiveness of carbamide peroxide in anhydrous glycerin as an earwax removal aid.

References


6. One comment contended that the Panel did not rely on controlled studies to support its conclusions on the safety and effectiveness of glycerin as an earwax removal aid.

Glycerin has been adequately demonstrated to be safe for topical use in the ear. However, a thorough review of the data cited by the Panel in support of the effectiveness of glycerin as an earwax removal aid indicates that the only published study referred to was an in vitro study by Senturia and Doubly (Ref. 1) of the effect different vehicles in their action on earwax removed from the human ear canal. Distilled water, hydrogen peroxide (1.5 and 3 percent), and saline solutions (1 and 2 percent) showed immediate reaction with the earwax, and total disintegration occurred in 60 minutes. Glycerin has no effect on the earwax after 60 minutes and showed only surface softening after 24 hours. The authors concluded that glycerin showed little effect upon earwax except that of surface softening. Glycerin has been used by itself in inflammations of the external auditory canal or the middle ear (Ref. 2), and "AMA Drug Evaluations" (Ref. 3) lists glycerin as one ingredient which might be instilled in the ears of patients who have chronic difficulty with impacted earwax; however, it cites no data to support this use. The agency is not aware of any well-controlled studies that demonstrate effectiveness. FDA believes, therefore, that the existing data are not adequate to support the effectiveness of glycerin as an earwax removal aid. The agency is placing glycerin in Category III so that studies may be performed to establish its effectiveness for this indication.

References


7. One comment suggested that it is unduly restrictive to limit the carbamide peroxide in anhydrous glycerin to a concentration of 6.5 percent in earwax removal aids. This comment proposed amending the monograph to allow for a range of 5 to 8 percent carbamide peroxide in anhydrous glycerin.

Only two products containing carbamide peroxide in anhydrous glycerin were submitted to the Panel for review, and both had a carbamide peroxide concentration of 6.5 percent. No evidence was presented to the Panel, and none has been submitted to the agency, to show that a 5- to 8-percent range of carbamide peroxide in anhydrous glycerin would be safe and effective. Thus, the agency cannot propose a concentration range for this ingredient without additional data being provided to support such a range.

C. General Comments on Topical Otic Labeling

8. One comment contended that FDA does not have the authority to legislate the exact wording of OTC labeling claims. The comment stated that limiting the indications to those in the monograph is overly restrictive because the Panel itself has used alternate terminology throughout the report in discussing the indications for these products. The comment stated that the following truthful claims could be made for earwax removal aids based on language not recommended by the Panel but contained in or referenced in its report: "to soften and loosen earwax," "to relieve the symptoms of fullness due to the accumulation of earwax," "aids in the removal of accumulated earwax," "mechanically softens and loosens earwax so that it can be washed out of the ear canal by irrigation with warm water," "mild mechanical action," "aids in the removal of earwax," and "topical earwax softening agent." The comment requested that more flexibility in labeling be permitted by adding to the approved indications a statement as follows: "* * * or similar indications statements which are in keeping with the Panel's report."

Since the inception of the OTC drug review, the agency has maintained that a monograph describing the conditions under which an OTC drug will be generally recognized as safe and effective and not misbranded must include both specific active ingredients and specific labeling. (This policy has become known as the "exclusivity rule." ) The agency's position has been that it is necessary to limit the acceptable labeling language to that developed and approved through the OTC drug review process in order to ensure the proper and safe use of OTC drugs. The agency has never contended, however, that any list of terms developed during the course of the
During the course of the review, FDA’s position on the “exclusivity rule” has been questioned many times in comments and objections filed in response to particular proceedings and in correspondence with the agency. The agency has also been asked by the Proprietary Association to reconsider its position. To assist the agency in resolving this issue, FDA plans to conduct an open public forum on September 29, 1982 where all interested parties can present their views. The forum will be a legislative type administrative hearing under 21 CFR Part 15 that will be held in response to a request for a hearing on the tentative final monograph for nighttime sleep-aids (published in the Federal Register of June 13, 1978; 43 FR 25544). Details of the hearing were announced in a notice published in the Federal Register of July 2, 1982 (47 FR 29002). In proposed and tentative final monographs issued in the meantime, the agency will continue to state its longstanding policy.

As discussed below in comment 12, FDA is proposing to modify the Panel’s recommended indication statement in § 344.50(b). In light of the Panel’s use of alternative terminology throughout its report, the agency has reviewed the other claims noted in the comment. FDA believes that a number of these statements are consistent with the labeling message that the Panel intended to convey and that these statements, with slight modifications to ensure accurate reflection of the agency’s and Panel’s positions on labeling of OTC topical ear products, will provide the consumer with meaningful information on the labeling of earwax removal aid drug products. Accordingly, a new § 344.50(b)(2) entitled “Other allowable statements” is being proposed in this tentative final monograph. The following statements, as included in this section, may also be made on the labeling of earwax removal aid drug products:

- “Aids in the removal of accumulated earwax.”
- “Aids in the removal of excessive earwax.”
- “Topical earwax softening and loosening agent.”

The phrases “mild mechanical action” and “mechanically softens and loosens earwax” have not been included in § 344.50(b). (See comment 13 below.) The claim “to relieve the symptoms of fullness due to the accumulation of earwax” also has not been included in § 344.50(b). (See comment 15 below.)

9. Comments contended that experience in mass communication was not a criterion for scientific advisory panelists participating in the OTC drug review and questioned whether some of the terminology used in the labeling for OTC topical ear products could be understood by the ordinary individual in accordance with 21 CFR 330.10(a)(4)(v). One of the comments suggested that FDA consult with behavioral scientists and linguistic experts to help translate the technical language, which is used both in the labeling and in other portions of the Panel report, into lay language that the average consumer can understand. Another comment stated that FDA should leave the implementation of labeling language to the industry, which has had years of experience developing terminology generally understood by the public.

Since its inception, the OTC drug review has focused on developing labeling of OTC drug products that can be understood by the average consumer. While the agency acknowledges that professional experience in mass communication was not a criterion for participation in the OTC drug advisory review panels, the clinical background of the physicians, pharmacists, and other health professionals on each panel involved direct experience with patients and an awareness of the terms used by them to refer to their symptoms. In addition to members of the scientific and medical communities, each panel included representatives from industry and consumer groups and thus had access to the experience of these groups in mass communication of medical terminology. Finally, any citizen interested in doing so could participate in the OTC drug review by presenting views at panel meetings, and, now that the Panels have concluded their reviews, by commenting on advance notices of proposed rulemaking or by commenting or objecting to tentative final monographs proposed by the agency. As mentioned in comment 8 above, a number of changes in the Panel’s recommended labeling of topical ear products have been incorporated into the agency’s proposed labeling as a result of comments received. The agency urges anyone having suggestions for making the labeling language used in the topical ear product monograph more understandable to the average consumer to submit these suggestions in comments responding to this document. After a final monograph for topical ear products is issued, such suggestions may be made in the form of a petition to amend the monograph according to the procedures described in 21 CFR 10.30.

10. One comment expressed concern about the minimal discussion on labeling in the Panel’s report and stated that a position on labeling should be made explicit by FDA. The comment provided a “Labeling General Statement” which it recommended be adopted by the agency. This labeling statement contains a general discussion of Categories I, II, and III, what labeling must contain to be acceptable, the function of FDA to clarify labeling, the role of the FDA in approving labeling for OTC drug products, the use of labeling indicating superiority of one product over another, the use of extra strength claims in labeling, other misleading superiority claims, claims implying a unique action, and claims relating to time that do not actually relate to the directions or indications, e.g., claims such as “fast” or “prompt.”

The “Labeling General Statement” recommended by the comment embodies many principles beyond the scope of the topical ear product monograph. Section 330.10(a)(4)(v) (21 CFR 330.10(a)(4)(v)) of the general regulations for classifying OTC drugs states the agency’s general labeling standards for OTC drug products. In its report, the Panel has provided a general discussion of Categories I, II, and III; specified the indications, directions for use, and the warnings for the labeling of OTC topical ear products; and identified those labeling claims (Category II) that it considers to be misleading and unsupported by scientific data and (in some instances) unsupported by sound theoretical reasoning. The agency believes that the labeling discussion in the Panel’s report is adequate and disagrees with the comment that the labeling discussion is minimal. The agency also disagrees with the need for the “Labeling General Statement” recommended by the comment because existing FDA regulations already state the agency’s labeling requirements. In addition, most panels have specifically addressed a number of the issues contained in the “Labeling General
The agency concludes that the signal word “warning,” rather than the potential dangers so that consumers will use or its use should be discontinued. 

11. One comment stated that the signal word “warning” is too strong for the types of precautionary information being conveyed. This comment argued that the word “warning” should be used only on certain types of consumer products to highlight imminent physical hazards associated with normal storage or use of products such as household cleaners, polishes, insecticides, or products marketed as aerosols. This comment suggested that the Panel’s recommendation § 344.50(c) be revised to read as follows: “Cautions. The labeling of the product shall contain the following precautionary statement under the heading “Cautions.”

This comment also suggested that in § 344.50(c)(ii) the signal word “caution” should be deleted as redundant because in no event should two signal words be necessary.

Section 352(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)(2)) states, in part, that any drug marketed OTC must bear in labeling ** * such adequate warnings * * * as are necessary for the protection of users.” Section 330.10(a)(4)(v) of the OTC drug regulations provides that labeling of OTC drug products shall state ** * warnings against unsafe use, side effects, and adverse reactions * * * .

The agency notes that historically there has not been a consistent usage of the signal words “warning” and “caution” in OTC drug labeling. For example, in § 369.20 and 369.21 [21 CFR 369.20 and 369.21], which list “warning” and “caution” are both used. In some instances either of these signal words is used to convey the same or similar precautionary information.

FDA has considered which of these signal words would be most likely to attract consumers’ attention to that information describing conditions under which the drug product should not be used or its use should be discontinued. The agency concludes that the signal word “warning” is more likely to flag potential dangers so that consumers will read the information being conveyed. Therefore, FDA has determined that the signal word “warning,” rather than the word “caution,” will be used routinely in OTC drug labeling that is intended to alert consumers to potential safety problems.

12. One comment questioned whether the term “obstructive” could be understood by the average consumer. The Panel used the phrase “Cautions.” in its recommended indication for topical otic drug products to indicate that these products were intended only for use by individuals who have a tendency to accumulate excessive earwax that needs to be removed occasionally and that these products were not to be used for routine ear cleansing. The agency agrees with the comment that the term “obstructive” may not be understood by the average consumer and therefore is proposing the term “excessive” instead. In keeping with the Panel’s intention and with the agency’s goal of providing understandable wording, the agency is proposing in this tentative final monograph to revise the indication statement in § 344.50(b) to read as follows: “For occasional use as an aid in the removal of excessive earwax.

13. One comment suggested that the phrase “mild mechanical action to soften and loosen earwax” be added to the monograph as an allowable indication for OTC earwax removal aids because the Panel itself had used this terminology in describing such ingredients in the report. The Panel used the term “mechanically softens and loosens” to distinguish agents which dissolve earwax from those which soften and loosen earwax so that it may be removed by irrigating the affected ear. The agency believes that the use of the words “mild mechanical action” to describe the mode of action of earwax removal aids would have no meaning to consumers. Therefore, a phrase describing these products as having a mild mechanical action will not be added to the monograph. However, because the phrase “softens and loosens excessive earwax” accurately describes the action of these products, the agency will allow use of this phrase on the labeling of OTC topical otic drug products. As described in comment 8 above, a new § 344.50(b)(2), entitled “Other allowable statements,” has been proposed in the tentative final monograph.

14. One comment questioned why the Panel placed the indication “removal and softening of earwax” in Category II because, but for a few words, the phrase is almost identical to the allowable Category I indication.

The agency points out that the Panel included the statement referred to in the comment in its discussion of the use of anesthetics and analgesics in OTC topical otic drug products. The above indication was one of six claims the Panel classified as Category II for topical otic anesthetics and analgesics, not for earwax removal agents. The Panel concluded, and the agency concurs, that the use of anesthetics and analgesics in the ear should be restricted to prescription use, and, therefore, ingredients and claims for these uses are placed in Category II.

15. Several comments proposed that the labeling be amended to include an additional indication “To relieve symptoms of fullness due to an excessive accumulation of earwax.” These comments noted that this indication was included in the general discussion of the Panel report. One comment contended that the warning “if symptoms of fullness persist, consult a physician” is only suitable if “relief of the symptoms of fullness” is allowed as an indication. Another comment stated that the term “fullness” is unclear and confusing in the context in which it is used.

As the comments pointed out, the Panel recognized that an excessive accumulation of earwax could cause symptoms of fullness in the ear canal. However, the agency believes that the word “fullness,” when used to describe an ear symptom, lacks precise meaning for most consumers. The agency is concerned that consumers might consider the symptoms of ear conditions that are more serious than excessive earwax as symptoms of fullness and thus risk the consequences of non-diagnosis and mistreatment. Therefore, the agency proposes that “symptoms of fullness” not be allowed as an indication for OTC earwax removal aids, and, correspondingly, proposes the warning, “if symptoms of fullness persist, consult a physician,” be deleted.

However, the agency believes that the labeling should state that, if the wax is not removed after using the product, the user should consult a physician. In the Panel report, it is clear that impacted earwax that cannot be removed with OTC earwax softening agents should be treated by a physician who may use agents that dissolve earwax or instruments which are not suitable for OTC use. In addition, the agency believes that the word “doctor” is more commonly used and more readily understood by consumers than the word “physician.” Therefore, the agency is proposing that the warning statement, “if symptoms of fullness persist, consult a physician” be replaced by the statement: “If excessive earwax remains after use of this product, consult a
doctor.” (See part II. paragraph 6. below.)

16. One comment recommended that "for use as an aid in the prevention of swimmer’s ear” be included in the topical otic monograph as an indication for OTC topical otic ingredients. Also, a physician requested that the ingredient propylene glycol be included in the topical otic monograph for the prevention and treatment of swimmer’s ear because he had been successfully using the ingredient for this purpose for the past 2 years. The comment included dosage instructions that the physician routinely provided to patients.

The Panel reviewed treatment of “swimmer’s ear” and placed this indication in Category II as inappropriate for an OTC topical otic product. The Panel considered “swimmer’s ear” to be an infection of the external ear and not amenable to self-diagnosis and self-treatment. FDA concurs. The Panel did not, however, specifically address the claim of prevention of swimmer’s ear, nor did it review any product containing propylene glycol as an active ingredient for this use. The Panel stated that “swimmer’s ear” is apparently due to excessive moisture in the external auditory meatus, which may be the result of various causes. Because the external auditory canal is a cul-de-sac well suited for the collection of moisture, and “swimmer’s ear” occurs with greater frequency during hot, humid weather and has been reported to occur in divers and swimmers, it is possible that propylene glycol may be useful in preventing swimmer’s ear because it absorbs moisture. However, the agency has not received any clinical data demonstrating that propylene glycol or any other ingredient is generally recognized as safe and effective in preventing swimmer’s ear. The information provided by the comment was only testimonial. Hence, currently there is no basis to include prevention of swimmer’s ear as an indication for OTC topical otic drug products. If clinical data are developed, they may be submitted within 12 months after the publication of this tentative final monograph, or thereafter in the form of a petition to amend the final monograph to include this statement. (§ 344.50(d)(i) include the statement: “For children under 12 years of age, there is no recommended dosage except under the advice and supervision of a physician.” The agency believes that this statement can be shortened to read as follows: “For children under 12 years of age, consult a doctor.” The agency also believes that, with this statement in the directions for use, there is no need for a similar statement in the warnings in § 344.50(c)(viii). Accordingly, the agency is proposing in this tentative final monograph to delete the statement from the warnings section.

References


18. One comment suggested that the Panel’s recommended warning in § 344.50(c)(v), “For external use only, not to be swallowed,” should be deleted. This comment argued that neither ingredient proposed to be classified in Category I poses a serious risk if ingested and that the use of the phrase “for external use only” labeling of OTC topical otic preparations may be confusing to consumers. Accordingly, the agency is proposing in this tentative final monograph to delete the warning “For external use only, not to be swallowed,” and to add the statement “FOR USE IN THE EAR ONLY” to the directions for use to state clearly that the product is to be used only in the ear. To emphasize the importance of this direction, the agency proposes that this statement should be printed in capital letters.

19. One comment questioned whether the words “drainage” and “perforation,” as used by the Panel in its recommended warnings, would be understood by the average consumer since they are infrequently used in everyday conversation.

The agency believes that these words would not be readily understood by the average consumer. Therefore, to explain the meanings of these terms, the agency has added to the Panel’s warning the word “hole” in parentheses after “ear drum perforation,” and the words “or discharge” after the term “drainage.”

20. One comment recommended the addition of a warning: “Do not use whenever an ear infection is suspected.”

The Panel did not believe that a consumer would be able to self-diagnose an ear infection. Therefore, instead of using the word “infection,” the Panel listed in the warnings the common symptoms of ear infections, such as ear pain and ear drainage. The agency believes that the Panel’s recommended warning in § 344.50(c)(ii) as amended in this tentative final monograph [now § 344.50(c)(1)] is adequate, and that the warning suggested in the comment would be redundant. Accordingly, FDA has not added this warning to the tentative final monograph.

21. A comment objected to the Panel’s recommended warning in § 344.50(c)(iii) not to use topical otic drug products following ear surgery. This comment contended that ear surgery should not preclude the use of a topical otic drug product forever and suggested that the warning should be revised to have a time limit of 6 weeks following ear surgery.

The agency agrees with the comment that it may be unnecessary to ban forever the use of these products following ear surgery. However, the time period of restriction from use will vary depending on the type of surgery performed. Therefore, the decision when to use a topical otic drug product following ear surgery should be made by...
the patient's physician. The agency believes that the warning should not be revised to state a specific time period during which these drug products should not be used following ear surgery. However, the agency is proposing in this tentative final monograph that the warning recommended by the Panel in § 344.50(c)(ii) be modified to state that these products should not be used after ear surgery only if directed by a doctor. (See comment 22 below.)

22. Several comments stated that some of the phrases in the warnings were redundant. One comment suggested a statement be added to the monograph which would allow for the general warnings to be combined when the intent of the warnings is not affected. Another comment suggested that three warning statements recommended by the Panel (§ 344.50(c)(ii), (iii), and (iv)) be combined and revised to read as follows:

1) "Do not use in the presence of ear drainage, pain, or dizziness, or whenever an infection is suspected. If these develop, consult a physician."

2) "Do not use in the presence of known injury or perforation (hole) of the ear drum or within six weeks following ear surgery except under the advice and supervision of a physician."

The agency agrees with the comments that some of the warnings could be combined without losing their intent. However, the references to ear infection and the 6-week period following ear surgery are not being adopted, as explained above in comments 20 and 21. The agency believes that the warning recommended by the Panel in § 344.50(c)(vii), "Discontinue use if irritation or rash appears," can be incorporated into the suggested revision of § 344.50(c)(ii) (which appears in this tentative final monograph as § 344.50(c)(1)) without changing the intent. Accordingly, the agency proposes in this tentative final monograph that the first two statements under the heading "Warnings" in § 344.50(c) read as follows:

1) "Do not use if you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor."

2) "Do not use if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor."

23. One comment expressed a belief that the consumer should be informed of the improper uses of topical otic drug products. It suggested that because misuse can lead to harmful aftereffects a warning should be added listing the symptoms for which the consumer ought not to use topical otic drug products. The comment proposed the following warning: "Warning: Avoid using to relieve minor irritation or pain for raw, inflamed tissues, swimmer's ear, anesthetizing, or itching."

The agency believes that the comment has misinterpreted the requirements for OTC drug labeling as set forth in § 330.10(f)(4)(v). It is not necessary or even possible for the agency to identify every improper use of a drug that could occur and to require the listing of such information on the OTC drug product label. FDA believes that the indications for use and the warnings proposed in this tentative final monograph are adequate to inform the consumer of the proper use of these products.

24. Several comments objected to the Panel's recommendation in § 344.50(d), which directs the user to "Place sufficient drops into affected ear and allow to remain at least 15 minutes." These comments contended that the term "sufficient" is too vague and could result in unnecessary underdosage or overdosage. One comment expressed the belief that it would be more meaningful and accurate to give the dosage in numbers of drops, e.g., 5 to 10 drops, and suggested revising the directions for administering the drops as follows: "Tilt head sideways and place 5 to 10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or by inserting cotton."

The agency agrees with this suggestion. Stating the amount is much more precise and is safer for the consumer. Also, the use of "5 to 10 drops" is consistent with the amount used in the studies reviewed by the Panel. Therefore, the agency is proposing that the directions in § 344.50(d) be modified accordingly. For additional clarity, the agency is changing the word "inserting cotton" to "placing cotton in the ear."

25. Comments objected to the Panel's recommendation in § 344.50(d) that direct the user to "Remove wax by gentle washing with lukewarm water using a soft rubber syringe. May be repeated a second time if necessary." One comment questioned whether the average consumer would know the meaning of the term "soft rubber syringe." Another comment cautioned that the use of an irrigation syringe should be discouraged when possible and its use indicated as an adjunct only for the removal of accumulated cerumen in difficult cases. The comment stated that in the case of carbamide peroxide in anhydrous glycerin it is not always necessary to use an irrigation syringe to remove the earwax. The comment stated that the mechanical effect of effervescence of carbamide peroxide loosens debris and in many cases this mechanical effect has been shown to accomplish removal of the earwax and debris without use of an irrigation syringe. The comment recommended extending the duration of treatment to 3 or 4 days and delaying the use of an irrigation syringe until the end of the treatment period, making clear that even then the use of an ear syringe should be optional. The comment suggested the following revision in directions for use of preparations containing carbamide peroxide in anhydrous glycerin: "Repeat twice daily for at least 3 to 4 days or as directed by a physician. Any remaining wax may be removed by gently flushing with warm water, using a soft rubber bulb ear syringe."

FDA agrees that "soft rubber bulb ear syringe" is a more meaningful term for the average consumer than the term "soft rubber syringe." The agency also concurs with the comment that the use of an irrigation syringe in the ear should be limited as much as possible and that the ear drops may be used for 3 to 4 days. FDA proposes to use the phrase "for up to 4 days if needed." With this modification, the agency accepts the revision suggested by the comment and proposes to revise § 344.50(d) to include the following as part of the directions for use: "Use twice daily for up to 4 days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe."

In addition, the agency believes that the failure to obtain relief after 4 days of treatment with an ear wax removal aid could indicate a more serious condition for which the patient should consult a doctor. Accordingly, the agency is proposing the following additional warning in § 344.50(c)(3): "Do not use for more than 4 days; if excessive ear wax remains after use of this product, consult a doctor."

II. The Agency's Tentative Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of ingredient categories.

The agency has reviewed all claimed active ingredients submitted to the Panel, as well as other data and information available at this time, and concurs with the Panel's categorization of carbamide peroxide in anhydrous glycerin in Category I and antipyrine and benzocaine in Category II. The
Panel also placed glycerin in Category I. FDA is proposing reclassification of glycerin in Category III because of a lack of sufficient data to demonstrate effectiveness.

2. Testing of Category II and Category III conditions. The agency notes that, because the Panel did not place any ingredients in Category III, it did not recommend any testing guidelines for Category III topical otic conditions. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any topical otic ingredient or condition included in the review by following the procedures outlined in the agency’s policy statement published in the Federal Register of September 29, 1981 (46 FR 47740). This policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency’s Changes in the Panel’s Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel’s report and recommended monograph with the changes described in FDA’s responses to the comments above and with other changes described in the summary below. A summary of the changes made in the Panel’s conclusions and recommendations follows.

1. As mentioned above, the Panel placed glycerin in Category I as an ear wax removal aid. FDA is proposing reclassification of glycerin in Category III for effectiveness. This reclassification is discussed in the agency’s response to comment 6 above.

2. In its report and recommended monograph, the Panel often referred to the active ingredient as carbamide peroxide in glycerin with subsequent discussion clarifying that the anhydrous form of glycerin is the vehicle to be used. Glycerin is glycerin U.S.P., which has a moisture content of approximately 5 percent, and anhydrous glycerin is an ingredient that may be prepared by heating glycerin U.S.P. at 150°C for 2 hours to drive off the moisture content (Ref. 1). The agency wishes to clarify that the active ingredient should correctly be referred to as carbamide peroxide formulated in an anhydrous glycerin vehicle.

Reference

§ 344.1 Scope.
(a) An over-the-counter topical otic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part in addition to each of the general conditions established in § 330.1.
(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 344.3 Definitions.
As used in this part:
(a) Anhydrous glycerin. An ingredient that may be prepared by heating glycerin U.S.P. at 150 °C for 5 hours to drive off the moisture content.
(b) Earwax removal aid. A drug used in the external ear canal that aids in the removal of excessive earwax.

Subpart B—Active Ingredients
§ 344.10 Topical otic active ingredient.
The active ingredient of the product consists of carbamidine peroxide 6.5 percent formulated in an anhydrous glycerin vehicle.

Subpart C—Labeling
§ 344.50 Labeling of topical otic drug products.
(a) Statement of identity. The labeling of the product contains the established name of the drug, if any, and identifies the product as an “earwax removal aid.”
(b) Indications. The labeling of the product contains a statement of the indications under the heading “Indications” that is limited to the following phrase:
(1) “For occasional use as an aid in the removal of excessive earwax.”
(2) Other allowable statements. In addition to the required information specified in paragraphs (a), (b)(1), (c) and (d) of this section, the labeling of the product may contain any of the following statements provided such statements 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.
(i) “Softens and loosens excessive earwax.”
(ii) “Aids in the removal of accumulated earwax.”
(iii) “Aids in the removal of excessive earwax.”
(iv) “Tropical earwax softening and lossening agent.”
(c) Warnings. The labeling of the product contains the following warnings under the heading “Warnings”:
(1) “Do not use if you have ear drainage or discharge, ear pain, irritation or rash in the ear or are dizzy; consult a doctor.”
(2) “Do not use if you have an injury or perforation (hole) of the ear drum or after ear surgery unless directed by a doctor.”
(3) “Do not use for more than 4 days; if excessive earwax remains after use of this product, consult a doctor.”
(4) “Avoid contact with the eyes.”
(d) Directions. The labeling of the product contains the following statement under the heading “Directions”: “FOR USE IN THE EAR ONLY. Adults and children over 12 years of age: Tilt head sideways and place 5 to 10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear. Use twice daily for up to 4 days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe. Children under 12 years of age: consult a doctor.”

Interested persons may, on or before September 7, 1982 submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency’s economic impact determination may be submitted on or before November 9, 1982. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, 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.

Interested persons, on or before July 11, 1983, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before September 9, 1983. These dates are consistent with the time periods specified in the agency’s final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and
comments may also be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on September 9, 1983. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the Federal Register unless the Commissioner finds good cause has been shown that warrants earlier consideration.

Arthur Hull Hayes, Jr., Commissioner of Food and Drugs.

Richard S. Schweiker, Secretary of Health and Human Services.
Part VII

Department of Labor

Mine Safety and Health Administration

Underground Coal Mine Safety Standards Review; Advance Notice of Proposed Rulemaking
DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 75

Underground Coal Mine Safety Standards Review; Advance Notice of Proposed Rulemaking

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Mine Safety and Health Administration (MSHA) invites public participation in the initial stages of its review of the underground coal mine safety standards in Title 30 of the Code of Federal Regulations, Part 75. The Agency specifically solicits comments with respect to possible regulatory action concerning standards for roof support, blasting and explosives, and the ventilation plan requirements and criteria in §75.316. As a result of a recent review, these standards have been identified as areas that MSHA believes can be improved. In addition, MSHA invites written comments from interested persons relating to any concerns that they may have with other underground coal mine safety standards, including suggestions for the order in which the standards should be reviewed. The purpose of this review is to eliminate unnecessary reporting and recordkeeping requirements, minimize conflicting provisions, delete irrelevant standards, simplify and consolidate existing regulations, update standards to conform to state-of-the-art technology, and clarify and reorganize standards, where necessary.

DATES: Comments must be received on or before September 7, 1982.

ADDRESS: Interested persons are invited to submit written comments and suggestions to the Office of Standards, Regulations and Variances, MSHA, 4015 Wilson Boulevard, Arlington, VA 22203.


SUPPLEMENTARY INFORMATION: MSHA has initiated a review of all safety standards for underground coal mines in 30 CFR Part 75. This comprehensive review is consistent with the goals of Executive Order 12291, the Regulatory Flexibility Act, the Paperwork Reduction Act, and the Department of Labor's initiatives with respect to improving regulations. A primary purpose of this comprehensive review of MSHA's underground coal mine safety standards is to improve the Agency's existing standards to promote the health and safety of miners and further the goals of regulatory reform. Particularly, MSHA will evaluate (1) the adequacy of existing standards; (2) changes in mining technology; (3) the continued relevancy of certain provisions; (4) duplicative or overlapping requirements; [5] inconsistencies with other MSHA, Federal, or State agency requirements; and (6) reporting and recordkeeping requirements.

MSHA considers early public participation in this standards review process to be particularly important. The Agency, therefore, urges the mining community and other interested parties to submit comments related to the applicability and effectiveness of any of the underground safety standards in Part 75.

As part of this review, MSHA is specifically soliciting suggestions for regulatory changes to Subpart C—Roof Support, and the ventilation requirements in §75.316. The Agency is particularly interested in any comments that the mining community has with respect to requirements related to the approval of roof control plans and plans for ventilation systems and methane and dust control. In addition, MSHA invites comments concerning blasting and explosives standards, including related requirements in 30 CFR Parts 15, 16 and 17.

List of Subjects in 30 CFR Part 75

Mine safety and health, Underground mining.

Dated: July 2, 1982.

Ford B. Ford,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 82-18630 Filed 7-8-82; 8:45 am]
BILLING CODE 4510-43-M
Grants for Planning and Construction of Public Telecommunications Facilities; Acceptance of Applications for Filing
DEPARTMENT OF COMMERCE
National Telecommunications and Information Administration

Grants for Planning and Construction of Public Telecommunications Facilities; Acceptance of Applications for Filing

I. New Applications and Major Amendments to Deferred Applications

Notice is hereby given that the following described applications for Federal financial assistance are accepted for filing under provisions of Title III, Part IV of the Communications Act of 1934, as amended (47 U.S.C. 390-94) and in accordance with 15 CFR Part 2301. All of the applications listed in this section were received or were postmarked by May 7, 1982. The effective date of acceptance of these proposals, unless otherwise indicated herein, is May 7, 1982. In the cases where “DateReceived” is indicated as being other than May 7, 1982, the “DateReceived” indicated shall serve as the effective date of acceptance of the application. Applications are listed alphabetically by their State.

The acceptance of applications for filing is a procedure designed for making preliminary determinations of eligibility and for providing the opportunity for public comment on applications. Acceptance of an application does not preclude subsequent return or disapproval of an application if it is found to be not in accordance with the provisions of either the Act or 15 CFR Part 2301, or if the applicant fails to file any additional information requested by the Public Telecommunications Facilities Program (PTFP). Acceptance of filing does not assure an application of being funded; it merely qualifies it to compete for funding with other applications which have also been accepted for filing.

Pursuant to 15 CFR 2301.09, applicants were required to publish in a newspaper of general circulation in the community to be served by the applicant, a notice that such application has been tendered to the PTFP of the National Telecommunications and Information Administration. The notice shall have been published once a week for two consecutive weeks on or before May 7, 1982. The notice included (1) information as to where within the community to be served a copy of the application and any amendments thereto, may be inspected by the public during normal business hours, and (2) an invitation for parties supporting or opposing the application to file comments with the Administrator. National Telecommunications and Information Administration, Public Telecommunications Facilities Program, Washington, D.C. 20230. All filings must be made within 15 calendar days from the date of this public notice of acceptance of the application, and must be accompanied by a certificate that the copy of the comments has been mailed to the applicant.

AK
File No. 2155CRB, Aurora Comty Brdscst Inc., Anchorage, AK 99508. Signed By: Mike Mense, President. Funds Requested: $177,943.00. Total Project Cost: $157,258.00. To extend the signal of KSKA-FM, operating on 103.1 MHz in Anchorage, AK, by increasing power from 3000 to 36,000 watts and changing frequencies from 103 to 91 FM, and to provide basic production facilities to take advantage of local programming resources.

File No. 2237CRB, Rainbow Cmty Brdscst Corp, 716 Totem Way, Ketchikan, AK 99901. Signed By: James Hanson, President, KCBC. Funds Requested: $31,884.00. Total Project Cost: $42,512.00. To replace the transmitter of public radio station KRB-D-FM, operating 105.9 MHz at Ketchikan, AK, which brings the only public radio service to the communities of Ketchikan, Metlakatla, Thorne, Bay, Hollis, Craig and Klawock in southeast Alaska.

AL
File No. 2214CTB, Alabama ETV Commission, 2101 Magnolia Ave, Birmingham, AL 35226. Signed By: Edward Wegener, General Manager. Funds Requested: $344,100.00. Total Project Cost: $714,300.00. To extend the coverage of WAIQ Channel 28, in Montgomery, Alabama, by the acquisition of a higher tower and new antenna which will provide first service to 271,992 persons.

File No. 2251CRB, Bd of Trustees for Univ of AL, 1029 7th Ave South, Birmingham, AL 35294. Signed By: Kenneth Hunt VP/Research. Funds Requested: $24,707.00. Total Project Cost: $32,943.00. To extend the radio reading service proton of public radio station WBHM-FM, operating on 90.3 MHz in Birmingham, AL, to other areas of the state via Alabama public television's existing microwave system.

File No 2252PTB, Lawson State Cmty Coll, 3060 Wilson Road, Birmingham, AL 35221. Signed By: Jesse J. Lewis, President. Funds Requested: $94,500.00. Total Project Cost: $24,500.00. To plan for a noncommercial TV station in the city of Birmingham, Alabama, to provide programming to the black population within the area.

AR

AZ
File No. 2010CTB, AZ Bd of Regents for AZ St Univ, Arizona State Univ, Tempe, AZ 85287. Signed By: Paige E. Mulholland, Exec. Vice Pres. Funds Requested: $1,275,000.00. Total Project Cost: $2,550,000.00. To replace antenna, tower, etc., and some studio equipment. Arizona State University operates noncommercial educational Channel 8 in Phoenix. Some of the existing equipment is 30 years old and spare parts are no longer obtainable.

File No 2089CRB, Apache Radio Broadcasting Corp, Box 510, Whiteriver, AZ 85941. Signed By: Billy Kane, Chairman, ARBC. Funds Requested: $65,276.00. Total Project Cost: $87,035.00. To extend this signal of tribal owned noncommercial FM radio station KNBN via translators. First service will be provided to five communities on White Mountain Indian Reservation (Apache). Earth station will provide reception of NPR at KNBN.

File No. 2328PTB, Navajo Community College, Tsaile, AZ 86536. Signed By: Dean C. Jackson, President. Funds Requested: $25,000.00. Total Project Cost: $25,000.00. To plan for a TV distribution network to serve the Navajo Nation in Arizona, New Mexico, and Utah. Network is needed to distribute Navajo programming to low power TV and cable systems on Navajo Nation. Overall objective is to establish an educational/public affairs TV network for the Navajo reservation.

CA
File No. 2017CTB, Corp on Disabilities & T/C, P.O. Box 27573, Los Angeles, CA 90027. Signed By: Neil Goldstein, Sec/Treas. Funds Requested: $1,482,220.00. Total Project Cost: $1,976,293.00. To establish a noncommercial TV station operating on Channel 68, Los Angeles, CA, to serve and employ disabled people.

File No. 2044CRB, University of the Pacific, 3601 Pacific Avenue, Stockton, CA 95211. Signed By: Clifford J. Hand, Acting President. Funds Requested: $51,593.00. Total Project Cost: $68,791.00.
To extend the signal of public radio station KUOP-FM, operating on 91.3 MHz at Stockton, CA, by relocating the primary transmitter at Mt. Oso, providing first service to portions of Stanislaus, Calaveras and other counties.

File No. 2075CTB, Santa Clara Cnty Board of Educ, 100 Skyport Drive, San Jose, CA 95115. Signed By: Maynard E. Orme, Gen Mgr. Funds Requested: $202,275.00. Total Project Cost: $269,700.00. To extend a full-service ITFS system at Monument Peak, CA, to serve various sites in Santa Clara County, CA.


File No. 2103CRB, California State Univ, Sacramento, 801 J St, Sacramento, CA 95819. Signed By: Phil Corriveau, Gen Mgr. Funds Requested: $77,827.00. Total Project Cost: $103,770.00. To improve the transmission capabilities of KXPR, operating on 88.9 at Walnut Grove, CA, by moving to Rio Linda, changing frequency to 90.9, increasing talk-back capability.

File No. 2108CTB, Office of the Supt of Schools, 135 S. Jackson, P.O. Drawer C, Independence, CA 95326. Signed By: Janet Watkins, Superintendent of Schools. Funds Requested: $82,165.00. Total Project Cost: $109,553.00. To improve an existing translator system in Inyo County, CA, by providing local origination facilities and a low power TV transmitter at Bishop, and a satellite earth station.

File No. 2103CRB, Voces Unidas Biling Brdcstg Fdn, P.O. Box 1243, Salinas, CA 93902. Signed By: Ann Caballero, President. Funds Requested: $5,250.00. Total Project Cost: $7,000.00. To establish FM radio (KUBO) translator in Benito County, CA, to provide first service to Watsonville, Hollister, and the Benito County area.

File No. 2106CTB, Black TV Workshop of LA, Inc, 7469 Melrose Avenue, Suite 28, Los Angeles, CA 90046. Signed By: Clinton Wilson II, Director. Funds Requested: $2,364,637.00. Total Project Cost: $3,152,850.00. To construct a noncommercial minority controlled and programmed television station to serve the Los Angeles area.

File No. 2111CTB, San Bernardino Comty Coll Dist, 701 South Mt Vernon Avenue, San Bernardino, CA 92410. Signed By: Dr. Richard A. Jones, Chancellor. Funds Requested: $80,000.00. Total Project Cost: $107,684.00. To extend the signal of public television station KVCR-TV, operating on Channel 24 at San Bernardino, CA, with translators at Crestline, Victorville, and Barstow, CA.

File No. 2118PON, County of Mendocino, 589 Lou Cap Road, Ukiah, CA 95482. Signed By: Albert P. Beltrami, County Administrator. Funds Requested: $19,760.00. Total Project Cost: $26,250.00. To plan for a comprehensive public service telecommunications network in Mendocino County to provide a multi-use, cost-effective, integrated system.

File No. 2124PTN, California St College Fctn, CA St Coll, Stanislaus, Turlock, CA 95380. Signed By: Frank C. Balbo, Treasurer. Funds Requested: $56,726.00. Total Project Cost: $90,746.00. To plan for an integrated telecommunications network serving regional colleges and institutions in central California.


File No. 2151ICON, San Joaquin Delta Comty College, 5151 Pacific Avenue, Stockton, CA 95207. Signed By: Lawrence A. DeRiccio, President-Superintendent. Funds Requested: $194,455.00. Total Project Cost: $336,617.00. To establish an ITFS system with local origination in Calaveras County, CA, to serve a learning center in San Andreas, California.

File No. 2157CTN, San Diego State Univ Fdn, San Diego State Univ, San Diego, CA 92180. Signed By: Frank Medeiros, VP for Academic Affairs. Funds Requested: $183,000.00. Total Project Cost: $244,000.00. To expand the ITFS system into northern San Diego County, CA, and to provide an audio talk-back capability.

File No. 2167PRB, Sonoma State University, 1801 E Cotati Avenue, Rohnert Park, CA 94928. Signed By: David S. Walls, Vice President. Funds Requested: $40,658.00. Total Project Cost: $58,654.00. To plan for a comprehensive telecommunications network serving several northern California counties, to extend university services in the area and evaluate campus communications needs.

File No. 2200CTB, The Peralta Cnty Coll District, 333 E Eighth Street, Oakland, CA 94606. Signed By: Donald B. Berz, Vice Chancellor. Funds Requested: $725,257.00. Total Project Cost: $965,077.00. To establish a microwave system in Alameda County, CA, to interconnect existing ITFS and cable facilities.

File No. 2206CRB, North Bay Public Radio, Broadcast Center, Angwin, CA 94506. Signed By: Robert B. Wareham, General Manager. Funds Requested: $160,533.00. Total Project Cost: $214,071.00. To extend the signal of public radio station KPRN-FM, operating on 89.9 MHZ at Angwin, CA, to provide first signal to rural counties using translators, and to replace obsolete studio equipment.

File No. 2220CRB, Hoopa Valley T/C Corp, P.O. Box 1220, Hoopa, CA 95546. Signed By: David A. Contreras, Chairman. Funds Requested: $19,303.00. Total Project Cost: $25,737.00. To extend the signal of noncommercial radio station KIDE-FM, Channel 217 (91.3 MHZ), at Hoopa, CA, with translators at Horse Mountain and Fickle Hill, CA.


File No. 2261CON, California State University, 6000 J Street, Sacramento, CA 95819. Signed By: Karl Von den Steinen, Executive Director. Funds Requested: $313,520.00. Total Project Cost: $463,520.00. To establish an interactive ITFS system at Sacramento, Pine Hill and Wolf Mountain, serving learning centers in Yuba, Placer, Nevada, and El Dorado counties.

File No. 2273PTN, Imperial County Office of Educ, 1398 Sperber Road, El Centro, CA 92243. Signed By: William H. Fisher, Assistant Superintendent. Funds Requested: $12,000.00. Total Project Cost: $18,000.00. To plan for an ITFS system to provide service to Imperial County, CA schools and to study various program sources.

File No. 2275CRB, California Public Radio, 365 8th Street, San Francisco, CA 94103. Signed By: Donovan Reynolds, Director. Funds Requested: $204,710.00. Total Project Cost: $272,946.00. To upgrade the production capabilities of California public radio in San Francisco,
by replacing and augmenting obsolete apparatus and facilities.

File No. 2279PON, Regents of the Univ of CA T/C, Univ of California, Irvine, CA 92717. Signed By: E. L. Bradt, Assistant Manager. Funds Requested: $35,280.00. Total Project Cost: $58,738.00. To plan for a teleconferencing capability, if feasible, using university facilities at Irvine to serve various agencies and businesses in Orange County, CA.

File No. 2300CTN, Calif St College, Stanislaus, Monte Vista Avenue, Turlock, CA 95380. Signed By: Frank C. Balbo, Business Manager. Funds Requested: $145,231.00. Total Project Cost: $238,831.00. To extend an ITFS system at Turlock CA, to rural and isolated places in Mariposa and Merced counties, and to provide interactive capability at learning centers.

File No. 2346ICON, California State Univ, 1000 E Victoria Street, Carson, CA 90747. Signed By: Donald A. MacPhee, Vice President/Planning. Funds Requested: $157,152.00. Total Project Cost: $246,215.00. To upgrade and extend the signal of KCFR-FM, $4,500.00. Total Project Cost: $6,000.00.

File No. 2354CTB, County of Hinsdale, P.O. Box 107, Lake City, CO 81435. Signed By: John Benvenuto, Commissioner, Hinsdale Cnty. Funds Requested: $34,815.00. Total Project Cost: $46,420.00. To construct translators on Blue Mesa and Round Top Mountain which extends the signal of Channel 6, KRMA-TV, Denver, to residents of Hinsdale County in western Colorado.

File No. 2154CTC, Gunnison Metropolitan Rec Dist, P.O. Box 1382, Gunnison, CO 81230. Signed By: Frank Edlin, Jr., President. Funds Requested: $18,500.00. Total Project Cost: $22,000.00. To extend the signal of KRMA-TV by translator from Monarch Pass to unserved residents of Gunnison and Hinsdale counties in western Colorado.

File No. 2201CTC, NW Colorado Council of Govts, P.O. Box 739, Frisco, CO 80443. Signed By: Thomas R. H. Glass, NWCCOG Exec Director. Funds Requested: $114,500.00. Total Project Cost: $157,000.00. To activate a low power TV facility at Williams Hill in Pitkin County, operating on Channel 16, which retransmits selected programming of Channel 6, KRMA, Denver, as well as locally and regionally produced materials to residents on the western slope of Colorado.

File No. 2247CRCB, Carbondale Cnty Access Radio, Box 1388, Carbondale, CO 81623. Signed By: Lee Swidler, President. Funds Requested: $27,974.00. Total Project Cost: $33,973.00. To establish a noncommercial radio operating on station 90.5 MHZ in Carbondale, CO, to bring first public radio service to portions of Garfield, Pitkin, and Eagle counties.

File No. 2271CRCB, San Miguel Educational Fund, Box 1098, Telluride, CO 81435. Signed By: Rita Robinson, Dir, Officer of Grants & Contract. Funds Requested: $84,795.00. Total Project Cost: $113,234.00. To plan for the extension of public radio services to at least 80 percent of the state, using the State of Colorado’s microwave system. This project would focus on currently unserved communities.

File No. 2095PRB, University of Denver, 2056 S York Street, Denver, CO 80208. Signed By: Howard L. Mai, Dir, Officer of Grants & Contract. Funds Requested: $77,062.00. Total Project Cost: $102,750.00. To activate a noncommercial radio station, operating on 88.7 MHZ in Alamosa, Colorado, to bring a first public radio signal to the residents of San Luis Valley.

File No. 2352CTB, Pitkin County, 506 E. Main, Aspen, CO 81611. Signed By: John Dady, Comm Eng. Funds Requested: $96,000.00. Total Project Cost: $98,000.00. To construct a solar-powered translator to provide first public television to residents of Marble area of Pitkin County, and to link the southwestern part of Colorado to Channel 62 being broadcast by Pitkin County.

DC

File No. 2009CBT, Howard University, 2222 4th Street, NW, Washington, DC 20059. Signed By: Dr. Caspa L. Harris, Treasurer. Funds Requested: $511,655.00. Total Project Cost: $811,655.00. To establish a satellite transmission station at WHMM, operating on Channel 32 in Washington, DC, to provide nationwide minority and general audience programming.

File No. 2951CRB, The American University, Washington, DC 20016. Signed By: John McKinley, Vice President. Funds Requested: $30,000.00. Total Project Cost: $40,000.00. To augment the production facilities of WAMU-FM, operating on 88.5 MHZ in Washington, DC, by replacing obsolete apparatus needed to deliver programming to the residents of the District and outlying areas.

File No. 2179CRCB, Pacifica Foundation, Inc., 700 H Street, NW, Washington, DC 20001. Signed By: Marita Rivera, Vice Pres & Gen Mgr. Funds Requested: $63,973.00. Total Project Cost: $85,297.00. To augment the production and transmission facilities of WPFW-FM, operating on 89.3 MHZ in Washington, DC, to provide more diverse programming to the communities within the coverage area.

DE

File No. 2031CTB, Delaware Citizens Committee, 122 North Front Str/PO Box 894, Seaford, DE 19973. Signed By: Shelton J. Merritt, President. Funds Requested: $453,151.00. Total Project Cost: $707,805.00. To increase power of WDPB-TV in Seaford and to construct a 1KW translator to provide first service to Dover. Funds to enhance WDPB’s existing studios are also requested.

FL

File No. 2177CRCB, Univ of South Florida, 4202 Fowler Avenue, Tampa, FL
in Florida.

available to this east central community
Public telecommunications facilities
Public Instruction, through the use of
Brevard County, including the Board of
College in Cocoa, Florida, to serve the
Cost: $53,000.00. To extend the signal of
Pensacola, FL, 32504. Signed

For the extension of a noncommercial
coverage of WSRE-TV, Channel
W. Walker, Vice President. Funds

To plan for the establishment of a
Spanish language SCA service for Palm
Beach County using the subcarrier

Total Project Cost: $54,500.00.

By: D. W. Ervin, Dir.
Sponsored Research. Funds Requested:
$40,875.00. Total Project Cost: $54,500.00.
To improve the programming for WSFP–FM
which serves the Ft. Myers, Naples,
and Port Charlotte areas of southwest
Florida by adding radio reception
capability to the Ft. Myers public TV
satellite earth terminal and an audio
reception system to receive the FM
signal from WUSF in Riverview, FL.
Also, the project proposes to add 500
SCA receivers to expand the radio
reading service to the handicapped
audience.

File No. 218CRB, Nathan B.
Stubblefield Fdn, 3838 Nebraska
Avenue, Tampa, FL 33603. Signed By:
Cam Hendrix, Technical Director. Funds
Requested: $31,560.00. Total Project
Cost: $42,080.00. To upgrade the
transmitter and installing a 20% more
capability to the Ft. Myers public TV
station WSMF in Tampa, Florida, operating on
88.5 MHz with a power of 70 KW, by
securing a circularly polarized antenna.

File No. 218PRB, Latinos In Pub
Radio of FL, Inc., 7002 Haden Road,
Suite 10, West Palm Beach, FL 33406.
Signed By: Andres A. Avello, II,
Executive Director. Funds Requested:
$25,000.00. Total Project Cost: $25,000.00.
To plan for the establishment of a
Spanish language SCA service for Palm
Beach County using the subcarrier
Channel of WHRS–FM in Boynton
Beach, Florida.

File No. 2192CTB, Pensacola Junior
College, 1000 College Boulevard,
Pensacola, FL 32504. Signed By: Dr. C.
W. Walker, Vice President. Funds
Requested: $1,088,495.00. Total Project
Cost: $1,451,326.00. To extend the signal
coverage of WSRE–TV, Channel 23 in
Pensacola, FL, by changing the location
and increasing the height of the tower,
by increasing the power of the
transmitter and installing a 20% more
efficient antenna, thereby providing first
service to 169,782 persons.

File No. 2224PTB, Brevard
Community College, 1519 Clearlake
Road, Cocoa, FL 32922. Signed By:
Maxwell C. King, President. Funds
Requested: $25,000.00. Total Project
Cost: $33,008.00. To plan the
ascertainment of the current and future
capabilities of Brevard Community
College in Cocoa, Florida, to serve the
educational needs of the citizens of
Brevard County, including the Board of
Public Instruction, through the use of
public telecommunications facilities
available to this east central community
in Florida.

File No. 2260CTB, School Board of
Marion Cnty, 512 Southeast Third Street,
Ocala, FL 34471. Signed By: H. Leon
Rogers, Supt of Schools. Funds
Requested: $274,449.00. Total Project
Cost: $467,071.00. To establish a multi-
Channel instructional TV fixed service
system in Ocala, FL, to provide local
educational programming to the Marion
County area, some of which is unserved,
and also provide state and national
programs through coordination with
WUF–TV/FM in Gainesville as well as with
other local telecommunications systems.

File No. 2264CRB, Bascomb Mem
Brdcstg Fdn, Inc, P.O. Box WDNA,
Miami, FL 33155. Signed By: Earl G.
Galloser, Treasurer/Secretary. Funds
Requested: $18,383.00. Total Project
Cost: $24,444.00. To equip a new on-air
production studio in downtown Miami
and thereby improve the local
production capability of WDNA–FM,
operating on 88.9 MHz in Miami,
Florida, which provides local minority
focused programming to 3.5 million
people in Dare and Monroe Counties.

File No. 2280PON, Florida A&M
University, Tallahassee, FL 32307.
Signed By: Dr. Sybil C. Mobley, Dean.
Funds Requested: $42,500.00. Total Project
Cost: $42,500.00. To plan for the
development of a national model for
integration of telecommunications into
business education, and explore new
methods of imparting business
instruction using non-broadcast
technology, both to on-campus and
community audiences in Tallahassee,
Florida.

File No. 2288PON, City of Atlanta,
GA, 2nd Floor CH, 68 Mitchell Bldg.
Atlanta, GA 30303. Signed By: Andrew
Young, Mayor. Funds Requested:
$29,519.00. Total Project Cost: $43,211.00.
To plan for the use of a communications
network utilizing the cable system. This
network will be used to provide a
computer aided fire dispatching system
in support of the bureau of fire services.

File No. 2259PON, Cohen
Communications, Inc, 1319 E Henry
Street, Savannah, GA 31404. Signed By:
Richard C. Morgan, Jr., Exec Dir.
Funds Requested: $10,000.00. Total Project
Cost: $10,000.00. To plan for a
community telecommunications center
that would provide local origination
capacity for minority programming.

HI

File No. 2060CTB, Hawaii Public
Brdscstg Auth, 2350 Dole Street,
Honolulu, HI 96822. Signed By: James B.
Young, Executive Director. Funds
Requested: $787,500.00. Total Project
Cost: $1,050,000.00. To expand
noncommercial television dissemination
facilities at station KMBE, Channel 10,
Wailuku, Maui. Also to replace obsolete
apparatus at noncommercial television
station KHET, Channel 11, Honolulu,
Hawaii. Both stations serve the
communities of Hawaii.

IA

File No. 2022CTB, Iowa Lakes
Community College, 300 South 18th
Street, Estherville, IA 51334. Signed By:
R. H. Blacker, Superintendent. Funds
Requested: $117,179.00. Total Project
Cost: $167,380.00. To extend and
improve the ITFS system by adding two
interactive receivers at Spirit Lake
and Sweda City, both unserved areas.

File No. 2127CTB, Marycrest College,
1607 W. 12th Street, Davenport, IA
52804. Signed By: A. Lynn Bryant,
President. Funds Requested: $131,175.00.
Total Project Cost: $174,900.00. To
establish a noncommercial TV station
on Channel 30 in Davenport, Iowa.
Station will provide ETV from
Marycrest College. The College now
operates a closed circuit TV production
facility for use on campus only, and is
operated by students in the
communications department. Station
will provide second service to area.

IL

File No. 2043CTB, Chicago ETV
Assoc, 5400 N Ste Louis Avenue,
Chicago, IL 60625. Signed By: John C.
Rahmann, Senior Vice President. Funds
Requested: $318,750.00. Total Project
Cost: $425,000.00. To extend the signal of
public television station WTTW,
Channel 11 in Chicago, Ill., by altering
the antenna pattern to deliver service to
unserved communities in western
Michigan, northern Indiana and
northwestern and western Illinois.

File No. 2068PRB, Springfield &
Sangamon Community Action, Inc., 1101
South 15th Street, Springfield, IL 62703.
Signed By: Gary E. Spears, Chairman,
Board of Directors. Funds Requested:
$71,060.00. Total Project Cost: $71,
060.00. To plan for a noncommercial
FM radio station to offer local news and
public affairs programming to minorities
residing in Sangamon County, IL.

File No. 2061CTB, Black Hawk
College, 8600 34th Avenue, Moline, IL
61265. Signed By: Dr. Richard J. Puffer,
Chancellor. Funds Requested: $163,000.00.
Total Project Cost: $239,700.00. To improve
noncommercial TV station WQPT, operating on
Channel 24 in Moline, Illinois, by replacing
obsolete equipment to current
technically compatible state-of-the-art,
in order to better serve the programming
needs of residents in the Greater Quad
Cities area.

File No. 2174CRB, Chicagoland Radio
Info Services, 425 N Michigan Avenue,
Chicago, IL 60611. Signed By: Kathryn A.
Bikos, Gen Mgr. Funds Requested:
telecommunications services to the
assure uninterrupted
noncommercial television station WNIT,
Cost:
Requested:
Brubaker, Exec Dir & Gen Mgr. Funds
IN
Brdcstg Corp, P.O. Box 34, South Bend,
Muncie, Indiana, in order to deliver
improve origination facilities at public
University, 246 Minnetrista
Fort Wayne.
Cost:
Requested:
$213,701.00. To extend the signal of
Navarro, President. Funds Requested:
Urbana, IL
Urbana, Ill.
communities surrounding Champaign-
FM radio station WILL-FM, on
Wayne, Indiana, through the
acquisition of subcarrier receivers and
origination facilities to bring specialized
program service to the print
handicapped residents of metropolitan
Chicago area.
File No. 2185CTB, Bd of Trustees of
Univ of IL, 354 Admin Building, Urbana,
IL 61801. Signed By: Linda Wilson,
Associate Vice Chancellor. Funds
Requested: $291,125.00. Total Project
Cost: $37,500.00. To replace failing
transmission facilities of noncommercial
FM radio station WILL-FM, on
frequency 90.9 MHz in Urbana, Illinois,
to enable continuous service to the
communities surrounding Champaign-
Urbana, Ill.
File No. 2188CTB, Bd of Trustees of
the Univ of IL, 354 Admin Building,
Urbana, IL 61801. Signed By: Linda
Wilson, Associate Vice Chancellor.
Funds Requested: $907,500.00. Total
Project Cost: $810,000.00. To replace
obsolete dissemination apparatus for
public television station WILL-TV,
Channel 12, University of Illinois,
Urbana, Illinois, in order to deliver
program services to the Champaign-
Urbana, Decatur-Springfield
metropolitan areas.

IN
File No. 2012CRB, Pub Brdcstg of NE
Indiana, Inc, 2000 N Wells Street, Fort
Wayne, IN 46804. Signed By: Rocco J.
Navarro, President. Funds Requested:
$100,270.00. Total Project Cost:
$213,701.00. To extend the signal of
noncommercial FM radio station WBNI,
operating on frequency 89.1 MHz in Fort
Wayne, IN, to provide first local service
to communities in northeast Indiana and
improve signal quality to residents of
Fort Wayne.
File No. 2107CTB, WIPB-Ball State
University, 246 Minnetrista Blvd,
Muncie, IN 47303. Signed By: Robert P
Bell, President. Funds Requested:
$905,500.00. Total Project Cost:
$542,000.00. To replace obsolete and
improve origination facilities at public
television station WIPB, Channel 49,
Muncie, Indiana, in order to deliver
noncommercial programming to
residents in the City of Muncie and
surrounding communities.
File No. 2108CTB, Michiana Public
Brdcstg Corp, P.O. Box 94, South Bend,
IN 46624. Signed By: Thomas E.
Brubaker, Exec Dir & Gen Mgr. Funds
Requested: $212,125.00 Total Project
Cost: $161,500.00. To replace obsolete and
failing origination facilities at noncommercial television station WNIT,
Channel 34, South Bend, Indiana, to
assure uninterrupted telecommunications services to the
communities in the station's service area.
File No. 2121CRB, Butler University,
4600 Sunset Ave, Indianapolis, IN 46208.
Signed By: Louis C. Wieman, Dean.
Funds Requested: $59,170.00. Total
Project Cost: $78,883.00. To extend the
service capability of public radio station
WJAC, 104.5 MHz, Butler University,
Indianapolis, Indiana, through the
acquisition of subcarrier receivers and
origination facilities to bring specialized
program service to the print
handicapped in the metropolitan area.
File No. 2206CTB, Fort Wayne Public
TV, Inc, P.O. Box 39, Fort Wayne, IN
46801. Signed By: Donald Sugarman,
MD, President. Funds Requested:
$618,861.00. Total Project Cost:
$836,000.00. To extend and improve the
services of noncommercial TV station
W39AA, Channel 39, Fort Wayne,
Indiana, by constructing new
dissemination and origination facilities
to provide telecommunications services
to Fort Wayne and surrounding
counties.
File No. 2284CTN, City of Lake
Station, 3625 Central Avenue, Lake
Station, IN 46405. Signed By:, Funds
Requested: $1,281,555.00. Total Project
Cost: $1,682,073.00. To establish
telecommunications service in the form of
cablevision and up stream return for
emergency services to better protect the
citizens of Lake Station, IN.
File No. 2233CTB, Bd of Trustees for
Vincennes Uni, 1002 N 1st Street,
Vincennes, IN 47591. Signed By: Dr.
Phillip Summers, President. Funds
Requested: $224,625.00. Total Project
Cost: $299,500.00. To improve obsolete
dissemination and origination facilities at
television station WVUT, Channel 22, Vincennes
University, Vincennes, Indiana, to
deliver programming to the communities
in the metropolitan area.
File No. 2340CRB, Vincennes
University, 1029 N 4th Street, Vincennes,
IN 47591. Signed By: Dr. Phillip M.
Summers, President. Funds Requested:
$21,485.00. Total Project Cost:
$33,055.00. To replace obsolete and
improve origination and dissemination
facilities at Vincennes University public radio
station WVUB-FM, 91.1 MHz,
Vincennes, Indiana, thereby enabling
delivery of locally produced programs to
communities in the metropolitan area.
File No. 2344CTB, City of Hobart, 414
Main Street, Hobart IN 46342. Signed By:
Caflin E. Green, Jr., Mayor. Funds
Requested: $1,738,500.00. Total Project
Cost: $2,318,857.00. To establish a cable
TV system to provide local programming
to the City of Hobart, Indiana.

KS
File No. 2002CRB, Friends University,
2100 University, Wichita, KS 67213.
Signed By: Richard Felix, President.
Funds Requested: $73,581.00. Total
Project Cost: $98,109.00. To reactivate
FM radio station KDSA by Friends
University in Wichita, KS. New call
letters (KSOF) have been assigned to an
old frequency, 91.1 MHz, to offer local
programming to the city of Wichita.
File No. 2027CTB, Washburn
University of Topeka, 301 North
Wanamaker Road, Topeka, KS 66604.
Signed By: Dr. John L. Green, President.
Funds Requested: $463,890.00. Total
Project Cost: $618,520.00. To upgrade
facilities and programming capabilities of
station KTWU-TV, Channel 11, in
Topeka, Kansas, by replacement of
outdated VTR's and purchase of
additional VTR's to develop
programming for nationwide
distribution.
File No. 2049CTB, Kansas Public T/C
Service Inc, 320 West 21st PO Box 288,
Wichita, KS 67201. Signed By: Zoel
Parenteau, Pres & General Manager.
Funds Requested: $782,580.00. Total
Project Cost: $1,043,843.00 Project
proposes to establish a UHF sister
station on Channel 15 to provide
alternative programming specifically
targeted to a populux which has a large
degree of unemployment.
File No. 2125CRB, KANZA Society,
Inc, Box 57, Pierceville, KS 67688.
Signed By: Kennis Bosley, Chairman Bd of
Directors. Funds Requested: $68,709.00.
Total Project Cost: $91,015.00. To extend
signal of KANZA-FM on 91.1 MHz in
Pierceville, KS, to the western regions of
Kansas, eastern Colorado, and northern
Oklahoma by means of ten watt
translators.
File No. 2211CTB, Smoaky Hills Public
Television P.O. Box 9, 6th & Elm Streets,
Bunker Hill, KS 67623. Signed By:
Kenneth F. Gardner, Vice President &
Gen Mgr. Funds Requested: $31,000.00.
Total Project Cost: $58,000.00. To extend
the signal of public television station
KSMH-TV, Channel 9, at Hays, KS to
north central Kansas (Phillips, Norton,
Smith, Rooks, and Osborne counties) by
means of a 100W translator.
File No. 2225CTB, Smoaky Hills Public
TV, P.O. Box 9, Bunker Hill, KS 67629.
Signed By: Kenneth F. Gardner, Vice
Pres & Gen Mgr. Funds Requested:
$44,620.00. Total Project Cost: $74,020.00.
To construct a TV translator station in
north central Kansas on Channel 64,
output 100W. This will supply first
service to five counties of Cloud, Clay,
Republican, Jewell, and Mitchell. The
originating station is KSMH, Channel 14, in Hays, KS.

KY
File No. 2070CRRB, Eastern Kentucky Univ., Lancaster Ave, Richmond, KY 40475. Signed By: J. C. Powell, President. Funds Requested: $91,297.00. Total Project Cost: $130,230.00. To activate a repeater noncommercial radio station on 90.9 frequency to broadcast the signal of WEKU-FM into Hazard and the southeastern counties of Kentucky, which are presently unserved.

File No. 2146CRRB, Western Kentucky Univ., College Heights, Bowling Green, KY 42101. Signed By: Dr. Donald W. Zacharlas, President. Funds Requested: $117,333.00. Total Project Cost: $156,445.00. To establish a noncommercial FM radio station on 89.9 MHz in Somerset, Kentucky, to provide first local service to the Taylor, Green, Adair, Cumberland, Clinton, Russell, Casey and Pulaski County areas of south central Kentucky.

LA
File No. 20005CRRB, LA State Univ. at Shreveport, 6515 Youree Drive, Shreveport, LA 71115. Signed By: E. Grady Bogue, Chancellor. Funds Requested: $280,083.00. Total Project Cost: $387,418.00. To activate a new noncommercial FM radio station on 89.9 MHz, in Shreveport, LA. Station will provide first service to 839,016 people in 18 counties. University also proposes to acquire satellite reception equipment.

File No. 2006CRRB, Louisiana St. Univ. at Alexandria, Alexandria, LA 71301. Signed By: H. Rouse Caffey, Chancellor. Funds Requested: $386,027.00. Total Project Cost: $514,703.00. To activate a new noncommercial FM radio station on 88.3 MHz in Alexandria, LA. Station will provide first service to 614,392 people in 16 parishes. University also proposes to acquire satellite reception equipment.

File No. 2140CTB, Louisiana ETV Authority, 2616 Wooddale Blvd., Baton Rouge, LA 70805. Signed By: A. Fred Frey, Exec. Director. Funds Requested: $234,708.00. Total Project Cost: $312,944.00. To replace the antenna and transmission line of WLPB-TV in Baton Rouge. WLPB has experienced disruption of service due to repeated equipment failure. Station is flagship station for the Louisiana public broadcasting system.

MA
File No. 2118CTB, WGBH Educational Foundation, Inc., 44 Hampden Street, Springfield, MA 01103. Signed By: Gordon Carpenter, Chairman of Board of Tribunes. Funds Requested: $145,031.00. Total Project Cost: $193,375.00. To increase the efficiency of the WGBY-TV transmitter, which is located in Springfield, MA, and to add a telrde amplifier to prolong the life of the station's Klystron.

File No. 2158PTN, City of Boston, One City Hall Square, Boston, MA 02201. Signed By: Michio F. Spring, Deputy Mayor. Funds Requested: $117,917.00. Total Project Cost: $207,711.00. To plan for the Boston's Public Institution Network, a separate institutional cable system to be developed for public, municipal and non-profit users.

ME

MI
File No. 2119CRRB, University of Maine, Alumni Hall, Orono, ME 04469. Signed By: William J. Sullivan, Treasurer. Funds Requested: $256,792.00. Total Project Cost: $353,355.00. To activate satellite radio station that will transmit the signal of Maine Public Broadcasting Network and will provide first public service to Waterville/ Winslow and Washington County, Maine.

File No. 2233PON, Medical Care Development, Inc., 11 Parkwood Drive, Augusta, ME 04330. Signed By: John A. LaCassee, Executive Director. Funds Requested: $87,608.00. Total Project Cost: $101,125.00. To plan for the provision of health education at home through the interconnection of existing closed circuit hospital systems with cable companies in rural Maine.

of a second service to meet expanded and specific target audience programming needs for the residents of West Michigan.

File No. 2015CRRB, Grand Valley State Colleges, College Landing, Allendale, MI 49401. Signed By: James Starkweather, Director of Budgets. Funds Requested: $64,260.00. Total Project Cost: $85,680.00. To upgrade the origination and production facilities of noncommercial radio station WSRX-FM to better serve the community.

File No. 2034CTB, Ojibwa Community College Learning Center, Rte. 1 Tribal Center, Baraga, MI 49908. Signed By: Gerry Blanchard, Washington Representative. Funds Requested: $11,903.00. Total Project Cost: $15,870.00. To extend and improve the television signal of public television station KMWU-TV, channel 13, Marquette, Michigan, by establishing a translator to Ojibwa Community College and Reservation, Baraga, Michigan, to bring public broadcasting to the Keweenaw Bay Indian Reservation.


File No. 2046CRRB, Central Michigan Univ Pub Brct, Mt. Pleasant, MI 48859. Signed By: Harold Abel, President. Funds Requested: $93,052.00. Total Project Cost: $172,677.00. To establish a noncommercial FM radio station operating on 90.1 MHz in Bay City, MI, to provide first service to the Bay City-Saginaw area and the "Thumb" counties of Michigan.

File No. 2109CRRB, Delta College, Delta Road, University Center, MI 48710. Signed By: Donald J. Carlyn, President. Funds Requested: $153,370.00. Total Project Cost: $249,100.00. To establish a noncommercial FM radio station operating on 90.1 MHz at Bay City, MI, to provide first service to the core counties of the Saginaw Valley and the northern tier counties of the "Thumb" area.

WNMU, Channel 13, Marquette, Michigan, to deliver programming to communities in the Northern Peninsula area.

File No. 2114CRB, Blue Lake Fine Arts Camp, WBLV, Route 2, Twin Lake, MI 49457. Signed By: William F. Stanseil, President. Funds Requested: $17,632.00. Total Project Cost: $25,510.00. To augment the noncommercial facilities of WBLV-FM in Twin Lake, MI. by installing a satellite receive dish to acquire NPR programming.

File No. 2221PON, Bay de Noc Community College, College Avenue, Escanaba, MI 49829. Signed By: Edwin Wuehle, President. Funds Requested: $82,360.00. To plan for a microwave/ITFS network of colleges, federal institutions, state institutions and public schools in Michigan’s Upper Peninsula. The network will study the technical requirements for a variety of public telecommunications services for instruction in colleges and uses in libraries, schools and with public television in libraries to the communities within the coverage area.

File No. 2332CTB, Delta College, Delta Road, University Center, MI 48710. Signed By: Donald J. Carlyon, President. Funds Requested: $137,250.00. Total Project Cost: $201,000.00. To extend the signal of public TV station WUCM-TV, operating on Channel 19, University Center, Michigan, by constructing a translator to serve Bad Axe, Michigan.

MN

File No. 2061CRB, Bemidji State University, Birchmont Drive, Bemidji, MN 56601. Signed By: Richard Haugo, President. Funds Requested: $64,750.00. Total Project Cost: $135,250.00. To provide SCA capabilities to Bemidji State University/Minnesota public radio station to bring specialized programming to the three largest Ojibwe Nations in Minnesota and non-Indian citizens in north central Minnesota.

File No. 2104CRB, Center for Communications and Development, 610 5th Avenue North, Minneapolis, MN 55403. Signed By: Jeanette Cotton, Station Manager. Funds Requested: $60,560.00. Total Project Cost: $120,755.00. To extend and improve the production and transmission facilities of public radio station KMOJ-FM, 89.7 MHz, Minneapolis, Minnesota, operated by The Center for Community Development, to utilize both broadcast and cable radio to serve the metropolitan area.

File No. 2123CRB, Minnesota Public Radio, Inc., 45 East 8th Street, St. Paul, MN 55101. Signed By: William H. Kling, President. Funds Requested: $270,000.00. Total Project Cost: $380,138.00. To establish a new 100 kilowatt public radio station on 90.5 in St. Peter, MN, to provide first local origination capability, and to extend the new station’s signal to the communities of Albert Lea and Owatonna by two translators.

File No. 2137CRB, Northern Community Radio, 1841 E. Hwy 169, Grand Rapids, MN 55744. Signed By: Patricia Clarke, Chairman, Bd of Directors. Funds Requested: $8,735.00. Total Project Cost: $11,947.00. To extend the signal of public radio station KAXE, 91.7 MHz, Grand Rapids, Minnesota, with translators located in Virginia and Brainerd to serve communities in northern Minnesota.

File No. 2142CRB, Mankato State University, MSU Box 198, Mankato, MN 56001. Signed By: Margaret R. Preska, President. Funds Requested: $37,500.00. Total Project Cost: $50,000.00. To improve public radio station KMSU-FM, operating on Frequency 89.7, Mankato State University, Mankato, Minnesota, by installing satellite origination and remote studio facilities to better serve the communities in south central Minnesota.

MO

File No. 2066PRB, Lincoln University, 1004 E. Dunklin Street, Jefferson City, MO 65101. Signed By: Dr. James Frank, President. Funds Requested: $42,541.00. Total Project Cost: $42,541.00. To plan for expansion of the facilities at station KLUM-FM (89.9 MHZ) in all aspects of mass media communications (AM/FM, TV, cable, etc.). The station is located at Lincoln University in Jefferson City, MO. Station provides a second service in the area.

File No. 2067CRB, Lincoln University, 1004 E. Dunklin Street, Jefferson City, MO 65101. Signed By: Dr. James Frank, Acting Pres. Funds Requested: $32,104.00. Total Project Cost: $32,805.00. To upgrade equipment to provide better programming for station KLUM-FM on 89.9 MHZ in Jefferson City, MO, particularly for the black minority population. The station is owned and operated by Lincoln University.


File No. 2259CRN, Missouri Federation Of The Blind, 2883 South Big Bend Blvd, Maplewood, MO 63143. Signed By: Fred C. Lilley, Executive Director. Funds Requested: $75,000.00. Total Project Cost: $100,000.00. Reactivation of KUMR sideband for transmission to the Blind and Print handicapped. KUMR operates out of Rolla, MO, on 88.5 MHZ and is a member of NPR. Other Stations involved will be KBIA-FM 91.3 MHZ Columbia, KWMU-FM 90.7 MHZ St. Louis, and KCUR-FM 89.3 MHZ Kansas City.

MS

File No. 2206PRB, Alcorn State University, Lorman, MS 38958. Signed By: Walter Washington, President, ASU. Funds Requested: $21,282.00. Total Project Cost: $27,859.00. To plan the establishment of FM station in Lorman, MS. Total population to be served is 25,000 of which 75% are black.

MT

File No. 2135CTB, Blaine Cnty Pub TV, Inc. Box 188, Chinook, MT 59523. Signed By: Bruce Moerter, Acting Chairman. Funds Requested: $56,875.00. Total Project Cost: $78,500.00. To establish a low power TV facility providing a public TV signal to be distributed over-the-air to residents of Blaine County and by the local cable system serving residents of Chinook.

File No. 2141CTB, Dull Knife Memorial College, Box 206, Lame Deer, MT 59043. Signed By: Darius T. Roseland, President. Funds Requested: $280,000.00. Total Project Cost: $380,000.00. To establish a low-power public TV station in Lame Deer, Montana, to serve the needs of the Northern Cheyenne Indian Reservation and residents of Rosebud and Big Horn counties in southeastern Montana.

File No. 2243CRB, Eastern Montana College, 1500 N. 30th Street, Billings, MT 59101. Signed By: William Johnstone, Acting Pres. Funds Requested: $30,000.00. Total Project Cost: $40,000.00. To extend by translator the signal of public radio station KEMC-FM of Billings to seven communities, six of which are in Montana and one in northern Wyoming.

File No. 2253CTN, Wolf Point TV District. P.O. Box 276, Wolf Point, MT 59219. Signed By: Bob Lundstrom, President. Funds Requested: $42,375.00. Total Project Cost: $56,500.00. To establish first local origination capability and to provide a public TV signal to be distributed over the local cable system serving the residents of Wolf Point, in rural Montana.

NC

File No. 2020CRB, Friends of Public Radio, P.O. Box 4234, Wilmington, NC 28406. Signed By: John A. Tiedeman, Agent. Funds Requested: $165,738.00. Total Project Cost: $220,985.00. To...
activate a new FM radio station on 90.7 MHZ in Wilmington, NC. Station would provide first service to 240,000 people within five county area.

**ND**

File No. 2122CTB, Praise Pub TV Inc., 4500 S. Univ Drive, Fargo, ND 58103. Signed By: Dennis L. Falk, Pres & Gen Mgr. Funds Requested: $392,415.00. Total Project Cost: $542,415.00. To improve the production facilities of the public television network originating from station KFME, Fargo, North Dakota, by replacing obsolete equipment needed to deliver programming to residents of North Dakota, northwest Minnesota and northeast Montana.

File No. 2223CRB, Fort Berthold Comm Enterprise, Box 549, New Town, ND 58673. Signed By: Austin Gillette, Chairman, FBCCE. Funds Requested: $30,170.00. Total Project Cost: $42,228.00. To augment a tribal owned FM radio station operating on 92.1 MHZ in New Town, North Dakota, by installing a satellite receive dish to receive NPR programming to better serve the community's 10,000 residents.

**NE**

File No. 2193CRB, Sunrise Communications, 1058 South 23rd Street, Lincoln, NE 68510. Signed By: Charles N. Quinn, Vice President. Funds Requested: $24,818.00. Total Project Cost: $35,387.00. To extend the signal of station KZUM-FM (93.3 MHZ) in Lincoln, NE, by increasing the power from 10W to 2KW.

File No. 2313CRB, Nebraska ETV Commission, P.O. Box 83111, Lincoln, NE 68501. Signed By: Jack G. Gillette, Secretary & Gen Mgr. Funds Requested: $240,000.00. Total Project Cost: $320,000.00. To replace an obsolete and worn-out TV transmitter. Project would provide upgraded and extended coverage in Alliance, NE.

**NJ**

File No. 2132CON, Educ Improvement Center, 3684 US Rte 1 Bldg 1, Princeton, NJ 08540. Signed By: Thomas J. Rockey, Exec Director. Funds Requested: $14,288.00. Total Project Cost: $19,051.00. To provide post-production facilities and training to interested high school students, and for production of educational programming to be distributed by cable to five central New Jersey counties.

File No. 2248PTB, City of Jersey City, 201 Cornelison Ave, Jersey City, NJ 07304. Signed By: Horatius A. Greene III, Director. Funds Requested: $3,607,000.00. Total Project Cost: $3,607,999.00. To plan a TV station for the City of Jersey City that would provide statewide TV service.

File No. 2277CRB, Mercer County Community College, 1200 Old Trenton Road, Trenton, NJ 08690. Signed By: John P. Hanley, President. Funds Requested: $63,907.00. Total Project Cost: $65,210.00. To increase production capability of WWMF, licensed to Mercer County Community College, to cover local issues in Trenton.

File No. 2289PRB, United Progress Inc., 401 Pennington Ave, Trenton, NJ 08618. Signed By: Albert M. Robinson, Executive Director. Funds Requested: $36,050.00. Total Project Cost: $36,050.00. To plan for a low powered radio station to serve the minorities and elderly in Trenton, New Jersey.

**NM**

File No. 2102CTB, Regents of the Univ of NM, Board of Educ City of Albuquerque, NM, 1130 University Blvd NE, Albuquerque, NM 87102. Signed By: Leontine M. Benton, Associate Director. Funds Requested: $614,250.00. Total Project Cost: $619,000.00. To improve KMEF-AM by improving the power on channel 5 in Albuquerque, NM, by replacing worn out and obsolete origination equipment. Station provides only service in central NM, parts of southern Colorado and eastern Arizona.

File No. 2185CRB, Alamo Navajo School Bd, Inc., P.O. Box 907, Magdalena, NM 88332. Signed By: William O. Berlin, Executive Director. Funds Requested: $48,819.00. Total Project Cost: $65,092.00. To activate a new daytime-only AM station to serve Alamo Navajo Reservation. Station will operate on 1500 MHZ and provide native American programming.

File No. 2285PRB, Realidades, A Comm Group, 1584 Five Points, SW, Albuquerque, NM 87105. Signed By: Eduardo Diaz, President. Funds Requested: $39,491.00. Total Project Cost: $39,491.00. To plan for a noncommercial FM radio station in the Santa Fe, NM area. Proposed station will provide a first local service to northern New Mexico. Will provide local bilingual service to unserved minorities in northern New Mexico.

File No. 2325CRB, Ramah Navajo School Board, Inc. Box 18, Ramah, NM 87321. Signed By: Bennie Cohoe, Executive Director. Funds Requested: $138,300.00. Total Project Cost: $184,401.00. To expand the service area of KTDB-FM to better serve the needs of the Ramah Navajo Reservation and surrounding areas. Project includes both a power increase and the use of translator networks.

File No. 2333CRB, Eastern New Mexico Univ, Portales, NM 88130. Signed By: Duane W. Ryan, Director of Brdcstg. Funds Requested: $202,768.00. Total Project Cost: $270,358.00. To activate a repeater FM station on 88.9 MHZ in Maljamar, NM. Station will repeat most of the programming of KENW-FM, Portales, NM. Also, station can be programmed separately from KENW-FM to provide local interest.

File No. 2336CTB, Eastern New Mexico Univ, Portales, NM 88130. Signed By: Duane W. Ryan, Director of Brdcstg. Funds Requested: $319,976.00. Total Project Cost: $426,635.00. To improve the facilities of KENW-TV in Portales, New Mexico. Equipment will provide upgrade to allow use of one-inch videotapes. Equipment will also improve on-the-air appearance of KENW-TV. Station provides only service in eastern New Mexico.

**NV**

File No. 2148CTB, Channel 5 Pub Brdcstg Inc., P.O. Box 8856, Reno, NV 89507. Signed By: Daniel Tone, Executive Director. Funds Requested: $333,900.00. Total Project Cost: $445,200.00. To provide additional local origination equipment for channel 5, Reno, Nevada. To also construct a translator station which will rebroadcast the signal of primary public TV station channel 5 into Carson City, Nevada.

File No. 2190CTB, City of Yerington, P.O. Box 478, Yerington, NV 89447. Signed By: Frank M. McGowan, City Manager. Funds Requested: $42,375.00. Total Project Cost: $56,500.00. To construct a noncommercial low-power TV station to serve Yerington, Nevada.

**NY**

File No. 2006CTN, Columbia-Greene Community College, P.O. Box 1000, Hudson, NY 12534. Signed By: Roger A. Van Winkle, Pres. Funds Requested: $196,111.00. Total Project Cost: $284,333.00. To augment, improve and interconnect the facilities of Columbia-Greene Community College to the local cable television facilities.

File No. 2041CTB, Western NY Public Brdcstg Assoc, P.O. Box 1283, Buffalo, NY 14240. Signed By: J. Michael Collins, President. Funds Requested: $1,741,104.00. Total Project Cost: $2,321,472.00. To extend the coverage area of WNED-TV, channel 17, in Buffalo, NY, by constructing a new tower which will increase the antenna height, and by increasing the transmitter power in order to provide first service to 112,789 persons.

File No. 2092CRB, North Country Public Radio, Payton Hall, SLU, Canton, NY 13617. Signed By: James A. Arvidson, Director of Brdcstg. Funds Requested: $11,250.00. Total Project Cost: $392,415.00. To improve the facilities of KENW-FM, Portales, NM. Also, station can be programmed separately from KENW-FM to provide local interest.
Cost: $15,786.00. To extend the signal of WSLU-FM at 96.7 MHz by activating a translator to bring first service into Franklin and Essex counties, known as the Tri-Lakes region; and to upgrade the transmission system by replacing the worn-out studio transmitter link.

File No. 2183CB, Dayton Public Radio, Inc., 370 W. First Street, Dayton, OH 45402. Signed By: Clark J. Haines, President. Funds Requested: $223,102.00. Total Project Cost: $397,470.00. To establish a noncommercial FM station for Dayton, Ohio, to provide first local service to west central Ohio.

**OK**

File No. 2083CB, Carrie Williams Comm Fdn, Inc. P.O. Box 48538, Tulsa, OK 74106. Signed By: Gerald L. Davis, Chairman, Bd of Directors. Funds Requested: $75,000.00. Total Project Cost: $223,102.00. To improve the transmission facilities of station KTUR, operating on Channel 3 in LaGrande, Oregon, by replacing obsolete equipment needed to deliver programming to the residents of northeastern Oregon.

File No. 2073CB, Oregon Public Bdrcstg, 2828 SW Front Street, Portland, OR 97201. Signed By: Gerald L. Appy, Exec Director. Funds Requested: $100,000.00. Total Project Cost: $223,102.00. To establish first service public television in central Oregon by relocating the Salem VHF station, KUDO-TV, operating on Channel 3, to Bend, Oregon. The move requires the construction of a new tower and microwave transmission links.

File No. 2182CB, State of Oregon Acting by and through the State Board of Higher Education, Southern Oregon State College, 1250 Siskiyou Boulevard, Ashland, OR 97522. Signed By: Donald E. Lewis, Dean of Administration. Funds Requested: $31,012.00. Total Project Cost: $41,350.00. To extend the signal of station KSOR-FM, operating on 90.1 MHz in Ashland, Oregon, by replacing existing translators and adding two new translators to cover rural areas of southern Oregon and northern California.
PA

File No. 209OCTB, NE Pennsylvania ETV Association, Old Boston Road, Pittston, PA 18640. Signed By: Dr. John E. Walsh, Pres & Gen Mgr. Funds Requested: $83,073.00. Total Project Cost: $110,765.00. To replace modulator exciter in transmitter and to purchase spare Klytron, for station WVIA-TV in Pittston, PA.

File No. 2181CRB, Temple Univ, 2020 N 13th Street, Philadelphia, PA 19122. Signed By: George Huganir, Univ Secretary. Funds Requested: $125,062.00. Total Project Cost: $166,750.00. To replace obsolete studio equipment and to replace telephone lines with a microwave STL.

File No. 222ECRB, Pittsburgh Cnty Brcstg Cncil, 4 Cable Place, Pittsburgh, PA 15213. Signed By: Raymond R. Christman, President. Funds Requested: $72,000.00. Total Project Cost: $98,000.00. To implement power increase and to replace obsolete studio equipment.

File No. 2223CRB, South Dakota ETV Board, 310 East Clark, Vermillion, SD 57069. Signed By: Martin P. Busch, Executive Director. Funds Requested: $81,420.00. Total Project Cost: $116,420.00. To construct FM radio transmitters in Reliance and Rapid City, South Dakota, to extend the current statewide public radio network to an estimated 135,000 additional population.

South

SD

File No. 2231CRB, South Dakota ETV Board, 310 East Clark, Vermillion, SD 57069. Signed By: Sherwood O. Berg, President. Funds Requested: $48,080.00. Total Project Cost: $139,080.00. To extend the signal and shift the transmitter location for KESD-FM in Garden City, South Dakota, by constructing a new public FM transmitting station at that location and displacing the old station to Reliance, South Dakota.

File No. 2267CRB, Lakota Educ.of N Texas, P.O. Box 688, Richardson, TX 75080. Signed By: Louis Barbash, Gen Mgr. Funds Requested: $17,820.00. To plan for the expansion of noncommercial radio and other telecommunications distribution systems to offer service to counties surrounding Chattanooga and to remote Appalachian communities.

TX

File No. 2097PRTBN, Chattanooga St Tech Cnty College, 4501 Amnicola Highway, Chattanooga, TN 37406. Signed By: Charles W. Branch, Pres & Gen Mgr. Funds Requested: $198,979.00. Total Project Cost: $214,450.00. To establish a tribal owned radio station. Station will allow for the replacement of old/obsolete origination equipment that no longer is manufactured.

File No. 2025CRB, South Texas Educ Brcstg Cncil, 4455 S. Padre Island Drive #38, Corpus Christi, TX 78411. Signed By: Terrel Cass, President & General Manager. Funds Requested: $8,025.00. Total Project Cost: $10,700.00. To construct a translator to extend the signal of KKED-FM in Corpus Christi.

By: Terrel Cass, President & General Manager. Funds Requested: $130,000.00. To improve the local origination capacity of KEDT-TV in Corpus Christi. Funding will allow for the replacement of old/obsolete origination equipment that no longer is manufactured.

File No. 2071PRB, Southwest Center for ETV, 7703 North Lamar, Suite 500, Austin, TX 78752. Signed By: Louis Barbash, Gen Mgr. Funds Requested: $17,820.00. Total Project Cost: $21,020.00. To plan for a minority owned and operated FM radio station. Station would serve 477,900 people in either Georgetown or San Marcos, Texas.

File No. 2123CTN, Assoc for Higher Educ of N Texas, P.O. Box 688, Richardson, TX 75080. Signed By: Gilbert A. Peters, President. Funds Requested: $160,837.00. Total Project Cost: $214,450.00. To extend the cable/ITFS system to provide instructional TV service to Tarrant County, Texas. Service would benefit 466,000 people in the City of Ft. Worth and Tarrant County.
Texas. Station would provide first service to the majority of Texas counties. Project will increase tower height and increase power to 100kW.

FIle No. 2194CON, Region IV Educ Service Center, P.O. Box 863, Houston, TX 77001. Signed By: Dr. Tom Pate, Jr., Executive Director. Funds Requested: $98,469.00 Total Project Cost: $79,935.00. To extend the signal of KTR-FM in Commerce, TX to serve ten Texas counties. Project will increase tower height and increase power to 100kW.

File No. 2194CRB, East Texas State Univ, P.O. Box BB, ET Station, Commerce, TX 75428. Signed By: Dr. Charles Austin, President. Funds Requested: $59,915.00 Total Project Cost: $78,935.00. To extend the signal of KETR-FM in Commerce, TX to serve ten Texas counties. Project will increase tower height and increase power to 100kW.

File No. 2150CRB, East Texas State Univ, P.O. Box BB, ET Station, Commerce, TX 75428. Signed By: Dr. Charles Austin, President. Funds Requested: $185,002.00 Total Project Cost: $246,670.00. To activate a new FM station in El Paso, Texas to serve the minority population. Station will operate on 89.5 MHZ and will be owned and operated by minorities. Applicant is also requesting satellite reception equipment.

UT
File No. 2032CRBN, University of Utah, 204 James Talmadge Building, Salt Lake City, UT 84112. Signed By: James J. Brophy, Vice President for Research. Funds Requested: $1,073,445.00 Total Project Cost: $1,431,260.00. To implement the second phase of a state plan, by extending the signal of KUSU-FM in Logan, UT, with FM translators; replacing two existing TV translators to rebroadcast KUED TV from Salt Lake City; providing a signal for a translator to serve Snowville, UT and Holbrook, ID; expanding the state's microwave looping system to include unserved areas; providing production facilities for UT College; and relocating Southern UT State's FM transmitter and providing STL, remote control, and production equipment.

VA
File No. 2054CRTN, Center for Excellence, Inc., P.O. Box 158, Williamsburg, VA 23185. Signed By: John A. Curtis, President. Funds Requested: $2,461,994.00 Total Project Cost: $5,507,492.00. To extend multimedia production and transmission capabilities of an existing telecommunications delivery system in eastern Virginia, to provide specialized educational and informational programming to the rural area population.

WA
File No. 2269CRB B, Fine Arts Radio, P.O. Box 1424, Richland, WA 99352. Signed By: Dennis Haasager, Vice President, Gen Mgr. Funds Requested: $41,715.00 Total Project Cost: $55,620.00. To extend the signal of KPAE-FM, which will be licensed in Richland, Washington, with translators located in eastern Washington, northwestern Oregon, and northwestern Idaho, to provide first service to the majority of the population in these rural areas.

File No. 2272CTB, Tacoma School District #10, 601 8th Avenue, P.O. Box 1357, Tacoma, WA 98402. Signed By: Del Cross, Superintendent. Funds Requested: $883,827.00 Total Project Cost: $1,178,436.00. To improve existing transmission facilities of station KTPS-TV in Tacoma, Washington, by relocating to a higher existing tower and operating on Channel 28 as well as replacing their current low power transmitter.
II. Deferred Applications

The following deferred applications were submitted and accepted for filing by PTFP in prior fiscal years, and have been assigned new processing numbers for fiscal year 1982. The applicant in each case indicated that it wants the application considered for Federal funding from monies appropriated in fiscal year 1982, and has furnished updated materials as required. (It is not necessary that these applicants republish notice in a local newspaper in the community to be served under 15 CFR 2301.09)

Reactivated Applications For 1982

AK

New file No. 2339CRB; old file No. 1680; University of Alaska, Fairbanks

AR

New file No. 2066CTB; old file No. 1513; Univ of Arkansas at Little Rock, Little Rock

AZ

New file No. 2030CTB; old file No. 1304; Casa Grande Union High School, Casa Grande

CA

New file No. 2134PTN; old file No. 1481; California State College, Bakersfield

New file No. 2230CTB; old file No. 1419; Rural CA Broadcasting Corp., Cotati

New file No. 2067PTN; old file No. 1732; Deaf Informed Comm Center, Inc., Fremont

New file No. 2198CRB; old file No. 1635; Radio Bilingue, Inc., Fresno

New file No. 2011CTB; old file No. 1383; Community TV of Southern Calif, Los Angeles

New file No. 2302CRB; old file No. 1768; International Institute of L.A., Los Angeles

New file No. 2236CRB; old file No. 1673; Morgan Hill Unified School Dist, Morgan Hill

New file No. 2063PTN; old file No. 1653; Open Channel, Inc., Santa Cruz

New file No. 2115CRB; old file No. 1622; California State Univ at Long Beach

CO

New file No. 2324PRTN; old file No. 1740; Univ of Denver (CO Seminary), Denver

CT

New file No. 2040PTN; old file No. 1579; Community Renewal Team, Hartford

New file No. 2156CTN; old file No. 1664; Connecticut Educ T/C Corp., Hartford

New file No. 2159 CTB; old file No. 1407; Connecticut Educ T/C Corp., Hartford

New file No. 2059PTN; old file No. 1825; City of New Britain, New Britain

DC

New file No. 2318CTB; old file No. 1712; Community T/C Dev Fdn, Inc., Washington

New file No. 2319CTB; old file No. 1357; Booker T Washington Fdn., Washington

New file No. 2057CTB; old file No. 1302; Greater Washington Educ T/C Asso, Washington

DE

New file No. 2099CTN; old file No. 1436; Delaware Tech & Cnty College, Newark

FL

New file No. 2045CRB; old file No. 1621; Broward Public Radio Assoc, Inc., Fort Lauderdale

New file No. 2038PRTB; old file No. 1842; School Board of Broward County, Ft. Lauderdale

New file No. 2004CTB; old file No. 1443; University of Florida, Gainesville

New file No. 2189CRB; old file No. 1531; WJCT, Inc., Jacksonville

New file No. 2218CRB; old file No. 1577; The School Bd of Dade Cnty, Miami

New file No. 2093CTB; old file No. 1457; Cnty TV Fdn of S Florida, Inc., Miami

New file No. 2242CTB; old file No. 1465; Community Comm, Inc., Orlando

New file No. 2007CRB; old file No. 1401; The School Bd of Broward County, Sunrise

New file No. 2176CTB; old file No. 1468; Florida State Univ, Tallahassee

New file No. 2297CRB; old file No. 1451; The Florida A&M Univ, Tallahassee

New file No. 2335CTB; old file No. 1345; University of South Florida, Tampa

New file No. 2133CTB; old file No. 1436; Florida W Coast Pub Brdsctg, Tampa

New file No. 2179CRB; old file No. 1819; Univ of South Florida, Tampa

New file No. 2336CTB; old file No. 1702; University of South Florida, Tampa

GA

New file No. 2303CRB; old file No. 1368; Clark College, Atlanta

IA

New file No. 2005PTB; old file No. 1727; Northern Trails Area Educ Agency, Clear Lake

New file No. 2341CRB; old file No. 1517; Urban Community Brdsctg Company, Des Moines

New file No. 2215PTB; old file No. 1516; Community Communications Fdn, Waterloo

New file No. 2331PON; old file No. 1499; Southeastern Community College, West Burlington

ID

New file No. 2328CTB; old file No. 1710; St Bd of Educ & Bd of Regents, Boise

IL

New file No. 2293CRB; old file No. 1845; Capital Area Vocational Center, Springfield

New file No. 2314CRB; old file No. 1799; Argo Community High School, Summit

IN

New file No. 2245CTN; old file No. 1804; NW Indiana Pub Brdsctg, Inc., Highland

New file No. 2036CTB; old file No. 1682; Metro Indianapolis TV Assoc Inc., Indianapolis

KS

New file No. 2077CRB; old file No. 1578; University of Kansas, Lawrence

New file No. 2166CTB; old file No. 1809; Johnson Cnty Cnty Coll, Overland Park

New file No. 2096CTN; old file No. 1751; Wichita Public Schools, Wichita

KY

New file No. 2078CTN; old file No. 1821; Appalachian Shop, Inc., Whitesburg

LA

New file No. 2138CTN; old file No. 1649; Louisiana ETV Authority, Baton Rouge
New file No. 2131CRB; old file No. 1450; VA Voice For Print Handicapped, Richmond
New file No. 2056CTN; old file No. 1328; Richmond Public Schools, Richmond
New file No. 2170CTB; old file No. 1344; Blue Ridge ETV Assoc, Roanoke
VT
New file No. 2028CRN; old file No. 1321; VT Radio Info Serv Enterprises, Burlington
New file No. 2160CTB; old file No. 1765; Univ of VT & State Agricultural, Winooski
WA
New file No. 2033CTB; old file No. 1748; University of Washington, Seattle
New file No. 2330CTB; old file No. 1331; University of Washington, Seattle
WI
New file No. 2166PTB; old file No. 1492; State of Wisconsin Dept of Admin, Madison
WV
New file No. 2191CRB; old file No. 1657; Trustees of Bethany College, Bethany

New file No. 2317CRB; old file No. 1679; Kanawha Economic Dev Corp, Institute

WY
New file No. 2304CTB; old file No. 1472; Sheridan TV Translator, Inc, Sheridan.

Dated: July 6, 1982.
Bernard J. Wunder, Jr.,
Administrator, National Telecommunications and Information Administration.

[FR Doc. 82-18674 Filed 7-18-82; 8:45 am]
BILLING CODE 3510-60-M
Part IX

Department of Justice

Immigration and Naturalization Service

Detention and Parole of Inadmissible Aliens; Interim Rule With Request for Comments
DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 212 and 235

Detention and Parole of Inadmissible Aliens; Interim Rule With Request for Comments

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule, published pursuant to an order of the District Court for the Southern District of Florida, sets forth the Service's policy regarding the detention and parole of aliens who seek to enter the United States illegally. The Administration has determined that a large number of Haitian nationals and others are likely to attempt to enter the United States illegally unless there is in place a detention and parole regulation meeting the approval of the District Court. Such a large scale influx would clearly be contrary to the public interest. This rule insures that the parole of illegal aliens will be carefully and narrowly exercised to conform to statutory purposes and legislative intent.

EFFECTIVE DATE: July 9, 1982.

ADDRESSES: Please submit written comments in duplicate to the Commissioner of Immigration and Naturalization, Room 7100, 425 I Street, N.W., Washington, DC 20536.


SUPPLEMENTARY INFORMATION: On June 18, 1982, the District Court for the Southern District of Florida held that the Service's present detention policy in regard to aliens who attempt to enter the United States illegally was "null and void." In its decision, Louis v. Nelson, No. 81-1280-CIV-EPS, the court found that the Service had not complied with the rule making provisions of the Administrative Procedure Act (APA) with respect to its detention policy. The court enjoined the enforcement of this policy with respect to those Haitians who were then detained in the United States.

In its subsequent order of July 2, 1982, the court stayed for 30 days, that portion of its order which enjoined enforcement of the detention policy with respect to future illegal entrants into the United States. The court expressly conditioned the stay of its order with respect to future illegal entrants upon the Service's publication, within a 30 day period, of rules embodying the Service's detention policy.

This rule is therefore being published in compliance with and consistently with the court's order, although the Service strongly disagrees with the analysis and conclusions of the court, strongly disagrees that the Service's detention policy is subject to and falls within the APA rule making requirements, and strongly disagrees that its detention policy is null and void because the Service did not engage in formal APA rule making. Accordingly, this rule is being published "under protest." The Service has sought judicial review of this order.

This rule is being published as an interim rule with comment, effective immediately upon publication, because the delays involved in customary publication would seriously impair the Service's ability to protect the country's borders and would be detrimental to the public interest. Accordingly, suspension of the normal 30 day publication requirement is essential under the "good cause" provision of 5 U.S.C. 553(d)(3).

The district court's order has created a vacuum in the Service's detention policy and in the enforcement of the immigration laws of the United States. This vacuum will be prolonged unless the 30 day publication requirement is suspended. If the requirement is not suspended, a significant number of persons who were previously deterred from attempting to enter the United States illegally by the Service's detention policy may now enter the United States without fear of being detained until publication is completed.

This potential emergency was expressly recognized by the district court in its July 2, 1982 order, where the court referred to the affidavit of Bob Graham, the Governor of Florida as follows:

The affidavit * * * states that there are between 20,000 and 40,000 Haitians in the Bahamas as well as "additional numbers of Haitians, Nicaraguans, El Salvadorans and other nationals currently residing in other areas within the Caribbean basin * * *

Consistent with the information obtained from the aforesaid reports your affiant fears a renewed influx of Haitian and other aliens into south Florida if the court's judgment dated June 29, 1982 is not stayed * * *".

The court recognizes the validity of this assessment in its July 2, 1982 order at page 3:

The appearance of an inability on behalf of the United States Government to control unlawful immigration into this country is "the greatest inducement to the ultimate swollen tide of undocumented aliens." Haitian Refugee Center v. Smith, No. 79-5953, slip op. 15182 n. 11 (11th Cir. May 4, 1982). This Court does not want its Final Judgment to render INS helpless and thereby induce further migration to these shores.

Publication of this rule as an interim rule is therefore the only possible course of action for the Service to follow in discharging its obligation to enforce the immigration laws of the United States.

Section 235(b) of the Immigration and Nationality Act directs that every alien, (other than crewmen, stowaways, and security risks who are covered by separate provisions) * * * who may not appear to the examining immigration officer at the port of arrival to be clearly and beyond a doubt entitled to land shall be detained for further inquiry to be conducted by a special inquiry officer." [Italics supplied.] Detention is therefore mandated by the statute.

In the event that an arriving alien covered by section 235(b) does not wish to withdraw his application and depart, the only exception to detention is through the exercise of parole authority under section 212(d)(5) of the Act. That section provides that parole may be exercised in the discretion of the Attorney General, and * * * under such conditions as he may prescribe for emergent reasons or reasons deemed strictly in the public interest * * *"

The legislative history of the parole provision shows a Congressional intent that parole be used in a restrictive manner. The drafters of the Immigration and Nationality Act of 1952 gave as examples situations where parole was warranted in cases involving the need for immediate medical attention, witnesses, and aliens being brought into the United States for prosecution. H. Rep. No. 1365, 82nd Cong., 2d Sess., at 52 (1952). In 1965, a Congressional committee stated that the parole provisions "were designed to authorize the Attorney General to act only in emergent, individual, and isolated situations, such as the case of an alien who requires immediate medical attention, and not for the immigration of classes or groups outside the limit of the law." S. Rep. No. 748, 89th Cong., 1st Sess., at 17 (1965). Finally, in the Refugee Act of 1980, Congress removed the Attorney General's authority to parole groups of aliens as refugees. Pub.
By regulation, the authority to parole aliens is delegated to district directors of the Service. However, in exercising this discretion, district directors should be guided by the fact that the statutory rule is one of detention, and that the use of parole authority is an exception to that rule and should be carefully and narrowly exercised to be in conformity with the statutory purpose and legislative intent.

Where an alien who appears to be inadmissible has arrived aboard a regular carrier which has entered into a contract with the Attorney General under section 238 of the Act, the placing of aliens in the custody of the carrier, as authorized by section 235 of the Act, will ordinarily satisfy the detention requirements of the statute. In cases where carrier custody appears to be inadequate to protect the safety of the public, or where the security precautions which the carrier will take appear to be inadequate or inappropriate to detain the alien, custody may be assumed by the Service.

Aliens who appear to be inadmissible and who have false or no documentation, and/or who arrive at places other than designated ports of entry, will be detained by the Service under section 235(b) of the Act. This policy is set forth in this rule. In addition, the rule defines a number of situations where exercise of the parole authority is justified for “emergent reasons” or would be “strictly in the public interest”: (1) Serious medical conditions; (2) pregnant women; (3) certain juveniles; (4) aliens with close family relatives in the United States; (5) other unusual situations warranting parole.

Compliance with 5 U.S.C. 553 as to notice of proposed rulemaking and delayed effective date is contrary to the public interest and is waived for good cause.

In accordance with 5 U.S.C. 605(d), the Commissioner of Immigration and Naturalization certifies that this rule will not have significant economic impact on a substantial number of small entities.

This rule is not a major rule within the meaning of section 1(b) of E.O. 12291, and it is exempt under section 8(a)(1) of E.O. 12291 from the normal procedures prescribed by virtue of the emergency situation which exists by virtue of a mass influx of illegal aliens.

List of Subjects
8 CFR Part 212
Administrative practice and procedure, Aliens, Bonds, Detention, Probation and parole.

8 CFR Part 235
Aliens, Bonds, Detention, Inspections, Port of Entry, Probation and parole.

Accordingly, Title 8 of the Code of Federal Regulations is amended as follows:

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

1. In Part 212, § 212.5 is revised to read as follows:

§ 212.5 Parole of aliens into the United States.

(a) In determining whether or not aliens detained in accordance with § 235.3(b) or (c) will be paroled, the district director shall consider the following:

1) The parole of aliens who have serious medical conditions in which continued detention would not be appropriate would generally be justified by “emergent reasons”;

2) The parole of aliens within the following groups would generally come within the category of aliens for whom the granting of the parole exception would be “strictly in the public interest”, provided that the aliens present neither a security risk nor a risk of absconding:

(i) Women who have been medically certified as pregnant;

(ii) Aliens who are defined as juveniles should only be placed in a juvenile facility or with an appropriate responsible agency or institution, recognized or licensed to accommodate juveniles by the laws of that state. A juvenile is generally defined as a person subject to the jurisdiction of a juvenile court. To determine what constitutes legal age or exceptions to the above definition in a particular state, the laws of the state where the alien is physically present will apply. Children of tender years who are too young to be placed in a juvenile facility or youth hall, and older juveniles who it is anticipated will remain in detention for a period longer than thirty days, should be placed with relatives or friends. In those extreme cases where it is impossible to accommodate a child of tender years accompanied by an adult or juvenile who will or has remained in detention for periods of over 30 days, consideration should be given to paroling the juvenile with the accompanying adult to a responsible

agency, relative, or friend. When it is determined that such juvenile should be paroled from detention, the following guidelines should be followed:

(A) Juveniles may be released to a relative (brother, sister, aunt, uncle) not in Service detention who is willing to sponsor a minor and the minor may be released to that relative notwithstanding that he has a relative who is in detention.

(B) If a relative who is not in detention cannot be located to sponsor the minor, the minor may be released with an accompanying relative who is in detention.

(C) If the Service cannot locate a relative in or out of detention to sponsor the minor, but the minor has identified a nonrelative in detention who accompanied him on arrival, the question of releasing the minor and the accompanying nonrelative adult shall be addressed on a case-by-case basis.

(iii) Aliens who have close family relatives in the United States (parent, spouse, children, or siblings) who are United States citizens or lawful permanent resident aliens who are eligible to file, and have filed, a visa petition on behalf of the detainee;

(iv) Aliens who will be witnesses in proceedings being, or to be, conducted by judicial, administrative, or legislative bodies in the United States;

(v) Aliens whose continued detention is not in the public interest as determined by the district director.

(3) Aliens subject to prosecution in the United States who are needed for the purposes of such prosecution may be paroled to the custody of the appropriate responsible agency or prosecuting authority.

(b) In the cases of all other arriving aliens except those detained under § 235.3(b) or (c), and paragraph (b) of this section, the district director in charge of a port of entry may, prior to examination by an immigration officer, or subsequent to such examination and pending a final determination of inadmissibility in accordance with sections 235 and 236 of the Act and this chapter, or after a finding of inadmissibility has been made, parole into the United States temporarily in accordance with section 212(d)(5) of the Act any such alien applicant for admission at such port of entry under such terms and conditions, including those set forth in paragraph (c) of this section, as he may deem appropriate.

(c) Conditions. In any case where an alien is paroled under paragraph (a) or (b) of this section, the district director may require reasonable assurances that the alien will appear at all hearings...
and/or depart the United States when required to do so. Not all factors listed need be present for parole to be exercised. The district director should apply reasonable discretion. The consideration of all relevant factors includes:

1. The giving of an undertaking by the applicant, counsel, or a sponsor to ensure appearances, and a bond may be exacted on Form I-552 in such amount as the district director may deem appropriate;
2. Community ties such as close relatives with known addresses; and
3. Agreement to reasonable conditions (such as periodic reporting of whereabouts).

(d) Termination of parole.—(1) Automatic. Parole shall be automatically terminated without written notice (i) upon the departure from the United States of the alien, or (ii) if not departed, at the expiration of the time for which parole was authorized, and in the latter case the alien shall be processed in accordance with paragraph (d)(2) of this section except that no written notice shall be required.

(2) On notice. In cases not covered by paragraph (d)(1) of this section, upon accomplishment of the purpose for which parole was authorized or when in the opinion of the district director in charge of the area in which the alien is located neither emergency nor public interest warrants the continued presence of the alien in the United States, parole shall be terminated upon written notice to the alien and he or she shall be restored to the status which he or she had at the time of parole. Any further inspection or hearing shall be conducted under section 238 or 239 of the Act and this chapter, or any order of exclusion and deportation previously entered shall be executed. If the exclusion order cannot be executed by deportation within a reasonable time, the alien shall again be released on parole unless in the opinion of the district director the public interest requires that the alien be continued in custody.

(e) Advance authorization. When parole is authorized for an alien who will travel to the United States without a visa, the alien shall be issued Form I-512.

(Sec. 103, 212 of the Immigration and Nationality Act, as amended; 8 U.S.C. 1103, 1182)

PART 235—INSPECTION OF PERSONS APPLYING FOR ADMISSION

2. In Part 235, § 235.3 is revised to read as follows:

§ 235.3 Detention and deferred inspection. (a) Prior to inspection. All persons arriving at a port in the United States by vessel or aircraft shall be detained aboard the vessel or at the airport of arrival by the master, commanding officer, purser, person in charge, agent, owner, or consignee of such vessel or aircraft until admitted or otherwise permitted to land by an officer of the Service. Notice or order to detain shall not be required.

(b) Aliens with no documentation or false documentation. Any alien who appears to the inspecting officer to be inadmissible, and who arrives without documents (except an alien for whom documentary requirements are waived under § 211.1(b)(3) or § 212.1 of this chapter) or who arrives with documentation which appears to be false, altered, or otherwise invalid, or who arrives at a place other than a designated port of entry, shall be detained in accordance with section 235(b) of the Act. Parole of such aliens shall only be considered in accordance with § 212.5(a) of this chapter.

(c) Aliens with documents. Any alien who appears to the inspecting officer to be inadmissible, but who does not fall within paragraph (b), may be detained, paroled, or paroled for deferred inspection by the inspecting officer. In determining whether or not a parole or a parole for deferred inspection is warranted the inspecting officer shall consider the likelihood that the alien will abscond or pose a security risk.

(d) Carrier custody. Any alien subject to detention under paragraph (b) or (c) of this section may be placed in the custody of the carrier if the carrier has entered into a contract with the Attorney General under section 238 of the Act. If in the opinion of the examining immigration officer it is not practical to resolve a question of admissibility at the time of arrival of a passenger on a vessel or aircraft, the officer shall execute Form I-259 to notify the agent for the vessel or aircraft and the master or commanding officer, if available, that the passenger is to be presented for further inspection. The Form I-259 shall list the name of each such passenger and shall contain instructions as to the date and place the passenger is to be presented for continued inspection or further proceedings under the Act. If the place specified is a designated port of entry to which the transportation company has carried or has contracted to carry the passenger, the transportation company shall remain under the obligation, described in the preceding paragraph, to prevent an unauthorized landing, unless the transportation company has been relieved of this obligation by removal under section 233(a) of the Act at the direction of the Service or unless the Service has paroled the alien under section 212(d)(5) of the Act without directing the carrier in writing to present the alien for further inspection. The term port of entry as used in this paragraph includes a Service district office or suboffice within the city or town or in local commuting distance of the seaport or airport at which the passenger arrived or of the onward seaport or airport specified by the examining immigration officer as the place for completion of inspection. In cases where carrier custody appears to be inadequate to protect the safety of the public, or where the security precautions which the carrier will take appear to be inadequate or inappropriate to detain the alien, custody may be assumed by the Service.

(Secs. 103, 233, 235 of the Immigration and Nationality Act, as amended; 8 U.S.C. 1103, 1223, 1225)

Dated: July 7, 1982.

Alan C. Nelson,
Commissioner of Immigration and Naturalization.

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