AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

2-22-85
Vol. 50 No. 36
Pages 7289-7568

# federal register

Friday
February 22, 1985

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**Air Pollution Control**
Environmental Protection Agency

**Archives and Records**
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# Presidential Documents

**Proclamation 5303 of February 20, 1985**

## National Safe Boating Week, 1985

**By the President of the United States of America**

**A Proclamation**

Americans increasingly look to the water for recreation and relaxation. This year, approximately one-quarter of us will enjoy boating in one or more of its many and varied forms. Therefore, it is important that all those involved in recreational boating observe proper safety practices, know and obey rules of safe boating, and show courtesy and consideration on the water.

In addition, all boaters should wear personal flotation devices while on the water. According to the United States Coast Guard, seventy-five percent of those who died in boating accidents last year might have been saved had they worn these devices.

The theme of this year's National Safe Boating Week emphasizes the dangers of combining alcohol consumption with operating a boat. The use of alcohol and other intoxicating substances is a major factor in boating accidents and fatalities. Boat operators who drink often cannot react promptly to hazards and thereby endanger not only themselves but also others on the water. The use of even small amounts of alcohol can significantly impair an operator's judgment and boat-handling skills. This is particularly true as fatigue caused by sun, glare, noise, wind, and boat motion intensifies the effects of alcohol. Through the observance of National Safe Boating Week, 1985, all Americans should be alerted to these dangers.

In recognition of the need for boating safety, the Congress, by joint resolution approved June 4, 1958, as amended (36 U.S.C. 161), authorized and requested the President to proclaim annually the week commencing on the first Sunday in June as National Safe Boating Week.

NOW, THEREFORE, I, RONALD REAGAN, President of the United States of America, do hereby proclaim the week beginning June 2, 1985, as National Safe Boating Week. I invite the Governors of the States, Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, and American Samoa, and the Mayor of the District of Columbia to provide for the observance of this week.

IN WITNESS WHEREOF, I have hereunto set my hand this twentieth day of February, in the year of our Lord nineteen hundred and eighty-five, and of the Independence of the United States of America the two hundred and ninth.

Ronald Reagan

[FR Doc. 85-4511
Filed 2-20-85; 3:36 pm]
Billing code 3195-01-M

# Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 910

[Lemon Regulation 504]

### Lemons Grown in California and Arizona; Limitation of Handling

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market at 260,000 cartons during the period February 24–March 2, 1985. Such action is needed to provide for orderly marketing of fresh lemons for the period due to the marketing situation confronting the lemon industry.

**DATES:** Effective for the period February 24–March 2, 1985.

**FOR FURTHER INFORMATION CONTACT:** William J. Doyle, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202–447–5975.

**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 certified that this action will not have a significant economic impact on a substantial number of small entities.

This final rule is issued under Marketing Order No. 910 as amended (7 CFR Part 910) regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The action is based upon recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy currently in effect. The committee met publicly on February 19, 1985, 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 that lemon demand is good on mid sizes and easier on the larger and smaller sizes of fruit.

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:**

Marketing agreements and orders, California, Arizona, Lemons.

### PART 910—[AMENDED]

Section 910.804 is added as follows:

**§ 910.804 Lemon Regulation 504.**

The quantity of lemons grown in California and Arizona which may be handled during the period February 24, 1985, through March 2, 1985, is established at 260,000 cartons.

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

Dated: February 20, 1985.

**Thomas R. Clark,**

*Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.*

[FR Doc. 85–4560 Filed 2–21–85; 8:45 am]

BILLING CODE 3410-02-M

## Farmers Home Administration

### 7 CFR Parts 1823, 1924, and 1942

### Community Facility Loans

**AGENCY:** Farmers Home Administration, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Farmers Home Administration (FmHA) amends its Community Facility Loan regulations. This action is in response to general public and FmHA staff requests for clarification of the Community Facility Loan regulations. The intended effect is to provide more comprehensive guidance to applicants in obtaining FmHA financial assistance for water and waste disposal systems and essential community facilities.

**EFFECTIVE DATE:** February 22, 1985.

**FOR FURTHER INFORMATION CONTACT:** Wallis B. McArthur, Loan Specialist, Water and Waste Disposal Division or Gary Morgan, Civil Engineer, Program Support Staff, Room 6322–S, Farmers Home Administration, Washington, DC 20250, telephone (202) 382–9583.

**SUPPLEMENTARY INFORMATION:** This final action has been reviewed under Departmental Regulation 1512–1 which implements Executive Order 12291, and has been determined to be a non-major action. This action will result in an annual effect on the economy of less than $100 million and will neither result in a major increase in cost or prices, nor adversely affect competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This action adopts existing administrative policies and is not expected substantially to affect budget outlay, to affect more than one agency, or to be controversial. It is anticipated that this action will not significantly impact Federal work-years or program costs. Facility planning, procurement and construction will continue to be reviewed by FmHA for compliance with applicable regulations. Additional efforts to administer the final changes are expected to be minimal. Increased program costs are, therefore, not anticipated. The net result is expected to be a more efficient use of financial and natural resources. Sensitive lands will be protected.

thereby discouraging flood plain development which will reduce potential flood damage. This will result in future savings of money, facilities, and lives. This amendment revises the planning, bidding, contracting, and constructing regulations for Community Facilities. These amendments implement the certain provisions of 7 CFR Part 3015, Uniform Federal Assistance Regulations and OMB Circular A-102, Attachment O, which establishes standards governing State and local grantee procurement. Affirmative steps to assure utilization of small and minority firms, women's business enterprises and labor surplus areas are expanded. Procurement methods are expanded to include small purchase procedures, competitive sealed bids, competitive negotiation, and noncompetitive negotiation. Reference to FmHA Environmental Program is incorporated and statements on flood plains and wetlands, coastal zone management, wild and scenic rivers, and endangered species are included. Provisions have been added to implement Executive Order 12185, "Conservation of Petroleum and Natural Gas." Facility designs should consider energy saving devices.

This Rule includes water conservation provisions for water supply and treatment. Owners are encouraged, when economically feasible, to incorporate water conservation measures into a facility's design. Water system losses must be minimized and water meters must be used where appropriate. All FmHA funded facilities must be designed and constructed according to sound architectural and engineering practices. Section 1942.18 is revised and some paragraphs are rewritten to improve clarity. Section 1942.19(h)(ii) has been revised to provide that loan funds obligated in different fiscal years must have separate debt instruments.

This subpart has been amended to incorporate provisions of FmHA Environmental Program, Subpart G of Part 1940 of this chapter and Suspension and Debarment Proceedings, Subpart E of Part 1924 of this chapter. Subpart A, §§ 1942.1 through 1942.20 are printed in their entity to aid the reader. Cross reference to Subpart A contained in Subparts G, H and I of Part 1942 and Subpart E of Part 1942 are amended to correspond with numbering changes contained in rule change to Subpart A of Part 1942 of this chapter.

Charles W. Shuman, Administrator, has determined that this action will not have a significant economic impact on a substantial number of small entities because these changes will provide more comprehensive guidance to applicants and make certain paragraphs consistent with other related actions.

This document has been reviewed in accordance with 7 CFR Part 1940, Subpart G, "Environmental Program." It is the determination of FmHA that the proposed 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. 92-190, an Environmental Impact Statement is not required.

The FmHA programs and projects which are affected by this regulation are subject to State and local clearinghouse review in the manner delineated in Part 1901 Subpart H of this chapter.

CFDA No. 10.418 Water and Waste Disposal Systems for Rural Communities.

CFDA No. 10.423 Community Facility Loans.

A Proposed Rule to amend the regulations for the administration of Community Facility loans was published in the **Federal Register** for comment on December 5, 1983, (48 FR 54485). The major changes proposed were: (1) Provide more comprehensive guidance to applicants; (2) make certain paragraphs consistent with other related sections; (3) provide a means of public participation on FmHA financed projects; (4) provide direction to FmHA State and District Office personnel to ensure uniform implementation of antidiscrimination policies; (5) provide direction for servicing and maintaining insurance for projects in operation; and (6) redefine policies on procurement, environmental considerations, resource, water, and energy conservation.

Thirty-nine comments were received in response to the publication. Most respondents addressed multiple issues. Nine of the comments were from FmHA employees, two from State agencies, nine from private individuals and nineteen from organizations and public interest groups.

**Discussion of Comments**

1. *Preamble*—One commenter was confused about the reference to community program loan and grant making. We removed the reference to grants.

2. *Section 1942.1(a)*—Three comments were received. Two comments supported requirements for handicapped anti-discrimination practices. The third commenter suggested that FmHA should specifically support officially adopted State policies for physical and economic development. The latter suggestion was not accepted because the regulations already specifically support State strategy for rural development, which would include such physical and economic development policies.

3. *Section 1942.2(e)*—One commenter suggested we furnish copies of referenced public law and other documents to each FmHA office. The reference in question (Pub. L. 95-334) is a part of the Consolidated Farm and Rural Development Act, (CONACT) as amended. We added a reference to the CONACT.

4. *Section 1942.5(d)(6)*—One commenter questioned the need to send a copy of Form FmHA 442-14 to the Finance Office. We deleted this requirement.

5. *Section 1942.5(d)(7)*—Five commenters suggested that the interest rate for a loan be the rate prevailing at either loan approval or loan closing, whichever is less. This suggestion could create problems when a FmHA grant is involved and if the interest rate changes from the time the grant was calculated, the amount of FmHA grant funds and loan funds could change. In addition, other problems would occur with bond issues and referendums due to fluctuations in loan amounts. We did not adopt this suggested change.

6. *Section 1942.9(b)*—One commenter suggested clarification of this section. We changed it to require National Office concurrence if a single contract is negotiated for more than $100,000.

7. *Section 1942.17(d)(1)*—Eight comments concerned eligible loan purposes. In response, we made two changes. One added natural gas distribution systems as an essential Community Facility and the other change clarified when the payment of tap fees and other utility connection charges can be considered as eligible loan purposes. Several commenters misunderstood the proposed rule language on tap fees and connection charges. We clarified the section so that tap fees and connection charges are eligible loan purposes when a system must pay such charges to purchase bulk services. Individual tap fees and connection charges are not considered as an eligible loan purpose.

One commenter suggested we include installation of water meters as an "essential community facility." The suggestion was not accepted. However, water meters are considered an element of "Water and Waste Disposal Facilities" and are therefore an eligible loan purpose.

8. *Section 1942.17(e)*—Two comments concerned facilities for public use. One change adopted clarifies that inequities within the proposed project's service

area are to be remedied by the owner, on or before completion of the project that includes FmHA funding. Other commenters suggested that stronger language be incorporated which would promote service to low income users or other areas which may be subject to discrimination. Some commenters suggested that inequities be corrected in either water or waste disposal services as a condition of FmHA assistance. In other parts of this regulation, references made to discrimination issues and providing services to rural users are adequate. Correcting inequities in water or waste disposal facilities may be hampered by restrictions on the use of funds by State statutes or bond ordinances.

9. *Section 1942.17(f)(7)*—Two commenters suggested flexibility in the maximum loan term where an FmHA grant is involved. The forty-year loan term and the FmHA grant have the purpose of reducing the user cost to a reasonable level. Any decrease in the loan term not only increases the amount of grant funds needed but also may increase the user rate. Since this would defeat the purpose of the long term loan and increase need for grant funds, we made no change.

10. *Section 1942.17(h)(ii)*—Five comments concerned potential user cash contributions. We revised the paragraph in response to one comment. Where State statutes or ordinances require mandatory use of the system and the applicant or legal entity having such authority agrees in writing to enforce such statutes or ordinances, an exception can be made to the requirement of a user cash contribution.

Four commenters suggested that meaningful user cash contributions be automatically waived for users in areas with community median incomes below 80 percent of the State non-metropolitan median household income. This suggestion has not been adopted since this regulation allows an exception for a meaningful user cash contribution where FmHA determines that the potential users as a whole in the applicant's service area cannot make such a contribution.

11. *Section 1942.17(j)*—(Paragraphs (j)(1) through (j)(8))—Four comments concerned the "General Requirements" in these paragraphs. A commenter on Fidelity Bonds was confused as to whether the bond covered only cash on hand, or cash and funds in a bank account or all funds (even savings or restricted fund accounts). Fidelity Bonds must provide coverage for all persons entrusted with the receipt and disbursement of all funds and the custody of valuable property. The method of which funds or property are held, is not an issue.

Requirements for monitoring insurance coverage and fidelity bonds have been revised to provide that FmHA is not responsible for continuous monitoring of insurance coverage.

Requirements for obtaining title insurance when General Obligation Bonds or assessment bonds serve as FmHA security, were reviewed at the request of one commenter. We feel that under the FmHA's responsibility to provide supervised credit, the borrower's interest in this area needs to be protected even though FmHA's security position is well protected.

12. *Section 1942.17(j)(9)*—Seven comments concerned the public information requirement. Four commenters endorsed the concept of public participation and urged that this section be retained in the Final Rule. One commenter's suggestion, which we adopted, is that a public hearing is not required for subsequent loans which are needed to complete financing of a project. The other commenters suggested that this requirement be strengthened to provide that certain topics be discussed at the meeting; however, we feel it is the applicant's responsibility to develop the agenda that will address critical project issues, which include but are not limited to: user rates, short and long term impacts, economically efficient designs, operation and maintenance, and financing costs.

13. *Section 1942.17(j)(10)*—Three of four commenters suggested that FmHA adopt a policy supporting service through individual installations. We feel that this technology may be applicable in certain cases; however, it should be considered along with all other designs in determining the design which best meets the users needs. The other commenters requested that the section be expanded to specify methods for denying service. We believe that this is unnecessary and that each individual project should be reviewed on its own merits.

14. *Section 1942.17(j)(11)*—One commenter pointed out that problems occur when one funding agency will not commit their funds until a second funding agency has done so and as a result, projects are being rejected although eligible under both agencies' rules. We realize that this does place a burden on the applicant to effectively communicate with funding agencies to obtain timely commitments of funds. We believe that the appropriate time will vary from project to project and also depends on the agencies' priorities and availability of funds. Therefore, we made no change.

15. *Section 1942.17(n)*—One commenter requested clarification as to whether current regulations should be used for grant recalculations. We have revised this paragraph to provide that any change in the FmHA funds will be based on revised project costs and the current number of users. However, other factors including FmHA regulations used at the time of loan/grant approval will remain the same.

Four commenters felt this provision would discourage participation from other funding agencies and eliminate joint financing of projects. The intent of this section is to adjust project funds from all sources after project costs are known, for example after bids have been opened. Any reduction of funds at this point should tailor funding needs to the project without adversely affecting funding from other sources.

16. *Section 1942.18(d)*—Four commenters addressed the topic "Design Policies." One commenter felt the Agency ignored life-cycle costs and recommended that it be stated as an Agency policy. However, the regulations provide that the design of FmHA-financed facilities should be in accordance with sound architectural and engineering practices. FmHA recognizes life-cycle costs as an element of sound architectural and engineering design practices.

Another commenter felt our requirements for pipe specifications would produce controversy since the ⅓ of operating pressure for surge allowance on ASTM specified pipe has been eliminated. We believe pipe should be designed to withstand the demands of the system surge pressures. This is a component of engineering design and should not be a matter of arbitrary limitations.

One commenter suggested that water system testing provisions be amended to provide test pressures at 1½ times working pressure or 150 PSI, whichever is greater. This paragraph was changed to provide a similar requirement which refers to the rated pressure of the pipe rather than 150 PSI.

17. *Section 1942.18 (e)(1)*—One commenter suggested that the requirement for the Office of the General Counsel review be eliminated on negotiated construction contracts under $10,000 where the contract amount is insignificant in the overall project. FmHA construction contract document guides are intended to provide borrowers with time tested methods of procurement of construction

services. We see no need to make an exception to this policy.

18. *Section 1942.18 (f)*—One commenter suggested that National Office approval of utility purchase contracts is not necessary where suitable alternative supplies are required. This paragraph is clarified to provide that National Office approval will be required only if a suitable alternative supply cannot be arranged within the repayment ability of the FmHA borrower.

19. *Section 1942.18 (h)*—Seven comments were received all related to discouraging borrowers from performing construction with their own forces. We agree that contracting for construction services with a general contractor is the preferred method to accomplish construction. However, we wish to retain flexibility to allow limited borrower construction in justifiable situations. We have clarified this point by adding language which will encourage owners to accomplish construction through contracts with others.

20. *Section 1942.18 (j)(2)*—Four commenters provided remarks on FmHA "Maximum Open and Free Competition" policy. One commenter supported our position; another was concerned about irrational claims from material and equipment suppliers and manufacturers. One saw this as an attempt by FmHA to impose its judgment on owners and their consultants. Another commenter felt FmHA was singling out pipe material to bear the burden of this provision. This provision adopts recommendations of a National Academy of Science study and is structured around the provisions of OMB Circular A-102, Attachment O. The intent of this paragraph is to provide competition which will ensure that the owner is obtaining the best price available for a design that will provide service to rural users in an economically efficient manner. This paragraph is not restricted only to pipe material but also applies to all materials and services. One point was clarified to allow the owner and its consultants to specify a singular material where conditions justify.

21. *Section 1942.18 (j)(5)*—Two commenters addressed provisions relating to small, minority, and women's businesses. This paragraph is not intended to establish Minority Business Enterprise requirements. The intent is to provide contracting opportunities to stimulate these private sector businesses.

22. *Section 1941.18 (j)(6)*—Three commenters expressed concern about an applicant's ability to perform price or cost analyses on architectural and engineering services. Another commenter was concerned about restrictions on contracts using percent of construction to determine a fee. We agree and have removed these requirements.

23. *Section 1942.18(j)(7)*—One commenter felt that this paragraph was misleading and that it prohibited the engineer from providing testing services during construction. This paragraph pertains to construction related work. The example the commenter used is closely related to professional services which are not covered by this paragraph.

24. *Section 1942.18(k)*—Eleven commenters expressed concern about the language in the provision for competitive negotiation which referenced architectural and engineering (A&E) services. Specific references to A&E services has been deleted. Two commenters were concerned about the improper use of noncompetitive procedures. The regulations have been clarified to provide that competitive sealed bids is the preferred procurement method for construction contracts. Sufficient reasons must exist for using any other procurement method.

One commenter noted that the proposed rule omits the phrase "Life-Cycle Costs." We have opted not to use this term at this point in the development of a project. This is an issue which is more suitably addressed during the design of a project and as we stated in paragraph 16 above, this is an element of sound architectural and engineering practices.

25. *Section 1942.18(l)*—One commenter recommended that for design/build projects, final plans should be required prior to start of construction. This has been adopted. Another commenter suggested the requirement be included for evaluation based on quality and the life-cycle cost analysis. Referring back to paragraphs 16 and 24 above, these items are considered as part of the design evaluation as a standard practice and need not be specified further.

26. *Section 1942.18(m)(3)*—Six commenters felt that an engineer or architect cannot determine that a contractor has fully "complied with the Plans and Specifications." This has been changed to provide for a certification of substantial compliance.

27. *Section 1942.18(n)(1)*—One commenter pointed out that California rarely allows liquidated damages and suggested the use of actual damages with a penalty. We believe the language allows sufficient latitude for departure where conditions warrant.

28. *Section 1942.18(n)(9)*—Three commenters expressed dismay on the paragraph relating to the Davis-Bacon Act. This paragraph only applies in very limited instances and is not a requirement under Community Facility loans. To avoid further confusion, this paragraph has been deleted. FmHA's policy on the Davis-Bacon Act can be found in 7 CFR Part 1901, Subpart D.

29. *Section 1942.18(n)(12)*—Seven commenters pointed out that the retainage provision conflicts with several State laws. The purpose of this paragraph is to clarify FmHA's position on retainage. We will continue to work with State agencies to arrive at a procedure which will allow both State and Federal regulations to be met.

Several commenters suggested the use of an escrow account for the retainage. We believe this adds confusion to the construction process and does not afford the owner the full measure of protection that retainage provides.

30. *Section 1942.18(o)*—One commenter suggested that the inspector's daily records should include both a daily diary and a daily inspection report. This has been adopted. Another commenter felt the inspector should determine that the contractor has complied with labor standards provisions of the construction contract when they exist. We fell that this is a contractor's responsibility and cannot be shifted to the owner through the inspector. Another commenter suggested that FmHA's prior approval on change orders which are less than 5 percent of construction cost not be required. Contract change orders may affect other items besides cost which may have a significant impact on a project. Even a change order of small dollar value can have a significant impact on owners with very limited financial resources. This recommendation was not adopted.

31. Some comments are general. One commenter suggested specific reference to Executive Orders 12372 and 12416, "Intergovernmental Review of Federal Programs." Current legislation for this FmHA program refers specifically to now obsolete OMB Circular A-95. We expect this to be corrected in the near future. One commenter suggested that any project extension be in compliance with current environmental regulations. This subject is addressed in Supart G of Part 1940 of this chapter.

The following additional changes were made for clarity and comprehension:

1. *Section 1942.17(d)(1)(i)(B)(8)*—To improve clarity, language was added to this paragraph to emphasize that funds may not be used in connection with

industrial parks to finance on-site utility systems or business and industrial buildings.

2. *Section 1942.17(e)(4)*—Language was added to specify that the State Director is to determine whether user rate schedules for portions of existing systems were developed under different financing, rates, terms, or conditions.

3. *Section 1942.17(g)(3)(i)*—A cross reference to the eligibility provisions of utility-type facilities was added.

4. *Section 1942.18(k)(2)(v)*—This paragraph was reworded to acknowledge that any or all bids may be rejected by the owner.

5. *Section 1942.18(o)(2)(iii)(B)*—Favorable developments to be reported has been expanded to include cost underruns or lower unit cost than originally planned and events which may result in less FmHA assistance.

**List of Subjects**

*7 CFR Parts 1823 and 1924*

Loan programs—agriculture.

*7 CFR Part 1942*

Community development, community facilities, loan programs—housing and community development, loan security, rural areas, waste treatment and disposal, domestic, water supply.

Therefore, FmHA amends Subparts B and H of Part 1823, Subpart E of Part 1924 and Subparts A, G, H, and I of Part 1942, Chapter XVIII, Title 7, Code of Federal Regulations as follows:

## PART 1823—ASSOCIATION LOANS AND GRANTS—COMMUNITY FACILITIES, DEVELOPMENT, CONSERVATION, UTILIZATION

### Subpart B—Association Loans for Shift-In-Land-Use Projects

1. § 1823.55 is amended by revising paragraph (o) to read as follows:

**§ 1823.55 Pasture and grazing associations.**

* * * * *

(o) *Dockets.* Dockets will include items shown below and any additional material, information, or documents found necessary or desirable by the State Director.

| Form No. | Name of item | Total number of copies | Number signed | Docket | Copy for borrower |
|---|---|---|---|---|---|
| AD 621 | Preapplication for Federal assistance | 2 | 1 | 1 | 0 |
| FmHA 400-1 | Equal opportunity agreement | 2 | 1 | 1 | 1 |
| FmHA 400-3 | Notice to contrsctors and applicants | 3 | 1 | 1 | 1 |
| FmHA 400-4 | Assurance agreement | 2 | 1 | 1 | 1 |
| FmHA 400-6 | Compliance statement | 3 | 3 | 1 | 1 |
| FmHA 422-1 | Appraisal report (farm tract) | 1 | 1 | 1 | 0 |
| FmHA 424-1 | Development plan (including contracts, if any) | 2 | 1 | 1 | 1 |
| FmHA 1940-1 | Request for obligation of funds | 5 | 0 and 1C | 1 | 1 |
| FmHA 440-2 | County committee certification or recommendation | 1 | 1 | 1 | 0 |
| FmHA 440-34 | Option to purchase real property | 3 | 2 | 1 | 1 |
| FmHA 442-7 | Operating budget | 2 | 1 | 1 | 1 |
| FmHA 1942-8 | Resolution of members or stockholders | 1 | 1 | 1 | 0 |
| FmHA 442-12 | Financial statement | 2 | 1 | 1 | 1 |
| FmHA 442-14 | Association project fund analysis | 3 | 0 | 1 | 0 |
| FmHA 442-17 | Membership list (grazing association) | 2 | 2 | 1 | 1 |
| FmHA 442-29 | Managers agreement (grazing association) | 2 | 2 | 1 | 1 |
| FmHA 442-33 | Shift-in-land-use plan | 1 | 0 | 1 | 0 |
| FmHA 442-36 | Application for membership in grazing association | 1 | 1 | 1 | 0 |
| FmHA 442-37 [1] | Management agreement—grazing association | 2 | 2 | 1 | 1 |
| FmHA 442-39 | Processing check list (other than public bodies) | 4 | 0 | 1 | 1 |
| FmHA 442-44 | Project summary (shift-in-land-use grazing) | 3 | 1 | 1 | 0 |
| FmHA 442-46 | Letter of intent to meet conditions | 2 | 1 | 1 | 1 |
| FmHA 442-48 | Grazing association loan resolution | 2 | 1 | 1 | 1 |
| | Legal service agreement | 3 | 1 | 1 | 1 |
| | Evidence of title to assets | 1 | 1 | 1 | 0 |
| | List of association officers | 1 | 1 | 1 | 0 |
| | Leases, permits, and other evidence of grazing rights | 1 | 0 | 0 | 0 |
| | Stock or membership certificate (facsimile or voided copy) | 1 | 0 | 1 | 0 |
| | Articles of incorporation | 2 | 1 | 1 | 1 |
| | Before and after maps | 1 | 1 | 1 | 1 |
| | By-laws | 2 | 1 | 1 | 1 |
| | Letters of conditions | 4 | 1 | 1 | 1 |

[1] Prepare enough additional copies so that each member is furnished a copy. Signed copy retained by Secretary.

### Subpart H—Association Loans for Irrigation and Drainage and Other Soil and Water Conservation Measures

2. Section 1823.234 is revised to read as follows:

**§ 1823.234 Loan processing.**

Applications will be processed in accordance with this subpart. Dockets will include items shown below and any additional material, information, or dockets found necessary or desirable by the State Director.

| Form No. | Name of item | Total number of copies | Number signed | Docket | Copy for borrower |
|---|---|---|---|---|---|
| AD 621 | Preapplication for Federal assistance | 2 | 1 | 1 | 0 |
| FmHA 400-1 | Equal opportunity agreement | 2 | 1 | 1 | 1 |
| FmHA 400-3 | Notice to contractors and applicants | 3 | 1 | 1 | 1 |
| FmHA 400-4 | Assurance agreement | 2 | 1 | 1 | 1 |
| FmHA 400-6 | Compliance statement | 3 | 3 | 1 | 1 |
| FmHA 422-1 | Appraisal report (farm tract) | 1 | 1 | 1 | 0 |
| FmHA 1940-1 | Request for obligation of funds | 5 | 0 and 1C | 1 | 1 |
| FmHA 424-1 | Development plan (including contracts, if any) | 2 | 1 | 1 | 1 |
| FmHA 440-2 | County committee certification or recommendation | 1 | 1 | 1 | 0 |
| FmHA 440-34 | Option to purchase real property | 3 | 2 | 1 | 1 |
| FmHA 442-7 | Operating budget | 2 | 1 | 1 | 1 |

| Form No. | Name of item | Total number of copies | Number signed | Docket | Copy for borrower |
|---|---|---|---|---|---|
| FmHA 1942-8 | Resolution of members of stockholders | 1 | 1 | 1 | 0 |
| FmHA 1942-9 | Resolution (security agreement) | 2 | 1 | 1 | 1 |
| FmHA 442-12 | Financial statement | 2 | 1 | 1 | 1 |
| FmHA 442-14 | Association project fund analysis | 3 | 0 | 1 | 0 |
| FmHA 442-19 | Agreement for engineering services | 3 | 1 | 1 | 1 |
| FmHA 442-39 | Processing check list (other than public bodies) | 3 | 1 | 1 | 0 |
| FmHA 442-42 | Project summary (irrigation, drainage, other soil and water conservation measures) | 3 | 1 | 1 | 0 |
| FmHA 442-46 | Letter of intent to meet conditions: | | | | |
| | List of association officers | 1 | 1 | 1 | 0 |
| | Certified membership list | 1 | 1 | 1 | 0 |
| | Stock of membership certificate (facsimile or voided copy) | 1 | 1 | 1 | 0 |
| | Articles of incorporation or charter of other evidence of creation | 2 | 1 | 1 | 1 |

## PART 1924—CONSTRUCTION AND REPAIR

### Subpart E—Suspension and Debarment Proceedings

3. In § 1924.216, paragraph (a)(2) is revised to read as follows:

**§ 1924.216 Procedure for debarment and suspension.**

(a) * * *

(2) Debarment proceedings may not commence and notice of proposed debarment many not be issued without the concurrence of OGC. In addition, debarment proceedings involving loans or grants under Subparts A and H of Part 1942 and Subparts A and E of Part 1980 of this chapter will be reviewed and concurred in the FmHA Administrator before notice is given under this subpart.

* * * * *

## PART 1942—ASSOCIATIONS

4. Subpart A of Part 1942 is revised to read as follows:

### Subpart A—Community Facility Loans

Sec.
1942.1 General.
1942.2 Processing applications.
1942.3 Preparation of appraisal reports.
1942.4 Borrower contracts.
1942.5 Application review and approval.
1942.6 Preparation for loan closing.
1942.7 Loan closing.
1942.8 Actions subsequent to loan closing.
1942.9 Planning, bidding, contracting, and constructing.
1942.10–1942.11 [Reserved]
1942.12 Loan cancellation.
1942.13 Loan servicing.
1942.14 Subsequent loans.
1942.15 Delegation and redelegation of authority.
1942.16 State supplements and guides.
1942.17 Community Facilities.
1942.18 Community Facilities—Planning, Bidding, Contracting, Constructing.
1942.19 Information pertaining to preparation of notes or bonds and bond transcript documents for public body applicants.
1942.20 Community Facility Guides.
1942.21–1942.49 [Reserved]
1942.50 OMB Control Number.

### Subpart A—Community Facility Loans

**§ 1942.1 General.**

(a) This subpart outlines the policies and procedures for making and processing insured loans for community facilities. The Farmers Home Administration (FmHA) shall cooperate fully with State and local agencies in making loans to assure maximum support to the State strategy for rural development. FmHA State Directors and their staffs shall maintain coordination and liaison with State agency and substate planning districts. Funds allocated for use under this subpart are also for the use of Indian tribes within the State, regardless of whether State development strategies include Indian reservations within the State's boundaries. Indians residing on such reservations must have equal opportunity to participate in the benefits of these programs as compared with other residents of the State. Federal statutes provide for extending FmHA financial programs without regard to race, color, religion, sex, national origin, marital status, age, or physical/mental handicap. The participants must possess the capacity to enter into legal contracts under State and local statutes.

(b) Indian tribes on Federal and State reservations and other Federally recognized Indian tribes are eligible to apply for and are encouraged to participate in this program. Such tribes might not be subject to State and local laws or jurisdiction. However, any requirements of this subpart that affect applicant eligibility, the adequacy of FmHA's security or the adequacy of service to users of the facility and all other requirements of this subpart must be met.

(c) The County Office will normally be the entry point for preapplications and serve as a local contact point. However, applications will be filed with the District Office and loans will be processed to the maximum extent possible by the District Office staff. The applicant's governing body should designate one person to coordinate the activities of its engineer, architect, attorney, and any other professional employees and to act as contact person during loan processing. FmHA personnel should make every effort to involve the applicant's contact person when meeting with the applicant's professional consultants and/or agents. The State Office staff will monitor community programs loan making and servicing, and will provide assistance to District Office personnel to the extent necessary to assure that the activities are being accomplished in an orderly manner consistent with FmHA regulations. The District Director will supply information on community program loan activity within the County Office service area to the County Supervisor at key points throughout the loan making process as described herein.

**§ 1942.2 Processing applications**

(a) *Preapplications.* (1) The County Office may handle initial inquiries and provide basic information about the program. They are to provide the preapplication, Form AD–621, "Preapplication for Federal Assistance." The County Supervisor will assist applicants as needed in completing Form AD–621, and in filing written notice of intent and request for priority recommendation with the appropriate clearinghouse (except Federally

recognized Indian tribes which will be dealt with in accordance with § 1901.352 (c) of Subpart H of Part 1901 of this Chapter). The County Supervisor will inform the applicant that it may be necessary to apply for credit from commercial sources. It will be explained that if credit for the project is available from commercial sources at reasonable rates and terms the applicant is not eligible for FmHA financing. Preapplications filed in the County Office will be forwarded immediately to the District Office. The applicant will be informed that further processing will be handled by the District Office. An information folder will be established and maintained by the County Office once a preapplication is received. In the event the preapplication is filed in the District Office, the District Director may assist the applicant in completing the preapplication requirements. The District Director will meet with the applicant, whenever appropriate, to discuss FmHA preapplication processing. The appropriate information to set up the County Office information file will be sent to the County Supervisor by the District Director. Guidance and assistance will be provided by the State Director, as needed, for orderly application processing. The District Director will determine that the preapplication is properly completed and fully review it. The District Director will then forward to the State Director:

(i) Eligibility determination and recommendations.

(ii) One copy of Form AD–621.

(iii) State intergovernmental review comments and recommendations (clearinghouse comments).

(iv) Priority recommendations.

(2) The State Director will review each Form AD–621 along with other information that is deemed necessary to determine whether financing from commercial sources at reasonable rates and terms is available. If credit elsewhere is indicated, the State Director will instruct the District Director to so inform the applicant and recommend the applicant apply to commercial sources for financing. Projects may be funded jointly with other lenders provided the requirements of § 1942.17 (g) of this subpart are met. Joint financing occurs when two or more lenders make separate loans to supply the funds required by one applicant for a project.

(i) In order to provide a basis for referral of preapplications of only those applicants who may be able to finance projects through commercial sources, State Directors should maintain liaison with representatives of banks, investment bankers, financial advisors, and other lender representatives in the State. State Directors with their assistance, should maintain criteria for determining preapplications which should be referred to commercial lenders. A list of lender representatives interested in receiving such referrals should be maintained.

(ii) The State Director shall maintain a working relationship with the State A–95 or other appropriate State agency and give full consideration to their comments when selecting preapplications to be processed.

(iii) The State Director will review the District Director's eligibility determination and recommendations in sufficient time for the District Director's use in preparing and issuing Form AD–622, "Notice of Preapplication Review Action."

(iv) Form AD–622 will be prepared by the District Director within forty-five (45) calendar days from receipt of the preapplication by FmHA, stating the results of the review action. The original will be signed and delivered to the applicant, a copy to the County Supervisor, and a copy to the State Director.

(3) For preapplications eligible for FmHA funding which have the necessary priority to compete with similar preapplications, FmHA will:

(i) Complete Form FmHA 1940–22, "Environmental Checklist for Categorical Exclusions," for projects excluded from environmental assessments under Subpart G of Part 1940 of this chapter prior to issuing Form AD–622 requesting an application; or

(ii) Issue an initial Form AD–622 for projects required to have environmental assessments under Subpart G of Part 1940 of this chapter containing the following statement:

You are advised against taking any actions or incurring any obligations which would either limit the range of alternatives to be considered, or which would have an adverse effect on the environment. You will be notified whether or not to proceed with a full application after you have provided the following materials to this office, and FmHA has completed its review.

(A) Form FmHA 1940–20, "Request for Environmental Information."

(B) Preliminary engineering or architectural report.

(C) Professional services agreement for engineering or architectural services.

(4) The following statement must be added to Form AD–622 when notifying preapplicants who are eligible, but do not have the priority necessary for further consideration at this time:

You are advised against incurring obligations which would limit the range of alternatives to be considered, or which cannot be fulfilled without FmHA funds until the funds are actually made available. Therefore, you should refrain from such actions as initiating engineering and legal work, taking actions which would have an adverse effect on the environment, taking options on land rights, developing detailed plans and specifications, or inviting construction bids until notified by Farmers Home Administration (FmHA) to proceed.

(5) Preapplicants issued an initial Form AD–622 requesting information referenced in § 1942.2 (a)(3)(ii) of this subpart will be issued a subsequent Form AD–622 upon review of the information and completion of an environmental assessment. Preapplicants will be advised whether to proceed with a full application.

(b) *Environmental review.* Environmental requirements will be documented in accordance with Subpart G of Part 1940 of this chapter and submitted to the State Director. Prior to requesting an application, the State Director will ensure that the appropriate environmental review is completed.

(c) *Applications.* The District Director should assist the applicant in application assembly and processing.

(1) State Directors should have applications in process representing approximately 150 percent of the current State allocation.

(2) The application docket will include Form AD–624, "Application for Federal Assistance (for construction programs)," and related forms, materials, and information. The application will be assembled in accordance with Guide 15 of this subpart or State guides developed under § 1942.16 of this subpart.

(3) When an applicant is notified to proceed with an application, the District Director should arrange for a conference with the applicant to provide copies of appropriate appendices and forms; furnish guidance necessary for orderly application processing; and to initiate a processing checklist for establishing a time schedule for completing items using Form FmHA 442–39, "Processing Check List (Other Than Public Bodies)," or Form FmHA 442–40, "Processing Check List (Public Bodies)," or other checklist adopted for use in the State. The District Director will confirm decisions made at this conference by letter to the applicant and by a copy of the processing checklist. The original and a copy of the processing checklist will be retained in the District Office and a copy will be forwarded to the State Office. The original and copy of the checklist retained in the District Office will be kept current as application processing

actions are taken. The copy will be sent to the State Office to use in updating its copy of this form. The State Office will then return the District Office's copy. As the application is being processed, and the need develops for additional conferences, the District Director will arrange with the applicant for such conference to extend and update the processing checklist.

(d) *Review of decision.* If at any time prior to loan approval it is decided that favorable action will not be taken on a preapplication or application, the District Director will notify the applicant in writing of the reasons why the request was not favorably considered. The notification to the applicant will state that a review of this decision by FmHA may be requested by the applicant under Subpart B of Part 1900 of this chapter.

(e) *Joint funding.* FmHA may finance projects jointly with funds from other sources, such as, commercial/private lenders, Federal agencies, State and local Governments, etc. Other departments, agencies, and executive establishments of the Federal Government may participate and provide financial and technical assistance jointly with FmHA to any applicant to whom FmHA is providing assistance. The amount of participation by the other department, agency, or executive establishment shall only be limited by its authorities except that any limitation on joint participation itself is superseded by Section 125 of Pub. L. 95–334 (Section 347, Consolidated Farm and Rural Development Act, as amended).

**§ 1942.3 Preparation of appraisal reports.**

When the loan approval official requires an appraisal, Form FmHA 422–10, "Appraisal Report—Water and Waste Disposal Systems," may be used with appropriate supplements. Form FmHA 442–10 may be modified as appropriate or other appropriate format may be used for facilities other than water and waste disposal. Appraisal reports prepared for use in connection with the purchase of existing essential community facilities or when required by § 1941.17 (g)(2)(iii)(B)(*2*), (g)(3)(iii)(B)(*2*), and (j)(4) of this subpart, may be prepared by the FmHA engineer/architect or, if desired by the State Director, some other qualified appraiser. The loan approval official may require an applicant to provide an appraisal prepared by an independent qualified appraiser; however, the loan approval official must determine that the appraised value shown in such reports reflects the present market value.

**§ 1942.4 Borrower contracts.**

The State Director will, with assistance as necessary by the Office of the General Counsel (OGC), concur in agreements between borrowers and third parties such as contracts for professional and technical services and contracts for the purchase of water or treatment of waste. State Directors are expected to work closely with representatives of engineering and architectural societies, bar associations, commercial lenders, accountant associations, and others in developing standard forms of agreements, where needed, and other such matters in order to expedite application processing, minimize referrals to OGC, and resolve problems which may arise.

**§ 1942.5 Application review and approval.**

(a) *Procedures for review.* Ordinarily FmHA staff review will proceed as applications are being developed. An overall review of the applicant's financial status, including a review of all assets and liabilities, will be a part of the docket review process by the staff and approval officials. The engineering/architect reports and associated data are to be reviewed by the FmHA staff engineer or architect, as appropriate, as soon as available but prior to the District Director's completion of the project summary. During the review the District Director in all cases will make certain that no low income or minority community within the service area has been omitted or discouraged from participating in the proposed project. The District Director will also determine how the service area was defined to assure that gerrymandering of specific communities or areas has not occurred. The findings should be documented in the running record. Prior to presenting the assembled application to the approval official, the assembled application ordinarily will be processed in the following sequence:

(1) The District Director will complete the project summary including written analysis and recommendations using either Form FmHA 1942–45, "Project Summary—Water and Waste Disposal and Other Utility-Type Projects," for utility type projects or Form FmHA 442–43, "Project Summary—Community Facilities (Other than utility-type projects)," for all other types of projects. The District Director will prepare a draft letter of conditions listing all the requirements which the applicant must agree to meet within a specific time.

(i) Requirements listed in letters of conditions will ordinarily include: maximum amount of loan which may be considered, term of loan and any payment deferment, number of users (members) and verification required, contributions, rates and charges, interim financing, disbursement of funds, security requirements, graduation requirements, organization, business operations, insurance and bonding (including applicant/borrower and contractor), construction contract documents and bidding, accounts, records, and audit reports required, adoption of Form FmHA 1942–47, "Loan Resolution (Public Bodies)," for public bodies or Form FmHA 1942–9, "Loan Resolution (Security Agreement)," for other than public bodies, closing instructions, and other requirements.

(ii) Each letter of conditions will contain the following paragraphs:

This letter establishes conditions which must be understood and agreed to by you before further consideration may be given to the application. Any changes in project cost, source of funds, scope of services, or any other significant changes in the project or applicant must be reported to and approved by FmHA by written amendment to this letter. Any changes not approved by FmHA shall be cause for discontinuing processing of the application."

This letter is not to be considered as loan approval or as representation to the availability of funds. The docket may be completed on the basis of a loan not to exceed $———. If FmHA makes the loan, the interest rate will be that charged by FmHA at the time a signed copy of Form FmHA 1940–1, "Request for Obligation of Funds," is mailed to you."

Please complete and return the attached Form FmHA 442–46, "Letter of Intent to Meet Conditions," if you desire that further consideration be given your application.

(iii) District Directors may add the following:

If the conditions set forth in this letter are not met within ——— days from the date hereof, FmHA reserves the right to discontinue the processing of the application.

(2) The FmHA staff engineer or architect, as appropriate, will include a written analysis and recommendations on Form FmHA 442–43 or Form FmHA 1942–45.

(3) The Chief, Community Programs or Community and Business Programs will review the assembled application and include on Form FmHA 442–43 or Form FmHA 1942–45 written analysis and recommendations, including the availability of other credit and other eligibility determinations. The draft letter of conditions will be reviewed and any necessary modifications made.

(b) *Project requiring National Office review.* Prior National Office review is required for certain proposals (See Subpart A of Part 1901 of this chapter).

(1) The District Director should assemble applications for the National

Office review in the following order from top to bottom and forward them to the State Director for review and recommedation prior to submission to the National Office:

(i) Transmittal memorandum including:

(A) Recommendation.

(B) Date of expected obligation.

(C) Any unusual circumstances.

(ii) Copies of the following:

(A) Proposed letter of conditions.

(B) Applicable State Intergovernmental review comments (FmHA Instruction 1940–J, available in any FmHA office).

(C) Forms FmHA 1942–45 or FmHA 442–43 (including the required copy of Forms FmHA 442–7, "Operating Budget," and FmHA 442–14, "Association Project Fund Analysis").

(D) Form FmHA 1942–51, "Water and Waste Disposal Grant Determination," if applicable.

(E) Preliminary architectural or engineering report.

(F) Form FmHA 442–3, "Balance Sheet." This form may be supplemented to provide further details if desired.

(G) For other essential community facility loan applicants whose proposals do not meet the assured income or tax based security requirements of § 1942.17 (g)(2)(iii) and (g)(3)(iii) of this subpart, an income and expense statement for the last five years of operation will be submitted if available.

(H) For other essential community facility loans secured under paragraph (b)(1)(ii)(G) of this section, submit a detailed explanation of the proposed security; evidence that the application cannot be processed and the loan secured under paragraph (b)(1)(ii)(G) of this section; evidence supporting the efforts by the applicant in persuading appropriate public bodies to provide the proposed facility and services and the results, and comments of the Regional Attorney concurring in the applicants' legal authority to give the proposed security.

(I) Financial Feasibility Report when required by § 1942.17 (h)(1).

(J) Proposed lease agreements, management agreements, or other agreements when facility management will be provided by other than the applicant.

(K) Other forms and documents on which there are specific questions.

(L) Environmental impact analysis and documentation.

(2) For applications to be reviewed in the State or field, at least those items in paragraph (b)(1)(ii) of this section, should be available.

(c) *For all applications.* All letters of conditions will be addressed to the applicant, signed by the District Director or other FmHA representative designated by the State Director, and delivered to the applicant. Upon signing the letter of conditions, the District Director will send two copies of the letter of conditions and two copies of Forms FmHA 442–43 or FmHA 1942–45 to the State Director. A copy of the letter of conditions and the appropriate project summary will be sent to the County Supervisor for information purposes. The State Director will immediately send one copy of Forms FmHA 442–43 or FmHA 1942–45 (including the required copy of Forms FmHA 442–7 and FmHA 442–14) and a copy of the letter of conditions to the National Office, Attention: Water and Waste Disposal Division or Community Facilities Division, as appropriate. The District Director, with assistance as needed from the State Office, will discuss the requirements of the letter of conditions with the applicant's representatives and afford them an opportunity to execute Form FmHA 442–46.

(1) The letter of conditions should not ordinarily be issued unless the State Director expects to have adequate funds in the State allocation to fund the project within the next 12 months based on historic allocations or other reliable projections.

(2) If the applicant declines to execute Form FmHA 442–46, the District Director will immediately notify the State Director and provide complete information as to the reasons for such declination. The District Director will provide the County Supervisor with an information copy of the report.

(3) If the applicant executes Form FmHA 442–46, the District Director will forward two copies of the completed Form FmHA 442–14; and the completed and executed original, a signed copy and an unsigned copy of Form FmHA 1940–1 to the State Director.

(d) *Loan approval and obligating funds.* Loans will be approved under this subpart and Subpart A of Part 1901 of this chapter (available in any FmHA office). The loan will be considered approved on the date the signed copy of Form FmHA 1940–1 is mailed to the applicant. The State Director or designee may request an obligation of funds when available within their State allocation and according to the following:

(1) Form FmHA 1940–1, authorizing funds to be reserved, may be executed by the loan approval official providing the applicant has the legal authority to contract for a loan and to enter into required agreements and has signed Form FmHA 1940–1.

(2) If approval was concurred in by the National Office, a copy of the concurring memorandum will be attached to the original of Form FmHA 1940–1.

(3) The State Director or designee will request an obligation of loan and/or grant funds from the Finance Office after signing Form FmHA 1940–1. The requesting official will furnish security identification as necessary. The requesting official will record the date, time of request, and their initials on the original Form FmHA 1940–1.

(4) Requests for obligation received by the Finance Office before 2:30 p.m. Central Time will be processed on the date of the request. For requests received after 2:30 p.m. Central Time, there may be instance in which a request will be processed on the next working day.

(5) Each working day the Finance Office will notify the State Office by telephone of all projects for which funds were reserved during the previous night's processing cycle. If funds cannot be reserved for a project, the Finance Office will notify the State Office by telephone of the reason. The obligation date and date the applicant is notified of loand and/or grant approval is six working days from the date funds are reserved in the Finance Office unless an exception is granted by the National Office. The Finance Office will mail Form FmHA 440–57, "Acknowledgement of Obligated Funds/Check Request," to the State Office confirming the reservation of funds with the obligation date.

(6) Immediately after notification by the Finance Office that the funds have been reserved, the State Director or designee will notify, by telephone, the Legislative Affairs and Public Information Staff in the National Office as required by FmHA Instruction 2015–C (available in any FmHA State Office).

(7) Loan approval and applicant notification will be accomplished by the State Director or designee by mailing to the applicant on the obligation date a copy of Form FmHA 1940–1 which has been previously signed by the applicant and loan aproval official. The date the applicant is notified is also the date the interest rate is established. The State Director or designee will record the date of applicant notification on the original of Form FmHA 1940–1 and include it as a permanent part of the District Office project file with a copy place in the State Office file. The District Director will notify the county Supervisor that the applicant has been notified of approval.

**§ 1942.6 Preparation for loan closing.**

(a) *Obtaining closing instructions.* Completed dockets will be reviewed by the State Director. The information required by OGC will be transmitted to OGC with a request for closing instructions. Upon receipt of the closing instructions from OGC, the State Director will forward them along with any appropriate instructions to the District Director. Upon receipt of closing instructions, the District Director will discuss with the applicant and its architect or engineer, attorney, and other appropriate representatives, the requirements contained therein and any actions necessary to proceed with closing.

(b) *Verification of users and other funds.* (1) In connection with a loan for a utility type roject to be secured by a pledge of user fees or revenues, the District Director will authenticate the number of users prior to loan closing or the commencement of construction, whichever occurs first. Such individual will review each signed user agreement and check evidence of cash contributions. If during the review any indication is received that all signed users may not connect to the system, there will be such additional investigation made as deemed necessary to determine the number of users who will connect to the system. The District Director will record the determination in a memorandum to the State Director.

(2) In all cases the availability and amounts of other funds to be used in the project will be verified by FmHA.

(c) *Initial compliance review.* An initial compliance review should be completed under Subpart E of Part 1901 of this chapter.

(d) *Ordering loan checks.* Checks will not be ordered until:

(1) Form FmHA 440–57 has been received from the Finance Office; and

(2) The applicant has complied with approval conditions and closing instructions, except for those actions which are to be completed on the date of loan closing or subsequent thereto; and

(3) The applicant is ready to start construction or funds are needed to pay interim financing obligations.

(e) *Multiple advances of FmHA funds.* When FmHA provides loan funds during the construction period using interim (temporary) instruments described in § 1942.19(g) of this subpart, the following action will be taken prior to the issuance of the permanent instruments:

(1) The Finance Office will be notified of the anticipated date for retirement of the interim instruments and issuance of permanent instruments of debt.

(2) The Finance Office will prepare a statement of account including accrued interest through the proposed date of retirement and also show the daily interest accrual. The statement of account and the interim financing instruments will be forwarded to the District Director.

(3) The District Director will collect interest through the actual date of the retirement and obtain the permanent instrument(s) of debt in exchange for the interim financing instruments. The permanent instruments and the cash collection will be forwarded to the Finance Office immediately. In developing the permanent instruments, the sequence of preference set out in § 1942.19(e) of this subpart will be followed.

**§ 1942.7 Loan closing.**

Loans will be closed in accordance with the closing instructions issued by the OGC and § 1942.17(o) of this subpart and as soon as possible after receiving the check.

(a) *Authority to execute, file, and record legal instruments.* District Office employees are authorized to execute and file or record any legal instruments necessary to obtain or preserve security for loans. This includes, as appropriate, mortgages and other lien instruments, as well as affidavits, acknowledgments, and other certificates.

(b) *Preparation of mortgages.* Unless otherwise required by State law or unless an exception is approved by the State Director with advice of the OGC, only one mortgage will be taken even though the indebtedness is to be evidenced by more than one instrument.

(c) *Source of funds for insured loans.* All loans will be made from the Rural Development Insurance Fund (RDIF).

(d) *Unused funds.* Obligated funds planned for project development which remain after all authorized costs have been provided for will be disposed of in accordance with § 1942.17(p)(6) of this subpart. See Subpart B of Part 1951 of this chapter as to the method of returning loan and grant funds.

(e) *Loan checks.* Whenever a loan check is received, lost, or destroyed, the District Director will take appropriate actions outlined in FmHA Instruction 102.1 (available in any FmHA office). Checks which cannot be delivered within a reasonable amount of time (no more than 20 calendar days) will be handled in accordance with FmHA Instruction 102.1.

(f) *Posting management system records.* Record on Form FmHA 2033–33, "Management System Card—Community Programs," any actions to be completed subsequent to loan closing.

(g) *Supervised bank accounts.* Supervised bank accounts will be handled under Subpart A of Part 1902 of this chapter.

**§ 1942.8 Actions subsequent to loan closing.**

(a) *Mortgages.* Real estate or chattel mortages or security instruments will be delivered to the recording office for recordation or filing, as appropriate. A copy of such instruments will be delivered to the borrower. The original instrument, if returnable after recording or filing, will be retained in the borrower's case folder.

(b) *Notes.* For a loan from the RDIF, a conformed copy of the note will be sent to the Finance Office immediately after loan closing.

(c) *Multiple advances—bond(s).* When temporary paper, such as bond anticipation notes or interim receipts, is used to conform with the multiple advance requirement, the original temporary paper will be forwarded to the Finance Office after each advance is made to the borrower. The borrower's case number will be entered in the upper right-hand corner of such paper by the District Office. The permanent debt instrument(s) should be forwarded to the Finance Office as soon as possible after the last advance is made.

(d) *Bond registration record.* Form FmHA 442–28, "Bond Registration Book," may be used as a guide to assist borrowers in the preparation of a bond registration book in those cases where a registration book is required and a book is not provided in connection with the printing of the bonds.

(e) *Disposition of title evidence.* All title evidence other than the opinion of title, mortgage title insurance policy, and water stock certificates will be returned to the borrower when the loan has been closed.

(f) *Material for State Office.* When the loan has been closed, the District Director will submit to the State Director:

(1) The complete docket; and

(2) A statement covering information other than the completion of legal documents showing what was done in carrying out loan closing instructions.

(g) *State Office review of loan closing.* The State Director will review the District Director's statement concerning loan closing, the security instruments, and other documents used in closing to determine whether the transaction was closed properly. All material submitted by the District Director, including the executed contract documents (if

required by OGC) with the certification of the borrower's attorney, along with a statement by the State Director that all administrative requirements have been met, will be referred to OGC for post closing review. OGC will review the submitted material to determine whether all legal requirements have been met. OGC's review of FmHA's standard forms will be only for proper execution thereof, unless the State Director brings specific questions or deviations to the attention of OGC. It is not expected that facility development including construction will be held up pending receipt of the opinion from OGC. When the opinion from OGC is received, the State Director will advise the District Director of any deficiencies that must be corrected and return all material that was submitted for review. After the loan has been properly closed, the District Director will inform the County Supervisor of that fact.

(h) *Safeguarding bond shipments.* FmHA personnel will follow the procedures for safeguarding mailings and deliveries of bonds and coupons outlined in FmHA Instruction 2018–E (available in any FmHA office), whenever they mail or deliver these items.

(i) *Water stock certificates.* Water stock certificates will be filed in the loan docket in the District Office.

**§ 1942.9 Planning, bidding, contracting, and constructing. [See §§ 1942.17(p) and 1942.18]**

(a) *Review of construction plans and specifications.* All plans and specifications will be submitted as soon as available to the State Office for review and comments.

(b) *Contract approval.* The State Director or designee is responsible for approving all construction contracts using legal advice and guidance of OGC as necessary. The use of negotiated procurement for a construction contract or a contracting method under § 1942.18(k)(4) or § 1942.18(l) of this subpart exceeding $100,000 must be concurred in by the National Office. Procurement under § 1942.18(l) of this subpart will not be considered when an FmHA grant is involved. When an applicant requests such concurrence, the State Director will submit the following to the National Office:

(1) State Director's and FmHA engineer/architect's comments and recommendations, and when noncompetitive negotiation is proposed, submit an evaluation of previous work of the proposed construction firm.

(2) Regional attorney's opinion and comments regarding the legal adequacy of the proposed procurement method and proposed contract documents.

(3) Copy of owner's written request and description of the procurement method proposed.

(4) Copy of the proposed contract.

(c) *Bid irregularities.* Any irregularities in the bids received or other matters pertaining to the contract award having legal implications will be cleared with OGC before the State Director consents to the contract award.

(d) *Noncompliance.* State Directors, upon receipt of information indicating borrowers or their officers, employees, or agents are not performing in compliance with § 1942.18(j)(1) of this subpart, may request the Regional Office of the Inspector General (OIG) to investigate the matter and provide a report. The State Director is responsible for resolving the issue.

(e) *County Office notification.* The District Director will notify the County Supervisor of each construction contract award and final inspection occurring within the County Office service area.

**§§ 1942.10–1942.11 [Reserved]**

**§ 1942.12 Loan cancellation.**

Loans which have been approved and obligations which have been established may be canceled before closing as follows:

(a) *Form FmHA 1940–10, "Cancellation of U.S. Treasury Check and/or Obligation."* The District Director or State Director may prepare and execute Form FmHA 1940–10 in accordance with the Forms Manual Insert (FMI). For a loan made from the RDIF, if the check has been received or is subsequently received in the District Office, the District Director will return it to the Finance Office with an original and one copy of Form FmHA 1940–10.

(b) *Notice of cancellation.* If the docket has been forwarded to OGC, that office will be notified of the cancellation by a copy of Form FmHA 1940–10. Any application for title insurance, if ordered, will be canceled. The borrower's attorney and engineer/architect, if any, should be notified of the cancellation. The District Director may provide the borrower's attorney and engineer/architect with a copy of the notification to the applicant. The State Director will notify the Director of Legislative Affairs and Public Information by telephone or electronic mail and give the reasons for such cancellation.

**§ 1942.13 Loan servicing.**

Loans will be serviced under Subpart E of Part 1951 of this chapter.

**§ 1942.14 Subsequent loans.**

Subsequent loans will be processed under this subpart.

**§ 1942.15 Delegation and redelegation of authority.**

The State Director is responsible for implementing the authorities in this subpart and for issuing State supplements redelegating authorities. Loan and grant approval authority is in Subpart A of Part 1901 of this chapter. Except for loan and grant approval authority, District Directors may redelegate their duties to qualified staff members.

**§ 1942.16 State supplements and guides.**

State Directors will obtain National Office clearance for all State supplements and guides under FmHA Instruction 2006–B (available in any FmHA office).

(a) *State supplements.* State Directors may supplement this subpart to meet State and local laws and regulations and to provide for orderly application processing and efficient service to applicants. State supplements shall not contain any requirements pertaining to bids, contract awards, and materials more restrictive than those in § 1942.18 of this subpart.

(b) *State guides.* State Directors may develop guides for use by applicants if the guides to this subpart are not adequate. State Directors may prepare guides for items needed for the application; items necessary for the docket; and items required prior to loan closing or start of construction.

**§ 1942.17 Community Facilities.**

(a) *General.* This section includes information and procedures specifically designed for use by applicants including their professional consultants and/or agents who provide such assistance and services as architectural, engineering, financial, legal or other services related to application processing and facility planning and development. This section is made available as needed for such use. It includes FmHA policies and requirements pertaining to loans for community facilities. It provides applicants with guidance for use in proceeding with their application. FmHA shall cooperate fully with appropriate State agencies to give maximum support of the State's strategies for development of rural areas. State and substate A–95 agencies may recommend priorities for applications. FmHA will fully consider all A–95 agency review comments and priority recommendations in selecting applications for funding.

(b) *Applicant eligibility.* Facilities financed by FmHA must primarily serve rural residents. For water or waste disposal facilities the terms "rural" and "rural area" will not include any area in any city or town with a population in excess of 10,000 inhabitants according to the latest decennial census of the United States. For essential community facilities the term "rural" and "rural area" will not include any area in any city or town with a population in excess of 20,000 inhabitants according to the latest decennial census of the United States. Facilities must be located in rural areas except for utility-type services, such as water, sewer, natural gas, or hydroelectric, serving both rural and non-rural areas. In such cases, FmHA funds may be used to finance only that portion serving rural users, regardless of facility location. Loans for water or waste disposal facilities will not be made to any city or town with a population in excess of 10,000. Loans for essential community facilities will not be made to any city or town with a population in excess of 20,000. Assistance to areas or communities adjacent to, or closely associated with, non-rural areas is limited by § 1942.17(c) of this subpart.

(1) *Type of applicants*—(i) *Public bodies* such as municipalities, counties, districts, authorities, or other political subdivisions of a State.

(ii) *Organizations operated on a not-for-profit basis* such as associations, cooperatives, and private corporations. Applicants organized under the general profit corporation laws may be eligible if they actually will be operated on a not-for-profit basis under their charter, bylaws, mortgage, or supplemental agreement provisions as may be required as a condition of loan approval.

(A) Essential community facility applicants other than utility-type must have significant ties with the local rural community. Such ties are necessary to ensure to the greatest extent possible that a facility under private control will carry out a public purpose and continue to primarily serve the local residents. Ties may be evidenced by items such as:

(*1*) Association with or controlled by a local public body or bodies, or broadly based ownership and controlled by members of the community;

(*2*) Substantial public funding through taxes, revenue bonds, or other local Government sources, and/or, substantial voluntary community funding such as would be obtained through a community-wide funding campaign.

(iii) *Indian tribes* on Federal and State reservations and other Federally recognized Indian tribes.

(2) *Credit elsewhere.* Applicants must certify in writing and FmHA shall determine and document that the applicant is unable to finance the proposed project from their own resources or through commercial credit at reasonable rates and terms.

(3) *Legal authority and responsibility.* Each applicant must have or will obtain the legal authority necessary for constructing, operating, and maintaining the proposed facility or service and for obtaining, giving security for, and repaying the proposed loan. The applicant shall be responsible for operating, maintaining, and managing the facility, and providing for its continued availability and use at reasonable rates and terms. This responsibility shall be exercised by the applicant even though the facility may be operated, maintained, or managed by a third party under contract, management agreement, or written lease. Leases may be used when this is the only feasible way to provide the service and is the customary practice. Management agreements should provide for at least those items listed in Guide 24 of this subpart.

(4) *Refinancing FmHA debt.* FmHA shall require an agreement that if at any time it shall appear to the Government that the borrower is able to refinance the amount of the indebtedness then outstanding, in whole or in part, by obtaining a loan for such purposes from responsible cooperative or private credit sources, at reasonable rates and terms for loans for similar purposes and periods of time, the borrower will, upon request of the Government, apply for and accept such loan in sufficient amount to repay the Government and will take all such actions as may be required in connection with such loan.

(c) *Priorities*—(1) *Truly rural areas.* FmHA program assistance will be directed toward truly rural areas and rural communities. Normally, priority will not be given to preapplications for projects that will serve other than truly rural areas. Truly rural areas are areas other than densely settled areas or communities adjacent to, or closely associated with, a city or town with a population exceeding 10,000 residents for water or waste disposal assistance, or 20,000 residents for essential community facility assistance. When determining whether a rural area or rural community is adjacent to, or closely associated with, a city or town with a population exceeding 10,000 residents for water and waste disposal, or 20,000 residents for essential community facility assistance, minor open spaces such as those created by physical or legal barriers, commercial or industrial development, parks, areas reserved for convenience or appearance, or narrow strips of cultivated land, will be disregarded. An area or community shall be considered adjacent to or closely related with a nonrural area when it constitutes for general, social, and economic purposes a single community having a contiguous boundary.

(2) *Project selection process.* The following paragraphs indicate items and conditions which must be considered in selecting preapplications for further development. When ranking eligible preapplications for consideration for limited funds, FmHA officials must consider the priority items met by each preapplication and the degree to which those priorities are met, and apply good judgement.

(i) *Preapplications.* The preapplication and supporting information submitted with it will be used to determine the proposed project's priority for available funds.

(ii) *State Office review.* All preapplications will be reviewed and scored and Form AD–622, "Notice of Preapplication Review Action," issued within the time limits in § 1942.2(a)(2)(iv) of this subpart. When considering authorizing the development of an application for funding, the State Director should consider the remaining funds in the State allocation, and the anticipated allocation of funds for the next fiscal year as well as the amount of time necessary to complete that application. Applicants whose preapplications are found to be ineligible will be so advised. These applicants will be given adverse notice through Form AD–622 and advised of their appeal rights under Subpart B of Part 1900 of this chapter. Those applicants with eligible lower scoring preapplications which obviously cannot be funded within an eighteen month period of time, and are not within 150 percent of the State's allocation, should be notified that funds are not available; and requested to advise whether they wish to have their preapplication maintained in an active file for future consideration. The State Director may request an additional allocation of funds from the National Office for such preapplications. Such requests will be considered along with all others on hand.

(iii) *Selection priorities.* The priorities described below will be used by the State Director to rate preapplications. The priorities should be applied to water and waste disposal or community facilities preapplications as directed. The format found in Part I of Guide 26 of

this subpart should be followed in scoring each preapplication. A copy of the score sheet should be placed in the case file for future reference.

(A) *Population priorities.* The following priorities apply to both Water and Waste Disposal and Community Facilities preapplications. Points will be distributed as indicated.

(*1*) The proposed project is located in a rural community having a population not in excess of 2,500—25 points.

(*2*) the proposed project is located in a rural community having a population not in excess of 5,500—20 points. (Points under this priority should not be assigned to a preapplication if points were assigned under paragraph (c)(2)(iii)(A)(*1*) of this section.)

(B) *Health priorities.* Points will be distributed as indicated.

(*1*) Water and Waste Disposal preapplications only. The proposed project is:

(*i*) Needed to alleviate the sudden unexpected diminution or deterioration of a water supply, or to meet health or sanitary standards which pertain to a community's water supply—25 points.

(*ii*) Required to correct an inadequate waste disposal system due to unexpected occurrences, or to meet health or sanitary standards which pertain to a community's waste disposal system—25 points.

(*2*) Community Facility preapplication only. The proposed project is required either to correct a health or sanitary problem, or to meet a health or sanitary standard—25 points.

(C) *Income priorities.* The following priorities apply to both Water and Waste Disposal and Community Facilities preapplications. Points will be distributed as indicated. The median income of the population to be served by the proposed facility is:

(*1*) Less than the poverty line for a family of four as prescribed by the Office of Management and Budget (OMB) as described under Section 624 of the Economic Opportunity Act of 1964 (U.S.C. 2971d)—25 points.

(*2*) More than the poverty line but less than 85% of the State's nonmetropolitan median household income—20 points.

(*3*) Between 85% and 100%, inclusive, of the State's nonmetropolitan median household income—15 points.

(D) *Other factors.* Points will be distributed as indicated.

(*1*) Water and Waste Disposal preapplications only. The proposed project will: merge ownership, management, and operation of smaller facilities providing for more efficient management and economical service; and/or enlarge, extend, or otherwise modify existing facilities to provide service to additional rural residents—10 points.

(*2*) Community Facilities preapplications only. The purpose of the proposed project is to construct, enlarge, extend or otherwise improve the following types of facilities. (Select only the factor most applicable to the proposed project.)

(*i*) Public safety—10 points. (Examples include fire, police, rescue and ambulance services.)

(*ii*) Health care—5 points. (Examples include clinics, nursing homes, convalescent facilities, and hospital projects designed to make the facility conform with life/safety codes, medicare and medicaid requirements, and minor expansions needed to meet the immediate requirements of the community. Points under this authority should not be awarded to a preapplication if points were awarded under § 1942.17(c)(2)(iii)(B)(*2*) of this subpart.)

(*3*) Water and Waste Disposal and Community Facilities preapplications.

(*i*) Applicant is a public body or Indian tribe—5 points.

(*ii*) Project is located in a "truly rural area" as described in § 1942.17(c)(1) of this subpart—10 points.

(*iii*) Amount of joint financing committed to the project is:

(*a*) 20% or more private, local or state funds except federal funds channeled through a state agency—10 points.

(*b*) 5%–19% private, local or state funds except federal funds channeled through a state agency—5 points.

(E) In certain cases the State Director may assign up to 15 points to a preapplication, in addition to those that may be scored under paragraphs (c)(2)(iii) (A) through (D), of this section. These points are primarily intended to address an unforeseen exigency or emergency, such as the loss of a community facility due to accident or natural disaster or the loss of joint financing if FmHA funds are not committed in a timely fashion. However, the points may also be awarded to projects in order to improve compatibility/coordination between FmHA's and other agencies' selection systems and to assist those projects that are the most cost effective. A written justification must be prepared and placed in the project file each time the State Director assigns these points.

(iv) *Results of State Office review.* After completing the review, the State Director will normally select the eligible preapplications with the highest scores for further processing. In cases where preliminary cost estimates indicate that an eligible, high scoring preapplication is unfeasible or would require an amount of funding from FmHA that exceeds either 25 percent of a State's current annual allocation or an amount greater than that remaining in the State's allocation, the State Director may instead select the next lower scoring preapplication(s) for futher processing provided the high scoring applicant is notified of this action and given an opportunity to revise the proposal and resubmit it. If it is found that there is no effective way to reduce costs, the State Director, after consultation with applicant, may submit a request for an additional allocation of funds for the proposed project to the National Office. The request should be submitted during the fiscal year in which obligation is anticipated. Such request will be considered along with all others on hand. A written justification must be prepared and placed in the project file when an eligible preapplication with a higher rating is not selected for further processing. The State Director will notify the District Director of the results of the review action. The State Director will return the preapplication information with an authorization for the District Director to prepare and issue Form AD–622 in accordance with § 1942.2(a)(2)(iv) of this subpart. Priority will be given to those preapplications and applications for funding which meet criteria in § 1942.17(c)(2)(iii)(A) (*1*) or (*2*); and the criteria in §1942.17(c) (2)(iii)(B)(*1*) (*i*) or (*ii*) or (B)(*2*) of this subpart.

(v) *Application development.* Applications should be developed expeditiously following good management practices. Applications that are not developed in a reasonable period of time taking into account the size and complexity of the proposed project may be removed from the State's active file. Applicants will be consulted prior to taking such action.

(vi) *Project obligations.* To ensure efficient use of resources, obligations should occur in a timely fashion throughout the fiscal year. Projects may be obligated as their applications are completed and approved.

(vii) *Requests for additional funding.* All requests for additional allocations of funds submitted to the National Office must follow the formats found in Parts I and II of Guide 26. In selecting projects for funding at the National Office level, additional points may be scored based on the priority assigned to the project by the State Office. These points will be scored in the manner shown below. Only the three highest priority projects can score points. In addition, the Administrator may assign up to 15 additional points to account for items

such as geographic distribution of funds and emergency conditions caused by economic problems or natural disasters.

| Priority | Points |
|---|---|
| 1 | 5 |
| 2 | 3 |
| 3 | 1 |

(viii) *Cost overruns.* A preapplication may receive consideration for funding before others at the State Office level or at the National Office level, if funds are not available in the State Office, when it is a subsequent request for a previously approved project which has encountered cost overruns due to high bids or unexpected construction problems that cannot be reduced by negotiations, redesign, use of bid alternatives, rebidding or other means.

(d) *Eligible loan purposes.* (1) Funds may be used:

(i) To construct, enlarge, extend, or otherwise improve water or waste disposal, and other essential community facilities providing essential service primarily to rural residents.

(A) "Water or waste disposal facilities" include water, sanitary sewerage, solid waste disposal, and storm waste-water facilities.

(B) "Essential community facilities" are those public improvements requisite to the beneficial and orderly development of a community operated on a nonprofit basis including but not limited to:

(*1*) Fire and rescue services;

(*2*) Health services;

(*3*) Community, social, or cultural services;

(*4*) Transportation facilities, such as streets, roads, and bridges;

(*5*) Hydroelectric generating facilities and related connecting systems and appurtenances, when not eligible for Rural Electrification Administration (REA) financing;

(*6*) Supplemental and supporting structures for other rural electrification or telephone systems (including facilities such as headquarters and office buildings, storage facilities, and maintenance shops) when not eligible for Rural Electrification Administration financing;

(*7*) Natural gas distribution systems; and

(*8*) Industrial park sites, but only to the extent of land acquisition and necessary site preparation, including access ways and utility extensions to and throughout the site. Funds may not be used in connection with industrial parks to finance on-site utility systems, or business and industrial buildings.

(C) "Otherwise improve" includes but is not limited to the following:

(*1*) The purchase of major equipment, such as fire trucks, ambulances, solid waste collection trucks, and X-ray machines, which will in themselves provide an essential service to rural residents;

(*2*) The purchase of existing facilities when it is necessary either to improve or to prevent loss of service;

(*3*) Payment of tap fees and other utility connection charges as provided in utility purchase contracts prepared under § 1942.18(f) of this subpart.

(ii) To construct or relocate public buildings, roads, bridges, fences, or utilities, and to make other public improvements necessary to the successful operation or protection of facilities authorized in paragraph (d)(1)(i) of this section.

(iii) To relocate private buildings, roads, bridges, fences, or utilities, and other private improvements necessary to the successful operation or protection of facilities authorized in paragraph (d)(1)(i) of this section.

(iv) To pay the following expenses, but only when such expenses are a necessary part of a loan to finance facilities authorized in paragraphs (d)(1)(i), (d)(1)(ii) and (d)(1)(iii) of this section.

(A) Reasonable fees and costs such as legal, engineering, architectural, fiscal advisory, recording, environmental impact analyses, archeological surveys and possible salvage or other mitigation measures, planning, establishing or acquiring rights.

(B) Interest on loans until the facility is self-supporting, but not for more than three years unless a longer period is approved by the National Office; interest on loans secured by general obligation bonds until tax revenues are available for payment, but not for more than two years unless a longer period is approved by the National Office; and interest on interim financing, including interest charges on interim financing from sources other than FmHA.

(C) Costs of acquiring interest in land; rights, such as water rights, leases, permits, rights-of-way; and other evidence of land or water control necessary for development of the facility.

(D) Purchasing or renting equipment necessary to install, maintain, extend, protect, operate, or utilize facilities.

(E) Initial operating expenses for a period ordinarily not exceeding one year when the borrower is unable to pay such expenses.

(F) Refinancing debts incurred by, or on behalf of, a community when all of the following conditions exist:

(*1*) The debts being refinanced are a secondary part of the total loan;

(*2*) The debts are incurred for the facility or service being financed or any part thereof;

(*3*) Arrangements cannot be made with the creditors to extend or modify the terms of the debts so that a sound basis will exist for making a loan.

(G) Prepay costs for which FmHA grant funds were obligated provided there is:

(*1*) No conflict with the loan resolution, State statutes, or any other loan requirements; and

(*2*) Full documentation showing that:

(*i*) Loan funds will only be utilized on a temporary basis; and

(*ii*) All FmHA loan funds are restored at a later date for purpose(s) for which they were obligated.

(v) To pay obligations for construction incurred before loan approval. Construction work should not be started and obligations for such work or materials should not be incurred before the loan is approved. However, if there are compelling reasons for proceeding with construction before loan approval, applicants may request FmHA approval to pay such obligations. Such requests may be approved if FmHA determines that:

(A) Compelling reasons exist for incurring obligations before loan approval; and

(B) The obligations will be incurred for authorized loan purposes; and

(C) Contract documents have been approved by FmHA; and

(D) All environmental requirements applicable to FmHA and the applicant have been met; and

(E) The applicant has the legal authority to incur the obligations at the time proposed, and payment of the debts will remove any basis for any mechanic, material, or other liens that may attach to the security property. FmHA may authorize payment of such obligations at the time of loan closing. FmHA's authorization to pay such obligations, however, is on the condition that it is not committed to make the loan; it assumes no responsibility for any obligations incurred by the applicant; and the applicant must subsequently meet all loan approval requirements. The applicant's request and FmHA authorization for paying such obligations shall be in writing. If construction is started without FmHA approval, post approval in accordance with this section may be considered.

(2) Funds may not be used to finance:

(i) On-site utility systems or business and industrial buildings in connection with industrial parks.

(ii) Facilities to be used primarily for recreation purposes.

(iii) Community antenna television services or facilities.

(iv) Electric generation or transmission facilities or telephone systems, except as provided in paragraph (d)(1)(i)(B)(*5*), (d)(1)(i)(B)(*6*) or (d)(1)(i)(B)(*7*) of this section; or extensions to serve a particular essential community facility as provided in paragraph (d)(1)(ii) or (d)(1)(iii) of this section.

(v) Facilities which are not modest in size, design, and cost.

(vi) Loan or grant finder's fees.

(vii) Projects located within the Coastal Barriers Resource System that do not qualify for an exception as defined in Section 6 of the Coastal Barriers Resource Act, Pub. L. 97–348.

(viii) New combined sanitary and storm water sewer facilities.

(e) *Facilities for public use.* All facilities financed under the provisions of this subpart shall be for public use and primarily serve rural residents.

(1) Utility-type service facilities will be installed so as to serve any user within the service area who desires service and can be feasibly and legally served. Applicants and borrowers must obtain written concurrence of the FmHA prior to refusing service to such user. Upon failure to provide service which is reasonable and legal, such user shall have direct right of action against the applicant/borrower. A notice of the availability of this service should be given by the applicant/borrower to all persons living within the area who can feasibly and legally be served by the phase of the project being financed.

(i) If a mandatory hookup ordinance will be adopted, the required bond ordinance or resolution advertisement will be considered adequate notification.

(ii) When any portion of the income will be derived from user fees and a mandatory hookup ordinance will not be adopted, each potent user will be afforded an opportunity to request service by signing a Users Agreement. Those declining service will be afforded an opportunity to sign a statement to such effect. FmHA has guides available for these purposes in all FmHA offices.

(2) In no case will boundaries for the proposed service area be chosen in such a way that any user or area will be excluded because of race, color, religion, sex, marital status, age, or national origin.

(3) This does not preclude:

(i) Financing or constructing projects in phases when it is not practical to finance or construct the entire project at one time; and

(ii) Financing or constructing facilities where it is not economically feasible to serve the entire area provided economic feasibility is determined on the basis of the entire system and not by considering the cost of separate extensions to or parts thereof; the applicant publicly announces a plan for extending service to areas not initially receiving service from the system; and those families living in the areas not to be initially served receive written notice from the applicant that service will not be provided until such time as it is economically feasible to do so.

(iii) Extending services to industrial areas when service is made available to users located along the extensions.

(4) The State Director will determine that, when feasibly and legally possible, inequities within the proposed project's service area for the same type service proposed (i.e., water or waste disposal) will be remedied by the owner on or before completion of the project that includes FmHA funding. Inequities are defined as flagrant variations in availability, adequacy or quality of service. User rate schedules for portions of existing systems that were developed under different financing, rates, terms or conditions, as determined by the State Director, do not necessarily constitute inequities.

(5) Before a loan is made to an applicant other than a public body, for other than utility type projects, the articles of incorporation or loan agreement will include a condition similar to the following:

> In the event of dissolution of this corporation, or in the event it shall cease to carry out the objectives and purposes herein set forth, all business, property, and assets of the corporation shall go and be distributed to one or more nonprofit corporations or public bodies as may be selected by the board of directors of this corporation and approved by at least 75 percent of the users or members to be used for, and devoted to, the purpose of a community facility project or other purpose to serve the public welfare of the community. In no event shall any of the assets or property, in the event of dissolution thereof, go or be distributed to members, directors, stockholders, or others having financial or managerial interest in the corporation either for the reimbursement of any sum subscribed, donated or contributed by such members or for any other purposes, provided that nothing herein shall prohibit the corporation from paying its just debts.

(f) *Rates and terms*—(1) *General.* Each loan will bear interest at the rate prescribed in FmHA Instruction 440.1, Exhibit B (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 entered 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) *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 condition 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 household income of the service area is below the poverty line for a 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).

(3) *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 household income of the service area is not more than 85 percent of the nonmetropolitan median household income of the State.

(4) *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 paragraph (f)(2) or (f)(3) of this section. It may be adjusted as provided in paragraph (f)(5) of this section.

(5) *Prime farmland.* For essential community facilities loans, the rate indicated by paragraphs (f)(2), (f)(3) or (f)(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, Exhibits B and J (available in any FmHA office).

(6) *Income determination.* The income data used to determine median household income should be that which most accurately reflects the income of the service area. The service area is that area reasonably expected to be served by the facility being financed by FmHA. The median household income of the service area and the nonmetropolitan median household income of the State will be determined from income data from the most recent decennial census of the U.S. This data will normally be published or unpublished Bureau of the Census data and may be updated on a national basis by the FmHA based on data provided by the Bureau of the Census, or other reliable sources. If there is reason to believe that the census data is not an accurate representation of the median household 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 household 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 household income of the State may be updated on a national basis by the FmHA National Office based on data provided by the Bureau of the Census, or other reliable sources. Updating income data for the median household income of the service area and the nonmetropolitan median household income of the State should be done concurrently, using data from the same year.

(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. Where FmHA funds are used in connection with an FmHA loan, the loan will be for the maximum term permitted by this subpart, State statute, or the useful life of the facility, whichever is less, unless there is an exceptional case where circumstances justify making an FmHA loan for less than the maximum term permitted. In such cases, the reasons must be fully documented. 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 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.

(g) *Security.* Loans will be secured by the best security position practicable in a manner which will adequately protect the interest of FmHA during the repayment period of the loan. Specific requirements for security for each loan will be included in a letter of conditions.

(1) *Joint financing security.* For projects utilizing joint financing, when adequate security of more than one type is available, the other lender may take one type of security with FmHA taking another type. For projects utilizing joint financing with the same security to be shared by FmHA and another lender, FmHA will obtain at least a parity position with the other lender. A parity position is to ensure that with joint security, in the event of default, each lender will be affected on a proportionate basis. A parity position will conform with the following unless an exception is granted by the National Office:

(i) *Terms.* It is not necessary for loans to have the same repayment terms to meet the parity requirements. Loans made by other lenders involved in joint financing with FmHA for facilities should be scheduled for repayment on terms similar to those customarily used in the State for financing such facilities.

(ii) *Use of trustee or other similar paying agent.* The use of a trustee or other similar paying agent by the other lender in a joint financing arrangement is acceptable to FmHA. A trustee or other similar paying agent will not normally be used for the FmHA portion of the funding unless required to comply with State law. The responsibilities and authorities of any trustee or other similar paying agent on projects that include FmHA funds must be clearly specified by written agreement and approved by the FmHA State Director and Regional Attorney. FmHA must be able to deal directly with the borrower to enforce the provisions of loan and grant agreements and perform necessary servicing actions.

(iii) *Regular payments.* In the event adequate funds are not available to meet regular installments on parity loans, the funds available will be apportioned to the lenders based on the respective current installments of principal and interest due.

(iv) *Disposition of Property.* Funds obtained from the sale or liquidation of secured property or fixed assets will be apportioned to the lenders on the basis of the pro rata amount loaned, but not to exceed their respective outstanding balances; provided, however, funds obtained from such sale or liquidation for a project that included FmHA grant funds will be apportioned as may be required by the grant agreement.

(v) *Protective advances.* Protective advances are payments made by a lender for items such as insurance or taxes, to protect the financial interest of the lender, and charged to the borrower's loan account. To the extent consistent with State law and customary lending practices in the area, repayment of protective advances made by either lender, for the mutual protection of both lenders, should receive first priority in apportionment of funds between the lenders. To ensure agreement between lenders, efforts should be made to obtain the concurrence of both lenders before one lender makes a protective advance.

(2) *Public bodies.* Loans to such borrowers will be evidenced by notes, bonds, warrants, or other contractual obligations as may be authorized by relevant State statutes and by borrower's documents, resolutions, and ordinances.

(i) Utility-type facilities such as water and sewer systems, natural gas distribution systems, electric systems, etc., will be secured by:

(A) The full faith and credit of the borrower when the debt is evidenced by general obligation bonds; and/or

(B) Pledges of taxes or assessments; and/or

(C) Pledges of facility revenue and, when it is the customary financial practice in the State, liens will be taken on the interest of the applicant in all land, easements, rights-of-way, water rights, water purchase contracts, sewage treatment contracts, and similar property rights, including leasehold interest, used or to be used in connection with the facility whether owned at the time the loan is approved or acquired with loan funds; and/or

(D) In those cases involving water and waste disposal projects where there is a substantial number of other than full-time residents and facility costs result in a higher than reasonable rate for such full-time residents, the loan will be secured by the full faith and credit of the borrower or by an assignment or pledge of taxes, or assessments for public bodies or other organizations having the authority to issue or pledge such taxes, or assessments.

(ii) *Solid waste projects* will be secured by bonds pledging solid waste disposal revenue, only when the revenue pledged includes that from the solid waste project plus revenue from other facilities of the applicant with tie-in enforcement rights, or by the taxing power of participating local governments.

(iii) *Other essential community facilities* other than utility type, such as those for public health and safety, social, and cultural needs and the like will meet the following security requirements:

(A) Such loans will be secured by one or a combination of the following and in the following order of preference:

(*1*) General obligation bonds.

(*2*) Assessments.

(*3*) Bonds which pledge other taxes.

(*4*) Bonds pledging revenues of the facility being financed when such bonds provide for the mandatory levy and collection of taxes in the event revenues later become insufficient to properly operate and maintain the facility and to retire the loan.

(*5*) Assignment of assured income which will be available for the life of the loan, from such sources as insurance premium rebates, income from endowments, irrevocable trusts, or commitments from industries, public bodies, or other reliable sources.

(*6*) Liens on real and chattel property when legally permissible and an assignment of the borrowers income from applicants who have been in existence and are able to present evidence of a financially successful operation of a similar facility for a period of time sufficient to indicate project success. National Office concurrence is required when the applicant has been in existence for less than five years or has not operated on a financially successful basis for five years immediately prior to loan application.

(*7*) Liens on real and chattel property when legally permissible and an assignment of income from an organization receiving Health and Human Services (HHS) operating grants under the "Memorandum of Understanding Between Health Resources and Services Administration, U.S. Department of Health and Human Services and Farmers Home Administration, U.S. Department of Agriculture" (see FmHA Instruction 2000–T, available in any FmHA office.)

(*8*) Liens on real and chattel property when legally permissible and an assignment of income from an organization proposing a facility whose users receive reliable income from programs such as social security, supplemental security income (SSI), retirement plans, long-term insurance annuities, medicare or medicaid. Examples are homes for the handicapped or institutions whose clientele receive State or local government assistance.

(*9*) When the applicant cannot meet the criteria in paragraph (g)(2)(iii)(A) (*1*) through (*8*) of this section, such proposals may be considered when all the following are met:

(*i*) The applicant is a new organization or one that has not operated the type of facility being proposed.

(*ii*) There is a demonstration of exceptional community support such as substantial financial contributions, and aggressive leadership in the formation of the organization and proposed project which indicates a commitment of the entire community.

(*iii*) The State Director has determined that adequate and dependable revenues will be available to meet all operation expenses, debt repayment, and the required reserve.

(*iv*) Prior National Office review and concurrence is obtained.

(B) Real estate and chattel property taken as security in accordance with paragraphs (g)(2)(iii)(A) (*6*) through (*9*) of this section:

(*1*) Ordinarily will include the property that is used in connection with the facility being financed; and

(*2*) Will have an as-developed present market value determined by a qualified appraiser equal to or exceeding the amount of the loan to be obtained plus any other indebtedness against the proposed security; and

(*3*) May have one of the lien requirements deleted when the loan approval official determines that the loan will be adequately secured with a lien on either the real estate or chattel property.

(C) When security is not available in accordance with paragraphs (g)(2)(iii)(A) (*1*) through (*5*) of this section and State law precludes securing the loan with liens on real or chattel property, the loan will be secured in the best manner consistent with State law and customary security taken by private lenders in the State, such as revenue bonds, and any other security the loan approval official determines necessary for a sound loan. Such loans will otherwise meet the requirements of (g)(2)(iii)(A) (*6*) through (*9*) of this section as appropriate.

(3) *Other-than-public bodies.* Loans to other-than-public body applicants will be secured as follows:

(i) Utility-type facilities eligible for FmHA assistance under paragraph (d) of this section such as water and sewer systems, natural gas distribution systems, electric systems, etc., will be secured as follows:

(A) Assignments of borrower income will be taken and perfected by filing, if legally permissable; and

(B) A lien will be taken on the interest of the applicant in all land, easements, rights-of-way, water rights, water purchase contracts, sewage treatment contracts and similar property rights, including leasehold interest, used, or to be used in connection with the facility whether owned at the time the loan is approved or acquired with loan funds. In unusual circumstances where it is not feasible to obtain a lien on such land (such as land rights obtained from Federal or local government agencies, and from railroads) and the loan approval official determines that the interest of FmHA otherwise is secured adequately, the lien requirement may be omitted as to such land rights.

(C) When the loan is approved or the acquisition of real property is subject to

an outstanding lien indebtedness, the next highest priority lien obtainable will be taken if the loan approval official determines that the loan is adequately secured.

(D) Other security. Promissory notes from individuals, stock or membership subscription agreements, individuals member's liability agreements, or other evidences of debt, as well as mortgages or other security instruments encumbering the private property of members of the association may be pledged or assigned to FmHA as additional security in any case in which the interest of FmHA will not be otherwise adequately protected.

(E) In those cases where there is a substantial number of other than full time residents and facility costs result in a higher than reasonable rate for such full time residents, the loan will be secured by an assignment or pledge of general obligation bonds, taxes or assessments from public bodies or other organizations having authority to issue bonds backed by taxes or assessments.

(ii) *Solid waste projects* will be secured by a pledge of solid waste disposal revenue, only when the revenue pledged includes that from the solid waste project plus revenue from other facilities of the applicant with tie-in enforcement rights, or by the taxing power of participating local governments.

(iii) *Essential community facilities* other than utility type such as those for public health and safety, social, and cultural needs and the like will meet the following security requirements:

(A) Such loans will be secured by one or a combination of the following and in the following order of preference:

(*1*) An assignment of assured income that will be available for the life of the loan, from sources such as insurance premium rebates, income from endowments, irrevocable trusts, or commitments from industries, public bodies, or other reliable sources.

(*2*) Liens on real and chattel property with an assignment of income from applicants who have been in existence and are able to present evidence of a financially successful operation of a similar facility for a period of time sufficient to indicate project success. National Office concurrence is required when the applicant has been in existence for less than five years or has not operated on a financially successful basis for at least the five years immediately prior to loan application.

(*3*) Liens on real and chattel property and an assignment of income from an organization receiving HHS operating grants under the "Memorandum of Understanding Between Health Resources and Services Administration, U.S. Department of Health and Human Services and Farmers Home Administration, U.S. Department of Agriculture" (see FmHA Instruction 2000–T, available in any FmHA office).

(*4*) Liens on real and chattel property when legally permissible and an assignment of income from an organization proposing a facility whose users receive reliable income from programs such as social security, supplemental security income (SSI), retirement plans, long-term insurance annuities, medicare or medicaid. Examples are homes for the handicapped or institutions whose clientele receive State or local government assistance.

(*5*) When the applicant cannot meet the criteria in paragraphs (g)(3)(iii)(A) (*1*) through (*4*) of this section, such proposals may be considered when all the following are met:

(*i*) The applicant is a new organization or one that has not operated the type of facility being proposed.

(*ii*) There is a demonstration of exceptional community support such as substantial financial contributions, and aggressive leadership in the formation of the organization and proposed project which indicates a commitment of the entire community.

(*iii*) The State Director has determined that adequate and dependable revenues will be available to meet all operation expenses, debt repayment, and the required reserve.

(*iv*) Prior National Office review and concurrence is obtained.

(*6*) Additional security may be taken as determined necessary by the loan approval official.

(B) Real estate and chattel property taken as security:

(*1*) Ordinarily will include the property that is used in connection with the facility being financed; and

(*2*) Will have an as-developed present market value determined by a qualified appraiser equal to or exceeding the amount of the loan to be obtained plus any other indebtedness against the proposed security; and

(*3*) May have one of the lien requirements deleted when the loan approval official determines that the loan will be adequately secured with a lien on either the real estate or the chattel property.

(h) *Economic feasibility requirements.* All projects financed under the provisions of this section must be based on taxes, assessments, revenues, fees, or other satisfactory sources of revenues in an amount sufficient to provide for facility operation and maintenance, a reasonable reserve, and debt payment. An overall review of the applicant's financial status, including a review of all assets and liabilities, will be a part of the docket review process by the FmHA staff and approval official.

(1) *Financial feasibility reports.* All applicants will be expected to provide a financial feasibility report prepared by a qualified firm or individual. These financial feasibility reports will normally be:

(i) Included as part of the preliminary engineer/architectural report using Guides 6 through 10 as applicable; or

(ii) Prepared by a qualified firm or individual not having a direct interest in the management or construction of the facility using Guide 5 when:

(A) The project will significantly affect the applicant's financial operations and is not a utility-type facility but is dependent on revenues from the facility to repay the loan; or

(B) It is specifically requested by FmHA.

(2) *Applicants for loans for utility-type facilities* dependent on users fees for debt payment shall base their income and expense forecast on realistic user estimates in accordance with the following:

(i) In estimating the number of users and establishing rates or fees on which the loan will be based for new systems and for extensions or improvements to existing systems, consideration should be given to the following:

(A) An estimated number of maximum initial users should not be used when setting user fees and rates since it may be several years before all residents in the community will need the services provided by the system. In establishing rates a realistic number of initial users should be employed.

(B) User agreements from individual vacant property owners will not be considered when determining project feasibility unless:

(*1*) The owner has plans to develop the property in a reasonable period of time and become a user of the facility; and

(*2*) The owner agrees in writing to make a monthly payment at least equal to the proportionate share of debt service attributable to the vacant property until the property is developed and the facility is utilized on a regular basis. A bond or escrowed security deposit must be provided to guarantee this monthly payment and to guarantee an amount at least equal to the owner's proportionate share of construction costs. If a bond is provided, it must be executed by a surety company that appears on the Treasury Department's most current list (Circular 570, as

amended) and be authorized to transact business in the State where the project is located. The guarantee shall be payable jointly to the borrower and the Farmers Home Administration; and

(3) Such guarantee will mature not later than 4 years from the date of execution and will be finally due and payable upon default of a monthly payment or at maturity, unless the property covered by the guarantee has been developed and the facility is being utilized on a regular basis.

(C) Income from other vacant property owners will be considered only as extra income.

(ii) Realistic user estimates will be established as follows:

(A) Meaningful potential user cash contributions. Potential user cash contributions are required except:

(1) For users presently receiving service, or

(2) Where FmHA determines that the potential users as a whole in the applicant's service area cannot make cash contributions, or

(3) Where State statutes or local ordinances require mandatory use of the system and the applicant or legal entity having such authority agrees in writing to enforce such statutes, or ordinances.

(B) The amount of cash contributions required in paragraph (h)(2)(ii)(A) of this section will be set by the applicant and concurred in by FmHA. Contribtions should be an amount high enough to indicate sincere interest on the part of the potential user, but not so high as to preclude service to low income families. Contributions ordinarily should be an amount approximating one year's minimum user fee, and shall be paid in full before loan closing or commencement of construction, whichever occurs first. Once economic feasibility is ascertained based on a demonstration of meaningful potential user cash contributions, the contribution, membership fee or other fees that may be imposed are not a requirement of FmHA under this section. However, borrowers do have an additional responsibility relating to generating sufficient revenues as set forth in paragraph (n)(2)(iii) of this section.

(C) Enforceable user agreement. Except for users presently receiving service, an enforceable user agreement with a penalty clause is required unless State statutes or local ordinances require mandatory use of the system and the applicant or legal entity having such authority agrees in writing to enforce such statutes or ordinances.

(iii) In those cases where all or part of the borrower's debt payment revenues will come from user fees, applicants must provide a positive program to encourage connection by all users as soon as service is available. The program will be available for review and approval by FmHA before loan closing or commencement of construction, whichever occurs first. Such a program shall include:

(A) An aggressive information program to be carried out during the construction period. The borrower should send written notification to all signed users at least three weeks in advance of the date service will be available, stating the date users will be expected to have their connections completed, and the date user charges will begin.

(B) Positive steps to assure that installation services will be available. These may be provided by the contractor installing the system, local plumbing companies, or local contractors.

(C) Aggressive action to see that all signed users can finance their connections. This might require collection of sufficient user contributions to finance connections. Extreme cases might necessitate additional loan funds for this purpose; however, loan funds should be used only when absolutely necessary and when approved by FmHA prior to loan closing.

(3) *Utility-type facilities for new developing communities or areas.* Developers are normally expected to provide utility-type facilities in new or developing areas and such facilities shall be installed in compliance with appropriate State statutes and regulations. FmHA financing will be considered to an eligible applicant in such cases when failure to complete development would result in an adverse economic condition for the rural area (not the community being developed); the proposal is necessary to the success of an area development plan; and loan repayment can be assured by:

(i) The applicant already having sufficient assured revenues to repay the loan; or

(ii) Developers providing a bond or escrowed security deposit as a guarantee sufficient to meet expenses attributable to the area in question until a sufficient number of the building sites are occupied and connected to the facility to provide enough revenues to meet operating, maintenance, debt service, and reserve requirements. Such guarantees from developers will meet the requirements in paragraph (h)(2)(i)(B) of this section; or

(iii) Developers paying cash for the increased capital cost and any increased operating expenses until the developing area will support the increased costs; or

(iv) The full faith and credit of a public body where the debt is evidenced by general obligation bonds; or

(v) The loan is to a public body evidenced by a pledge of tax assessments; or

(vi) The user charges can become a tax lien upon the property being served and income from such lien can be collected in sufficient time to be used for its intended purposes.

(i) *Reserve requirements.* Provision for the accumulation of necessary reserves over a reasonable period of time will be included in the loan documents and in assessments, tax levies, or rates charged for services. In those cases where statutes providing for extinguishing assessment liens of public bodies when properties subject to such liens are sold for delinquent State or local taxes, special reserves will be established and maintained for the protection of the borrower's assessment lien.

(1) *General obligation or special assessment bonds.* Ordinarily, the requirements for reserves will be considered to have been met if general obligation or other bonds which pledge the full faith and credit of the political subdivision are used, or special assessment bonds are used, and if such bonds provide for the annual collection of sufficient taxes or assessments to cover debt service, operation and maintenance, and a reasonable amount for emergencies and to offset the possible nonpayment of taxes or assessments by a percentage of the property owners, or a statutory method is provided to prevent the incurrence of a deficiency.

(2) *Other than general obligation or special assessment bonds.* Each borrower will be required to establish and maintain reserves sufficient to assure that loan installments will be paid on time, for emergency maintenance, for extensions to facilities, and for replacement of short-lived assets which have a useful life significantly less than the repayment period of the loan. It is expected that borrowers issuing bonds or other evidences of debt pledging facility revenues as security will ordinarily plan their reserve to provide for a total reserve in an amount at least equal to one average loan installment. It is also expected the ordinarily such reserve will be accumulated at the rate of at least one-tenth of the total each year until the desired level is reached.

(j) *General requirements*—(1) *Membership authorization.* For

organizations other than public bodies, the membership will authorize the project and its financing except that the State Director may, with the concurrence of OGC, accept the loan resolution without such membership authorization when State statutes and the organization's charter and bylaws do not require such authorization; and

(i) The organization is well established and is operating with a sound financial base; or

(ii) For utility-type projects the members of the organization have all signed an enforceable user agreement with a penalty clause and have made the required meaningful user cash contribution, except for members presently receiving service or when State statutes or local ordinances require mandatory use of the facility.

(2) *Planning, bidding, contracting, constructing.* (See § 1942.18).

(3) *Insurance and bonding.* Needed insurance coverage and fidelity bonds will be obtained by the time of loan closing or start of construction, whichever occurs first. Ordinarily, FmHA should be listed as mortgagee on the property insurance when FmHA has a lien on the property. Insurance policies are not required to be filed in the case file. However, the borrower must continue to maintain insurance in adequate amounts to protect the Government's interest for the life of the loan. Normally, after the first year of operation, a listing of insurance in annual audits or management reports will be considered as sufficient evidence of insurance maintenance. A copy of the fidelity bond(s) should be filed in the borrower's case file. Insurance requirements will not normally be over and above those proposed by the borrower provided coverage is found to be adequate, and in accordance with the following:

(i) *Property insurance.* Fire and extended coverage may be required on all aboveground structures, including borrower-owned equipment and machinery housed therein, usually in the amount of their replacement value. This does not apply to water reservoirs, standpipes, elevated tanks, and other noncombustible materials used in treatment plants, clearwells, clarification units, filters, and the like. Property insurance on subsurface lift stations is not required except for the value of the pumping equipment and electrical equipment therein.

(ii) *Flood insurance.* Facilities located in special flood and mudslide prone areas must comply with the eligibility and insurance requirements of Subpart B of Part 1806 of this chapter (FmHA Instruction 426.2).

(iii) *Worker's compensation.* The borrower will carry worker's compensation insurance for all of its employees in accordance with applicable State laws.

(iv) *Liability and property damage insurance.* Requirements for liability insurance will be carefully and thoroughly considered in connection with each project financed. Public liability and property damage insurance amounts will be established accordingly. It the borrower owns trucks, tractors, or other vehicles that are driven over public highways, public liability and property damage insurance will be required.

(v) *Malpractice insurance.* The need and requirements for malpractice insurance will be carefully and thoroughly considered in connection with each health care facility financed. The applicant will maintain such insurance as determined necessary by the governing body, with the advice of the applicant's attorney and concurrence of FmHA.

(vi) *Fidelity bonds.* The borrower will provide fidelity bond coverage for the positions of persons entrusted with the receipt and disbursement of its funds and the custody of valuable property. The amount of the bond will be at least equal to the maximum amount of money that the borrower will have on hand at any one time, exclusive of loan funds deposited in a supervised bank account. Unless prohibited by State law, the United States, acting through the Farmers Home Administration, will be named as co-obligee in the bond. Corporate fidelity bonds will be obtained except that in unusual circumstances FmHA may give prior approval to cash bonds. Form FmHA 440–24, "Position Fidelity Schedule Bond," may be used. A certified power-of-attorney with effective date will be attached to each bond.

(4) *Acquisition of land, easements, water rights, and existing facilities.* Applicants are responsible for acquisition of all property rights necessary for the project and will determine that prices paid are reasonable and fair. FmHA may require an appraisal by an independent appraiser or FmHA employee.

(i) *Title for land, rights-of-way, easements, or existing facilities.* The applicant must certify and provide a legal opinion relative to the title to rights-of-way and easements. Form FmHA 442–21, "Rights-of-Way Certificate," and Form FmHA 442–22, "Opinion of Counsel Relative to Rights-of-Way," may be used.

(A) *Rights-of-way and easements.* Applicants are responsible for and will obtain valid, continuous and adequate rights-of-way and easements needed for the construction, operation, and maintenance of the facility. Form FmHA 442–20, "Right-of-Way Easement," may be used. When a site is for major structures for utility-type facilities such as a reservoir or pumping station and the applicant is able to obtain only a right-of-way or easement on such a site rather than a fee simple title, the applicant will furnish a title report thereon by the applicant's attorney showing ownership of the land and all mortgages or other lien defects, restrictions, or encumbrances, if any. It is the responsibility of the applicant to obtain and record such releases, consents or subordinations to such property rights from holders of outstanding liens or other instruments as may be necessary for the construction, operation, and maintenance of the facility and give FmHA the required security.

(B) *Title for land or existing facilities.* Title to land essential to the successful operation of facilities or title to facilities being purchased, must not contain any restrictions that will adversely affect the suitability, successful operation, security value, or transferability of the facility. Title opinions must be provided by the applicant's attorney. The opinions must be in sufficient detail to assess marketability of the property. Form FmHA 427–9, "Preliminary Title Opinion," and Form FmHA 427–10, "Final Title Opinion," may be used to provide the required title opinions. If other forms are used they must be reviewed and approved by FmHA and OGC.

(*1*) In lieu of receiving title opinions from the applicant's attorney, the applicant may use a title insurance company. If a title insurance company is used, the company must provide FmHA a title insurance binder, disclosing all title defects or restrictions, and include a commitment to issue a title insurance policy. The policy should be in an amount at least equal to the market value of the property as improved. The title insurance binder and commitment should be provided to FmHA prior to requesting closing instructions. FmHA will be provided a title insurance policy which will insure FmHA's interest in the property without any title defects or restrictions which have not been waived by FmHA.

(*2*) The loan approval official may waive title defects or restrictions, such as utility easements, that do not adversely affect the suitability, successful operation, security value, or transferability of the facility. If the

District Director is the loan approval official and is unable to waive the defect or restriction, the title opinion or title insurance binder will be forwarded to the State Director. If the State Director, with the advice of the OGC, determines that the defect or restriction cannot be waived, the defect or restriction must be removed.

(ii) *Water rights.* When legally permissible, an assignment will be taken on water rights owned or to be acquired by the applicant. The following will be furnished as applicable:

(A) A statement by the applicant's attorney regarding the nature of the water rights owned or to be acquired by the applicant (such as conveyance of title, appropriation and decree, application and permit, public notice and appropriation and use).

(B) A copy of a contract with another company or municipality to supply water; or stock certificates in another company which represents the right to receive water.

(iii) *Land purchase contract:* (A) A land purchase contract (known in some areas as a contract for deed) is an agreement between two or more parties which obligates the purchaser to pay the purchase price, gives the purchaser the rights of immediate possession, control, and beneficial use of the property, and entitles the purchaser to a deed upon paying all or a specified part of the purchase price.

(B) Applicants may obtain land through land purchase contracts when all of the following conditions are met:

(*1*) The applicant has exhausted all reasonable means of obtaining outright fee simple title to the necessary land.

(*2*) The applicant cannot obtain the land through condemnation.

(*3*) There are not other suitable sites available.

(*4*) National Office concurrence is obtained in accordance with paragraph (j)(4)(iii)(D)(*2*) of this section.

(C) The land purchase contract must provide for the transfer of ownership by the seller without any restrictions, liens or other title defects. The contract must not contain provisions for future advances (except for taxes, insurance, or other costs needed to protect the security), summary cancellations, summary forfeiture, or other clauses that may jeopardize the Government's interest or the purchaser's ability to pay the FmHA loan. The contract must provide that if the purchaser fails to make payment that FmHA will be given at least 90 days written notice with an option to cure the default before the contract can be cancelled, terminated or foreclosed. Then FmHA must have the option of making the payment and charging it to the purchaser's account, making the payment and taking over the ownership of the purchase contract, or taking any other action necessary to protect the Government's interest.

(D) Prior to loan closing or the beginning of construction, whichever occurs first, the following actions must be taken in the order listed below:

(*1*) The land purchase contract and any appropriate title opinions must be reviewed by the Regional Attorney to determine if they are legally sufficient to protect the interest of the Government.

(*2*) The land purchase contract, the Regional Attorney's comments, and the State Director's recommendations must be submitted to the National Office for concurrence.

(*3*) The land purchase contract must be recorded.

(5) *Lease agreements.* Where the right of use or control of real property not owned by the applicant/borrower is essential to the successful operation of the facility during the life of the loan, such right will be evidenced by written agreements or contracts between the owner(s) of the property and the applicant/borrower. Lease agreements shall not contain provisions for restricted use of the site of facility, forfeiture or summary cancellation clauses and shall provide for the right to transfer and lease without restriction. Lease agreements will ordinarily be written for a term at least equal to the term of the loan. Such lease contracts or agreements will be approved by the FmHA loan approval official with the advice and counsel of the Regional Attorney, OGC, as to the legal sufficiency of such documents. A copy of the lease contract or agreement will be included in the loan docket.

(6) *Notes and bonds.* Notes and bonds will be completed on the date of loan closing except for the entry of subsequent multiple advances where applicable. The amount of each note will be in multiples of not less than $100. The amount of each bond will ordinarily be in multiples of not less than $1,000.

(i) Form FmHA 440–22, "Promissory Note (Association or Organization)," will ordinarily be used for loans to nonpublic bodies.

(ii) § 1942.19 contains instructions for preparation of notes and bonds evidencing indebtedness of public bodies.

(7) *Environmental requirements.* Environmental requirements will be documented by FmHA in accordance with Subpart G Part 1940 of this chapter. The applicant will provide any information required.

(8) *Health care facilities.* The applicant will be responsible for obtaining the following documents:

(i) A statement from the responsible State agency certifying that the proposed health care facility is not inconsistent with the State Medical Facilities Plan.

(ii) A statement from the responsible State agency or regional office of the Department of Health and Services certifying that the proposed facility meets the standards in § 1942.18(d)(4).

(9) *Public information.* Applicants should inform the general public regarding the development of any proposed project. Any applicant not required to obtain authorization by vote of its membership or by public referendum, to incur the obligations of the proposed loan or grant, will hold at least one public information meeting. The public meeting must be held after the preapplication is filed and not later than loan approval. The meeting must give the citizenry an opportunity to become acquainted with the proposed project and to comment on such items as economic and environmental impacts, service area, alternatives to the project, or any other issue identified by FmHA. The applicant will be required, at least 10 days prior to the meeting, to publish a notice of the meeting in a newspaper of general circulation in the service area, to post a public notice at the applicant's principal office, and to notify FmHA. The applicant will provide FmHA a copy of the published notice and minutes of the public meeting. A public meeting is not normally required for subsequent loans which are needed to complete the financing of the project.

(10) *Service through individual installation.* Community owned water or waste disposal systems may provide service through individual installations or small clusters of users within the applicant's service area. When individual installations or small clusters are proposed, the loan approval official should consider items such as: quantity and quality of the individual installations that may be developed; cost effectiveness of the individual facility compared with the initial and long term user cost on a central system; health and pollution problems attributable to individual facilities; operational or management problems peculiar to individual installations; and permit and regulatory agency requirements.

(i) Applicants providing service through individual facilities must meet the eligibility requirements in § 1942.17(b).

(ii) FmHA must approve the form of agreement between the owner and individual users for the installation, operation and payment for individual facilities.

(iii) If taxes or assessments are not pledged as security, owners providing service through individual facilities must obtain security as necessary to assure collection of any sum the individual user is obligated to pay the owner.

(iv) Notes representing indebtedness owed the owner by a user for an individual facility will be scheduled for payment over a period not to exceed the useful life of the individual facility or the loan, whichever is shorter. The interest rate will not exceed the interest rate charged the owner on the FmHA indebtedness.

(v) Owners providing service through individual or cluster facilities must obtain:

(A) Easements for the installation and ingress to and egress from the facility; and

(B) An adequate method for denying service in the event of nonpayment of user fees.

(11) *Funds from other sources.* FmHA loan funds may be used along with or in connection with funds provided by the applicant or from other sources. Since "matching funds" is not a requirement for FmHA loans, shared revenues may be used with FmHA funds for project construction.

(k) *Other Federal, State, and local requirements.* Each application shall contain the comments, necessary certifications and recommendations of appropriate regulatory or other agency or institution having expertise in the planning, operation, and management of similar facilities. Proposals for facilities financed in whole or in part with FmHA funds will be coordinated with appropriate Federal, State, and local agencies in accordance with the following:

(1) *Compliance with special laws and regulations.* Applicants will be required to comply with Federal, State, and local laws and any regulatory commission rules and regulations pertaining to:

(i) Organization of the applicant and its authority to construct, operate, and maintain the proposed facilities;

(ii) Borrowing money, giving security therefore, and raising revenues for the repayment thereof;

(iii) Land use zoning; and

(iv) Health and sanitation standards and design and installation standards unless an exception is granted by FmHA.

(2) *State Pollution Control or Environmental Protection Agency Standards.* Water and waste disposal facilities will be designed, installed, and operated in such a manner that they will not result in the pollution of water in the State in excess of established standards and that any effluent will conform with appropriate State and Federal Water Pollution Control Standards. A certification from the appropriate State and Federal agencies for water pollution control standards will be obtained showing that established standards are met.

(3) *Consistency with other development plans.* FmHA financed facilities will not be inconsistent with any development plans of State, multijurisdictional areas, counties, or municipalities in which the proposed project is located.

(4) *State agency regulating water rights.* Each FmHA financed facility will be in compliance with appropriate State agency regulations which have control of the appropriation, diversion, storage and use of water and disposal of excess water. All of the rights of any landowners, appropriators, or users of water from any source will be fully honored in all respects as they may be affected by facilities to be installed.

(5) *Civil Rights Act of 1964.* All borrowers are subject to, and facilities must be operated in accordance with, Title VI of the Civil Rights Act of 1964 and Subpart E of Part 1901 of this chapter, particularly as it relates to conducting and reporting of compliance reviews. Instruments of conveyance for loans and/or grants subject to the Act must contain the covenant required by § 1901.202(e) of Subpart E of Part 1901 of this chapter.

(6) *Title IX of the Education Amendments of 1972.* No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or education activity receiving FmHA financial assistance except as otherwise provided for in the Education Amendments of Title IX. The FmHA State Director will provide guidance and technical assistance to carry out the intent of this paragraph.

(7) *Section 504 of the Rehabilitation Act of 1973.* Under section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), no handicapped individual in the United States shall, solely by reason of their handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving FmHA financial assistance.

(8) *Age Discrimination Act of 1975.* This Act provides that no person in the United States shall on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. This Act also applies to programs or activities funded under the State and Local Fiscal Assistance Act of 1972 (31 U.S.C. 1221 et. seq.). This Act does not apply to: (i) age distinctions contained in Federal, State or local statutes or ordinances adopted by an elected, general purpose legislative body which provide benefits or assistance based on age; (ii) establish criteria for participation in age-related terms; (iii) describe intended beneficiaries or target groups in age-related terms; and, (iv) any employment practice of any employer, employment agency, labor organization, or any labor-management joint apprenticeship training program except for any program or activity receiving Federal financial assistance for public service employment under the Comprehensive Employment and Training Act of 1974 (CETA) (29 U.S.C. 801 et. seq.).

(l) *Professional services and contracts related to the facility*—(1) *Professional services.* Applicants will be responsible for providing the services necessary to plan projects including design of facilities, preparation of cost and income estimates, development of proposals for organization and financing, and overall operation and maintenance of the facility. Professional services of the following may be necessary: engineer, architect, attorney, bond counsel, accountant, auditor, appraiser, and financial advisory or fiscal agent (if desired by applicant). Contracts or other forms of agreement between the applicant and its professional and technical representatives are required and are subject to FmHA concurrence. Form FmHA 1942-19, "Agreement for Engineering Services," may be used when appropriate. Guide 20, "Agreement for Engineering Services (FmHA/EPA—Jointly Funded Projects)" may be used on projects jointly funded by FmHA and EPA. Guide 14 may be used in the preparation of the legal services agreement.

(2) *Bond counsel.* Unless otherwise provided by § 1942.19(b), public bodies are required to obtain the service of recognized bond counsel in the preparation of evidence of indebtedness.

(3) *Contracts for other services.* Contracts or other forms of agreements for other services including management, operation, and maintenance will be developed by the applicant and presented to FmHA for review and approval. Management

agreements should provide at least those items in Guide 24.

(4) *Fees.* Fees provided for in contracts or agreements shall be reasonable. They shall be considered to be reasonable if not in excess of those ordinarily charged by the profession for similar work when FmHA financing is not involved.

(m) *Applying for FmHA loans*—(1) *Preapplication.* Applicants desiring loans will file Form AD–621, "Preapplication for Federal Assistance," and comments from the appropriate A–95 clearinghouse agency normally with the appropriate FmHA County office. The County Supervisor will immediately forward all documents to the District Office. The District Director has prime responsibility for all community program loan making and servicing activities within the District.

(2) *Preapplication review.* Upon receipt of the preapplication, FmHA will tentatively determine eligibility including the likelihood of credit elsewhere at reasonable rates and terms and availability of FmHA loan funds. The determination as to availability of other credit will be made after considering present rates and terms available for similar proposals (not necessarily based upon rates and terms available from FmHA); the repayment potential of the applicant; long-term cost to the applicant; and average user or other charges. In those cases where FmHA determines that loans at reasonable rates and terms should be available from commercial sources, FmHA will notify the applicant so that it may apply for such financial assistance. Such applicants may be reconsidered for FmHA loans upon their presenting satisfactory evidence of inability to obtain commercial financing at reasonable rates and terms.

(3) *Incurring obligations.* Applicants should not proceed with planning nor obligate themselves for expenditures until authorized by FmHA.

(4) *Results of preapplication review.* After FmHA has reviewed the preapplication material and any additional material that may be requested, Form AD–622 will be sent to the applicant. Ordinarily the review will not exceed 45 days.

(5) *Application conference.* Before starting to assemble the application and after the applicant selects its professional and technical representatives, it should arrange with FmHA for an application conference to provide a basis for orderly application assembly. FmHA will provide applicants with a list of documents necessary to complete the application. Guide 15 may be used for this purpose. Applications will be filed with the District Office.

(6) *Application completion and assembling.* This is the responsibility of the applicant with guidance from FmHA. The applicant may utilize their professional and technical representatives or other competent sources.

(7) *Review of decision.* If an application is rejected, the applicant may request a review of this decision under Subpart B of Part 1900 of this chapter.

(n) *Actions prior to loan closing and start of construction*—(1) *Excess FmHA loan and grant funds.* If there is a significant reduction in project cost, the applicant's funding needs will be reassessed before loan closing or the start of construction, whichever occurs first. In such cases applicable FmHA forms, the letter of conditions, and other items will be revised. Decreases in FmHA funds will be based on revised project costs and current number of users, however, other factors including FmHA regulations used at the time of loan/grant approval will remain the same. Obligated loan or grant funds not needed to complete the proposed project will be deobligated.

(2) *Loan resolutions.* Loan resolutions will be adopted by both public and other-than-public bodies using Form FmHA 1942–47, "Loan Resolution (Public Bodies)," or Form FmHA 1942–9, "Loan Resolution (Security Agreement)." These resolutions supplement other provisions in this subpart. The applicant will agree:

(i) To indemnify the Government for any payments made or losses suffered by the Government on behalf of the association. Such indemnification shall be payable from the same source of funds pledged to pay the bonds or any other legally permissible source.

(ii) To comply with applicable local, State and Federal laws, regulations, and ordinances.

(iii) To provide for the receipt of adequate revenues to meet the requirements of debt service, operation and maintenance, establishment of adequate reserves, and to continually operate and maintain the facility in good condition. Except for utility-type facilities, free service use may be permitted. If free services are extended no distinctions will be made in the extension of those services because of race, color, religion, sex, national origin, marital status, or physical or mental handicap.

(iv) To acquire and maintain such insurance coverage including fidelity bonds, as may be required by the Government.

(v) To establish and maintain such books and records relating to the operation of the facility and its financial affairs and to provide for required audit thereof in such a manner as may be required by the Government and to provide the Government without its request, a copy of each such audit and to make and forward to the Government such additional information and reports as it may, from time to time, require.

(vi) To provide the Government at all reasonable times, access to all books and records relating to the facility and access to the property of the system so that the Government may ascertain that the association is complying with the provisions hereof and of the instruments incident to the making or insuring of the loan.

(vii) To provide adequate service to all persons within the service area who can feasibly and legally be served and to obtain FmHA's concurrence prior to refusing new or adequate services to such persons. Upon failure of the applicant to provide services which are feasible and legal, such person shall have a direct right of action against the applicant organization.

(viii) To have prepared on its behalf and to adopt an ordinance or resolution for the issuance of its bonds or notes or other debt instruments or other such items and in such forms as are required by State statutes and as are agreeable and acceptable to the Government.

(ix) To refinance the unpaid balance, in whole or in part, of its debt upon the request of the Government if at any time it should appear to the Government that the association is able to refinance its bonds by obtaining a loan for such purposes from responsible cooperative or private sources at reasonable rates and terms.

(x) To provide for, execute, and comply with Form FmHA 400–4, "Assurance Agreement," and Form FmHA 400–1, "Equal Opportunity Agreement," including an "Equal Opportunity Clause," which is to be incorporated in or attached as a rider to each construction contract and subcontract in excess of $10,000.

(xi) To place the proceeds of the loan on deposit in a manner approved by the Government. Funds may be deposited in institutions insured by the State or Federal Government as invested in readily marketable securities backed by the full faith and credit of the United States. Any income from these accounts will be considered as revenues of the system.

(xii) Not to sell, transfer, lease, or otherwise encumber the facility or any portion thereof or interest therein, and

not to permit others to do so, without the prior written consent of the Government.

(xiii) Not to borrow any money from any source, enter into any contract or agreement, or incur any other liabilities in connection with making enlargements, improvements or extensions to, or for any other purpose in connection with the facility (exclusive of normal maintenance) without the prior written consent of the Government if such undertaking would involve the source of funds pledged to repay the debt to FmHA.

(xiv) That upon default in the payments of any principal and accrued interest on the bonds or in the performance of any covenant or agreement contained herein or in the instruments incident to making or insuring the loan, the Government, at its option, may:

(A) Declare the entire principal amount then outstanding and accrued interest, due and payable;

(B) For the account of the association (payable from the source of funds pledged to pay the bonds or notes or any other legally permissiable source), incur and pay reasonable expenses for repair, maintenance and operation of the facility and such other reasonable expenses as may be necessary to cure the cause of default; and/or

(C) Take possession of the facility, repair, maintain and operate, or otherwise dispose of the facility. Default under the provisions of the resolution or any instrument incident to the making or insuring of the loan may be construed by the Government to constitute default under any other instrument held by the Government and executed or assumed by the association and default under any such instrument may be construed by the Government to constitute default hereunder.

(3) *Interim financing.* In all loans exceeding $50,000, where funds can be borrowed at reasonable interest rates on an interim basis from commercial sources for the construction period, such interim financing will be obtained so as to preclude the necessity for multiple advances of FmHA funds. Guide 1 or Guide 1a, as appropriate, may be used to inform the private lender of FmHA's commitment. When interim commercial financing is used, the application will be processed, including obtaining construction bids, to the stage where the FmHA loan would normally be closed, that is immediately prior to the start of construction. The FmHA loan should be closed as soon as possible after the disbursal of all interim funds. Interim financing may be for a fixed term provided the fixed term does not extend beyond the time projected for completion of construction. For this purpose, a fixed term is when the interim lender cannot be repaid prior to the end of the stipulated term of the interim instruments. When an FmHA Water and Waste Disposal grant is included, any interim financing involving a fixed term must be for the total FmHA loan amount. Multiple advances may be used in conjunction with interim commercial financing when the applicant is unable to obtain sufficient funds through interim commercial financing in an amount equal to the loan. The FmHA loan proceeds (including advances) will be used to retire the interim commercial indebtedness. Before the FmHA loan is closed, the applicant will be required to provide FmHA with statements from the contractor, engineer, architect, and attorney that they have been paid to date in accordance with their contracts or other agreements and, in the case of the contractor, that any suppliers and subcontractors have been paid. If such statements cannot be obtained, the loan may be closed provided:

(i) Statements to the extent possible are obtained;

(ii) The interest of FmHA can be adequately protected and its security position is not impaired; and

(iii) Adequate provisions are made for handling the unpaid accounts by withholding or escrowing sufficient funds to pay such claims.

(4) *Obtaining closing instructions.* After loan approval, the completed docket will be reviewed by the State Director. The information required by OGC will be transmitted to OGC with request for closing instructions. Upon receipt of the closing instructions from OGC, the State Director will forward them along with any appropriate instructions to the District Director. Upon receipt of closing instructions, the District Director will discuss with the applicant and its architect or engineer, attorney, and other appropriate representatives, the requirements contained therein and any actions necessary to proceed with closing.

(5) *Applicant contribution.* An applicant contributing funds toward the project cost shall deposit these funds in its construction account on or before loan closing or start of construction, whichever occurs first. Project costs paid prior to the required deposit time with applicant funds shall be appropriately accounted for.

(6) *Evidence of and disbursement of other funds.* Applicants expecting funds from other sources for use in completing projects being partially financed with FmHA funds will present evidence of the commitment of these funds from such other sources. This evidence will be available before loan closing, or the start of construction, whichever occurs first. Ordinarily, the funds provided by the applicant or from other sources will be disbursed prior to the use of FmHA loan funds. If this is not possible, funds will be disbursed on a pro rata basis. FmHA funds will not be used to pre-finance funds committed to the project from other sources.

(o) *Loan closing*—(1) *Closing instructions.* Loans will be closed in accordance with the closing instructions issued by OGC.

(2) *Obtaining insurance and fidelity bonds.* Required property insurance policies, liability insurance policies, and fidelity bonds will be obtained by the time of loan closing or start of construction, whichever occurs first.

(3) *Distribution of recorded documents.* The originals of the recorded deeds, easements, permits, certificates of water rights, leases, or other contracts and similar documents which are not to be held by FmHA will be returned to the borrower. The original mortgage(s) and water stock certificates, if any, if not required by the recorder's office will be retained by FmHA.

(4) *Review of loan closing.* In order to determine that the loan has been properly closed the loan docket will be reviewed by the State Director and OGC.

(p) *Project monitoring and fund delivery during construction*—(1) *Coordination of funding sources.* When a project is jointly financed, the State Director will reach any needed agreement or understanding with the representatives of the other source of funds on distribution of responsibilities for handling various aspects of the project. These responsibilities will include supervision of construction, inspections and determinations of compliance with appropriate regulations concerning equal employment opportunities, wage rates, nondiscrimination in making services or benefits available, and environmental compliance. If any problems develop which cannot be resolved locally, complete information should be sent to the National Office for advice.

(2) *Multiple advances.* In the event interim commercial financing is not legally permissible or not available, multiple advances of FmHA loan funds are required. An exception to this requirement may be granted by the National Office when a single advance is necessitated by State law or public exigency. Multiple advances will be used only for loans in excess of $50,000.

Advances will be made only as needed to cover disbursements required by the borrower over a 30-day period. Advances should not exceed 24 in number nor extend longer than two years beyond loan closing. Normally, the retained percentage withheld from the contractor to assure construction completion will be included in the last advance.

(i) § 1942.19 contains instructions for making multiple advances to public bodies.

(ii) Advances will be requested by the borrower in writing. The request should be in sufficient amounts to pay cost of construction, rights-of-way and land, legal, engineering, interest, and other expenses as needed. The applicant may use Form FmHA 440–11, "Estimate of Funds Needed for 30 Day Period Commencing _____," to show the amount of funds needed during the 30-day period.

(iii) FmHA loan funds obligated for a specific purpose, such as the paying of interest, but not needed at the time of loan closing will remain in the Finance Office until needed unless State statutes require all funds to be delivered to the borrower at the time of closing. Loan funds may be advanced to prepay costs under paragraph (d)(1)(iv)(G) of this section. If all funds must be delivered to the borrower at the time of closing to comply with State statutes, funds not needed at loan closing will be handled as follows:

(A) Deposited in an appropriate borrower account, such as the debt service account, or

(B) Deposited in a supervised bank account under paragraph (p)(3)(i) of this section.

(3) *Use and accountability of funds.*—(i) *Supervised bank account.* Loan funds and any funds furnished by the applicant/borrower to supplement the loan including contributions to purchase major items of equipment, machinery, and furnishings may be deposited in a supervised bank account if determined necessary as provided in Subpart A of Part 1902 of this chapter.

(ii) *Other than supervised bank account.* If a supervised bank account is not used, arrangements will be agreed upon for the prior concurrence by FmHA of the bills or vouchers upon which warrants will be drawn, so that the payments from loan funds can be controlled and FmHA records kept current. If a supervised bank account is not used, use Form FmHA 402–2, "Statement of Deposits and Withdrawals," or similar form to monitor funds. Periodic reviews of nonsupervised accounts shall be made by FmHA at the times and in the manner as FmHA prescribes in the conditions of loan approval. State laws regulating the depositories to be used shall be complied with.

(iii) *Use of minority owned banks.* Applicants are encouraged to use minority banks (a bank which is owned at least 50 percent by minority group members) for the deposit and disbursement of funds. A list of minority owned banks can be obtained from the Office of Minority Business Enterprise, Department of Commerce, Washington, D.C. 20230 and is also available in all FmHA offices.

(4) *Development inspections.* The District Director will be responsible for monitoring the construction of all projects being financed, wholly or in part, with FmHA funds. Technical assistance will be provided by the State Director's staff. Project monitoring will include construction inspections and a review of each project inspection report, each change order and each partial payment estimate and other invoices such as payment for engineering/architectural and legal fees and other materials determined necessary to effectively monitor each project. These activities will not be performed on behalf of the applicant/borrower, but are solely for the benefit of FmHA and in no way are intended to relieve the applicant/borrower of corresponding obligations to conduct similar monitoring and inspection activities. Project monitoring will include periodic inspections to review partial payment estimates prior to their approval and to review project development in accordance with plans and specifications. Each inspection will be recorded using Form FmHA 424–12, "Inspection Report." The original Form FmHA 424–12 will be filed in the project case folder and a copy furnished to the State Director. The State Director will review inspection reports and will determine that the project is being effectively monitored. In all cases where the governing body has entered into an agreement for technical services with an engineer/architect or if such services are being made available by another Federal or State agency, the District Director is authorized to review partial payment estimates prepared by the project engineer/architect and accept them for payments after approval by the borrower. Each such payment estimate will contain a certification by the project engineer or architect that all material purchased and all work performed is in accordance with the plans and specifications. When there is no project engineer or architect, the District Director may review and accept estimates for payments which have been approved by the borrower after determining that funds are requested for authorized purposes. If there is any indication that construction is not being completed in accordance with the plans and specifications or that any other problems exist, the District Director should notify the State Director immediately and withhold all payments on the contract.

(5) *Payment for construction.* Each payment for project costs must be approved by the borrower's governing body. Payment for construction must be for amounts shown on payment estimate forms. Form FmHA 424–18, "Partial Payment Estimate," may be used for this purpose or other similar forms may be used with the prior approval of the State Director or designee. However, the State Director or designee cannot require a greater reporting burden than is required by Form FmHA 424–18. Advances for contract retainage will not be made until such retainage is due and payable under the terms of the contract. The review and acceptance of project costs, including construction partial payment estimates by FmHA, does not attest to the correctness of the amounts, the quantities shown, or that the work has been performed under the terms of agreements or contracts.

(6) *Use of remaining funds.* Funds remaining after all costs incident to the basic project have been paid or provided for will not include applicant contributions. Applicant contributions will be considered as funds initially expended for the project. Funds remaining, with exception of applicant contributions, may be considered in direct proportion to the amount obtained from each source. Remaining funds will be handled as follows:

(i) *FmHA loan and/or grant funds.* Remaining funds may be used for purposes authorized by paragraph (d) of this section and § 1942.354 of Subpart H of Part 1942 of this chapter, provided the use will not result in major changes to the facility design or project and that the purpose of the loan and/or grant remains the same.

(a) On projects that only involve an FmHA loan and no FmHA grant, funds that are not needed will be applied as an extra payment on the FmHA indebtedness unless other disposition is required by the bond ordinance, resolution, or State statute.

(B) On projects that involve an FmHA grant, all remaining FmHA funds will be considered to be grant funds up to the full amount of the grant. Grant funds not expended under paragraph (p)(6)(i) of this section will be deobligated.

(ii) *Funds from other sources.* Funds remaining from other sources will be handled according to rules, regulations and/or the agreement governing their participation in the project.

(q) *Borrower accounting methods, management reporting and audits*—(1) *Accounting methods and records.*—(i) *Method of accounting and financial statements.* Financial statements must be prepared on the accrual basis of accounting unless State statutes or regulatory agencies provide otherwise, or an exception is made by FmHA. This requirement is for accrual basis financial statements and not for accrual basis accounting systems. Organizations may keep their books on an accounting basis other than accrual and then make adjustments so that the financial statements are presented on the accrual basis.

(ii) *Approval requirement.* Before loan closing or start of construction, whichever is first, each borrower shall provide to, and obtain approval from the FmHA loan approval official for its accounting and financial reporting system, including the agreement with its auditor, if an auditor is required.

(iii) *Records.* Form FmHA 1930–5, "Bookkeeping System—Small Borrower," may be used by small organizations as a method of recording and maintaining accounting transactions.

(iv) *Record retention.* Each borrower shall retain all records, books, and supporting material for 3 years after the issuance of the audit reports and financial statements. Upon request, this material will be made available to FmHA, the Comptroller General, or to their representatives.

(2) *Management reports.* These reports will furnish the management with a means of evaluating prior decisions and serve as a basis for planning future operations and financial conditions. In those cases where revenues from multiple sources are pledged as security for an FmHA loan, two reports will be required; one for the project being financed by FmHA and one combining the entire operation of the borrower. In those cases where FmHA loans are secured by general obligation bonds or assessments and the borrower combines revenues from all sources, one management report combining all such revenues will suffice. The following management data will be submitted by the borrower to the FmHA District Director.

(i) *Financial information.* (A) Form FmHA 442–2, "Statement of Budget, Income and Equity," which includes Schedule 1, "Statement of Budget, Income and Equity" and Schedule 2, "Projected Cash Flow."

(B) Prior to the beginning of each fiscal year, two copies, with data entered in column three only of page one, annual budget of Schedule 1 and all of Schedule 2, will be submitted to the District Director. Twenty (20) days after the end of each of the first three quarters of each year, two copies with all information furnished on Schedule 1 will be submitted. For the fourth quarter of each year, submit together with the year-end financial requirements of paragraphs (q) (4) and (5) of this section. More frequent submissions may be required by FmHA when necessary. The submission dates to the District Director will be 90 days following year-end for audited statements and 60 days following year-end for unaudited statements. The fourth quarter submission may serve the dual purpose of management report and year-end financial requirement for Statement of Income.

(ii) *Additional information.* (A) A list of the names and addresses of all members of the governing body as appropriate, also indicating the officers and their terms of office, will be included with the other information required at the end of the year.

(B) Borrowers delinquent on payment to FmHA or experiencing financial problems, will develop a positive action plan to resolve financial problems. The plan will be reviewed with FmHA and updated at least quarterly. Guide 22 may be used for developing a positive action plan.

(3) *Substitute for management reports.* When FmHA loans are secured by the general obligation of the public body or tax assessments which total 100 percent of the debt service requirements, the State Director may authorize an annual audit to substitute for other management reports.

(4) *Borrowers required to have aduits*—(i) *Audit requirements*—(A) *Annual audits.* Audits are required each year from:

(*1*) Borrowers whose gross annual income exceeds $100,000.

(*2*) Others as FmHA State Director may require.

(B) *Audit guide.* Audits will be prepared in accordance with the requirements of the handbook, "Instructions to Independent Certified Public Accountants and Licensed Public Accountants Performing Audits of Farmers Home Administration Borrowers and Grantees." The handbook is available at all FmHA officers.

(C) *Independent public accountant defined.* Audits shall be conducted in accordance with generally accepted auditing standards by independent certified public accountants or by independent licensed public accountants licensed on or before December 31, 1970, who are certified or licensed by a regulatory authority of a State or other political subdivision of the United States.

(ii) *Public body borrowers.* Audit reports prepared in accordance with State statutes or regulatory agencies are acceptable provided they contain the financial information necessary and are prepared on a frequency sufficient to furnish borrowers and FmHA the information for proper loan analysis. A copy of the audit report will be submitted to the District Director as soon as possible but in no case later than 90 days following the period covered by the audit. Public bodies should refer to the FmHA audit guide for further information and guidance.

(iii) *Other borrowers.* Borrowers other than public bodies and public bodies where the State has no audit requirements are requested to have their records audited by an independent public accountant on an annual basis. A copy of the audit report will be submitted to the District Director as soon as possible but in no case later than ninety (90) days following the period covered by the audit.

(5) *Borrowers not required to have audits.* Borrowers whose gross annual income for a full year of operation is less than $100,000 and who do not have an annual audit made by an independent public accountant, will within 60 days following the end of each fiscal year, furnish the FmHA with annual financial statements, consisting of a verification of the organization's balance sheet and statement of income and expense by an appropriate official of the organization. Forms FmHA 442–2 and FmHA 442–3 may be used. For borrowers using Form FmHA 442–2, the dual purpose of fourth quarter management reports, when required, and annual statements of income will be met with this one submission.

(r) *FmHA actions for borrower supervision and servicing*—(1) *Management assistance and management reports.* Management assistance will be based on such factors as observation of borrower operations and review of the periodic financial reports. The amount and type of assistance provided will be that needed to assure borrower success and compliance with its agreements with FmHA.

(i) *The District Director* is responsible for obtaining all management report

data from the borrower and promptly reviewing and making any necessary recommendations to the borrower within 40 calendar days. However, after receiving management reports for borrowers whose FmHA indebtedness exceeds $500,000 and for delinquent and problem case borrowers, the District Director will forward them with comments to the State Director for review.

(ii) *District Director reviews of borrower operations.* (A) A review of the borrower's total operational and management practices, including records and accounts to be maintained, will be made between the beginning of the ninth and the end of the eleventh full month of the first year of operation. A report will be made to the State Director by sending a copy of Form FmHA 442–4, "District Director Report." Earlier reviews will be made when needed to resolve operational and management problems that may arise.

(B) Subsequent reviews will be made for all delinquent and other borrowers having financial problems and reported to the State Director by a copy of Form FmHA 442–4. These borrowers will adopt a positive action plan (see Guide 22). The plan will be reviewed quarterly by the District Director until the delinquency is eliminated or other servicing actions are recommended.

(C) The District Director may, after the end of the borrower's third fiscal year of operation, exempt it from submitting management reports provided it:

(*1*) Is current on its loan payments.

(*2*) Is meeting the conditions of its agreements with FmHA.

(*3*) Has demonstrated its ability to successfully operate and manage the organization and has not obtained subsequent loans in the last 3 years which have significantly altered the scope of the project.

(*4*) Has the State Director's written concurrence for all borrowers whose FmHA indebtedness exceeds $500,000.

(D) Borrowers qualifying for this exemption will still be required to submit a copy of its audits or annual financial statements.

(E) Ordinarily and exception will not be made to the requirement for the borrower to submit a copy of its annual budget.

(F) The District Director or State Director may reinstate the requirements for submission for periodic management reports for those borrowers who became delinquent or otherwise are not carrying out their agreements with FmHA or require more frequent submission of management reports. This requirement will be reinstated for borrowers receiving a subsequent loan which will significantly alter the scope of the project.

(G) The District Director may accept management reports which are not prepared on page 1 of Form FmHA 442–2 Schedule 1 but contain like information. However, page 2 of this form must be used by all borrowers required to furnish management reports.

(iii) *The State Director* is responsible for:

(A) The review of the District Director's submission for all borrowers whose indebtedness exceeds $500,000. The State Director will forward comments to the District Director in order that a response, if necessary, can be sent to the borrower within 40 calendar days after the borrower's submission of its management reports.

(B) The review of all delinquent and problem case borrower management reports. Ordinarily, review findings and instructions regarding further management assistance will be determined within 20 calendar days of submission for delinquent and problem borrowers.

(C) Forwarding to the National Office copies of review findings, instructions for further assistance, and positive action plans on delinquent borrowers and borrowers experiencing financial problems.

(2) *Audits and financial statements*—(i) *The District Director* is responsible for obtaining all audit reports and financial statements from the borrower. Those received from borrowers whose FmHA indebtedness exceeds $500,000 and from delinquent and problem case borrowers will be promptly reviewed and forwarded to the State Director with appropriate comments.

(ii) *The District Director* is responsible for the review of audits and financial statements and for recommendations and instructions for borrower assistance. For borrowers required to have audits, the District Director will review each audit for conformance with "Instructions to Independent Certified Public Accountants and Licensed Public Accountants Performing Audits for FmHA Borrowers and Grantees." The borrower will be required to furnish any additional information necessary to satisfy the audit requirement. Guide 21 may be used in the audit review process.

(iii) *The State Director* is responsible for the review of audits of borrowers whose indebtedness exceeds $500,000 and delinquent and problem case borrowers. The State Director may recommend to the District Director any necessary actions to be taken.

(3) *Security inspections.* A representative of the borrower will ordinarily accompany the District Director during each inspection.

(i) *Post construction inspection.* The District Director will inspect each facility between the beginning of the ninth and the end of the eleventh full month of the first year of operation. This will normally coincide with the District Director's review of the borrower's total operational and management practices described in paragraph (r)(1)(ii)(A) of this section. The results of this inspection will be reported to the State Director on Form FmHA 424–12. Earlier inspections will be made when operational or other problems indicate a need. The State Director will provide guidance to the District Director to assure that action will be taken to correct project deficiencies.

(ii) *Subsequent inspections.* The District Director will make subsequent inspections of borrower security property and facilities during each third year after the post construction inspection. The results of this inspection will be reported to the State Director on Form FmHA 424–12.

(iii) *Special inspections.* The District Director may request, or the State Director may determine, the need for a member of the State staff to make certain security inspections. In such cases, the State Director will detail a staff member to make such inspections.

(iv) *Follow-up inspections.* If any inspection discloses deficiencies or exceptions, or otherwise indicates a need for subsequent inspections prior to the third year, the State Director will prescribe the type and frequency of follow-up inspections. These inspections will be made until all deficiencies and exceptions have been corrected.

(4) *Civil rights compliance reviews* will be performed under Subpart E of Part 1901 of this chapter for the life of the loan.

(5) *Other loan servicing actions* will be in accordance with Subpart E of Part 1951 of this chapter.

(s) *Loans under Pub. L. 98–8 (Emergency Jobs Bill).* Each FmHA project that is funded utilizing FmHA loan funds authorized by the Pub. L. 98–8 (Emergency Jobs Bill), will also comply with § 1942.372 (b) and (c) of Subpart H of Part 1942 of this chapter.

**§ 1942.18 Community Facilities—Planning, Bidding, Contracting, Constructing.**

(a) *General.* This section is specifically designed for use by owners including the professional or technical consultants and/or agents who provide assistance and services such as

architectural, engineering, inspection, financial, legal or other services related to planning, bidding, contracting, and constructing community facilities. These procedures do not relieve the owner of the contractual obligations that arise from the procurement of these services. For this section, an owner is defined as an applicant, borrower, or grantee.

(b) *Technical services.* Owners are responsible for providing the engineering or architectural services necessary for planning, designing, bidding, contracting, inspecting, and constructing their facilities. Services may be provided by the owner's "in house" engineer or architect or through contract, subject to FmHA concurrence. Architects and engineers must be licensed in the State where the facility is to be constucted.

(c) *Preliminary reports.* Preliminary architectural and engineering reports must conform with customary professional standards. Preliminary report guidelines for water, sanitary sewer, solid waste, storm sewer, and other essential community facilities are available from FmHA.

(d) *Design policies.* Facilities financed by FmHA will be designed and constructed in accordance with sound engineering and architectural practices, and must meet the requirements of Federal, State and local agencies.

(1) *Natural resources.* Facility planning should be responsive to the owner's needs and should consider the long-term economic, social and environmental needs as set forth in this section. FmHA's environmental considerations are under Subpart G of Part 1940 of this chapter.

(i) *Floodplains and wetlands.* Facilities must avoid, to the extent possible, the long- and short-term adverse impacts associated with the occupancy and modification of floodplains and wetlands, and avoid direct or indirect support of floodplain and wetland development whenever there is a practicable alternative. This subject is more fully discussed in Executive Order 11988, Executive Order 11990, and Water Resources Council's Floodplain Management Guidelines (43 FR 6030) which is available in all FmHA offices. Facilities located in special flood and mudslide prone areas must comply with FmHA's eligibility and insurance requirements in Subpart B of Part 1806 of this chapter (FmHA Instruction 426.2).

(ii) *Coastal Zone Management.* Facilities shall be designed and constructed in a manner consistent with approved State management programs, under the Coastal Zone Management Act of 1972 (Pub. L. 92–583 Section 307 (c)(1) and (2)) as supplemented by the Department of Commerce regulations 15 CFR Part 930.

(iii) *Wild and Scenic Rivers.* Facilities shall be designed and constructed in order that designated wild and scenic rivers be preserved in free-flowing condition and that they and their immediate environments be protected for the benefit and enjoyment of present and future generations under the Wild and Scenic Rivers Act of 1978 (Pub. L. 95–625).

(iv) *Endangered species.* Facilities shall be designed and constructed in a manner to conserve, to the extent practicable, the various endangered and threatened species of fish or wildlife and plants, and will not jeopardize their continued existence and will not result in destruction or modification of the habitat of species in the Endangered Species Act of 1973 (Pub. L. 93–205).

(2) *Historic preservation.* Facilities should be designed and constructed in a manner which will contribute to the preservation and enhancement of sites, structures, and objects of historical, architectural, and archaeological significance. All facilities must comply with the National Historic Preservation Act of 1966 (16 U.S.C 470) as supplemented by 36 CFR Part 800 and Executive Order 11593, "Protection and Enhancement of the Cultural Environment." Subpart F of Part 1901 of this chapter sets forth procedures for the protection of Historic and Archaeological Properties.

(3) *Architectural barriers.* All facilities intended for or accessible to the public or in which physically handicapped persons may be employed or reside must be developed in compliance with the Architectural Barriers Act of 1968 (Pub. L. 90–480) as implemented by the General Services Administration regulations 41 CFR 101–19.6 and Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112) as implemented by 7 CFR Parts 15 and 15b.

(4) *Health care facilities.* The proposed facility must meet the minimum standards for design and construction contained in the Public Health Service/ Health Resources and Services Administration (PHS/HRS), Health and Human Services Publication No. (HRS-M-HF) 84–1, "Guidelines for Construction and Equipment for Hospital and Medical Facilities." The facility must also meet the life/safety aspects of the 1981 edition of the National Fire Protection Association (NFPA) 101 Life Safety Code, or any subsequent codes that may be designated by the Secretary of HHS. Under § 1942.17(j)(8)(ii) of this subpart, a statement by the responsible regulatory agency that the facility meets the above standards will be required. Any exceptions must have prior National Office concurrence.

(5) *Energy conservation.* Facility design should consider cost effective energy saving measures or devices.

(6) *Lead base paints.* Lead base paints shall not be used in facilities designed for human habitation. Owners must comply with the Lead Base Paints Poisoning and Prevention Act of 1971 (42 U.S.C. 4801) and the National Consumer Health Information and Health Promotion Act of 1976 (Pub. L. 94–317) with reference to paint specifications used according to Exhibit H of Subpart A of Part 1924 of this chapter.

(7) *Fire protection.* Water facilities must have sufficient capacity to provide reasonable fire protection to the extent practicable.

(8) *Growth capacity.* Facilities must have sufficient capacity to provide for reasonable growth to the extent practicable.

(9) *Water conservation.* Owners are encouraged, when economically feasible, to incorporate water conservation practices into a facility's design. For existing water systems, evidence must be provided showing that the distribution system water losses do not exceed reasonable levels.

(10) *Water quality.* All water facilities must meet the requirements of the Safe Drinking Water Act (Pub. L. 93–523) and provide water of a quality that meets the current Interim Primary Drinking Water Regulations (40 CFR Part 141).

(11) *Combined sewers.* New combined sanitary and storm water sewer facilities will not be financed by FmHA. Extensions to existing combined systems can only be financed when separate systems are impractical.

(12) *Compliance.* All facilities must meet the requirements of Federal, State, and local agencies having the appropriate jurisdiction.

(13) *Dam safety.* Projects involving any artificial barrier which impounds or diverts water, or the rehabilitation or improvement of such a barrier, should comply with the provisions for dam safety as discussed in the Federal Guidelines for Dam Safety (Government Printing Office stock No. 041–001–00187–5) as prepared by the Federal Coordinating Council for Science, Engineering and Technology.

(14) *Pipe.* All pipe used shall meet current American Society for Testing Materials (ASTM) or American Water Works Association (AWWA) standards.

(15) *Water system testing.* For new water systems or extensions to existing water systems, leakage shall not exceed

10 gallons per inch of pipe diameter per mile of pipe per 24 hours when tested at 1½ times the working pressure or rated pressure of the pipe, whichever is greater.

(16) *Metering devices.* Water facilities financed by FmHA will have metering devices for each connection. An exception to this requirement may be granted by the FmHA State Director when the owner demonstrates that installation of metering devices would be a significant economic detriment and that environmental consideration would not be adversely affected by not installing such devices.

(e) *Construction contracts.* Contract documents must be sufficiently descriptive and legally binding in order to accomplish the work as economically and expeditiously as possible.

(1) *Standard construction contract documents* are available from FmHA. When FmHA's standard construction contract documents are used, it will normally not be necessary for the Office of the General Counsel (OGC) to perform a detailed legal review. If the construction contract documents utilized are not in the format of guide forms previously approved by FmHA, OGC's review of the construction contract documents will be obtained prior to their use.

(2) *Contract review and approval.* The owner's attorney will review the executed contract documents, including performance and payment bonds, and will certify that they are adequate, and that the persons executing these documents have been properly authorized to do so. The contract documents, bids bonds, and bid tabulation sheets will be forwarded to FmHA for approval prior to awarding. All contracts will contain a provision that they are not in full force and effect until they have been approved by FmHA. The FmHA State Director or designee is responsible for approving construction contracts with the legal advice and guidance of the OGC when necessary.

(3) *Separate contracts.* Arrangements which split responsibility of contractors (separate contracts for labor and material, extensive subcontracting and multiplicity of small contracts on the same job), should be avoided whenever it is practical to do so. Contracts may be awarded to suppliers or manufacturers for furnishing and installing certain items which have been designed by the manufacturer and delivered to the job site in a finished or semifinished state such as perfabricated buildings and lift stations. Contracts may also be awarded for material delivered to the job site and installed by a patented process or method.

(f) *Utility purchase contracts.* Applicants proposing to purchase water or other utility service from private or public sources shall have written contracts for supply or service which are reviewed and approved by the FmHA State Director or designee. To the extent practical, FmHA review and approval of such contracts should take place prior to their execution by the owner. Form FmHA 442-30, "Water Purchase Contract," may be used when appropriate. If the FmHA loan will be repaid from system revenues, the contract will be pledged to FmHA as part of the security for the loan. Such contracts will:

(1) Include a commitment by the supplier to furnish, at a specified point, an adequate quantity of water or other service and provide that, in case of shortages, all of the supplier's users will proportionately share shortages. If it is impossible to obtain a firm commitment for either an adequate quantity or sharing shortages proportionately, a contract may be executed and approved provided adequate evidence is furnished to enable FmHA to make a determination that the supplier has adequate supply and/or treatment facilities to furnish its other users and the applicant for the foreseeable future; and

(i) The supplier is subject to regulations of the Federal Energy Regulatory Commission or other Federal or State agency whose jurisdiction can be expected to prevent unwarranted curtailment of supply; or

(ii) A suitable alternative supply could be arranged within the repayment ability of the borrower if it should become necessary; or

(iii) Prior approval is obtained from the National Office. The following information should be submitted to the National Office:

(A) Transmittal memorandum including:

(*1*) Alternative supplies considered; and

(*2*) Recommendations and comments; and

(*3*) Any other necessary supporting information.

(B) Copies of the following:

(*1*) Proposed letter of conditions; and

(*2*) Form FmHA 442-7, "Operating Budget"; and

(*3*) Form FmHA 442-3, "Balance Sheet"; and

(*4*) Preliminary Engineering Report; and

(*5*) Proposed Contract.

(C) Owner and FmHA engineer's comments and recommendations.

(D) Documentation and statement from the supplier that it has an adequate supply and treatment facilities available to meet the needs of its users and the owner for the foreseeable future.

(2) Set out the ownership and maintenance responsibilities of the respective parties including the master meter if a meter is installed at the point of delivery.

(3) Specify the initial rates and provide some kind of escalator clause which will permit rates for the association to be raised or lowered proportionately as certain specified rates for the supplier's regular customers are raised or lowered. Provisions may be made for altering rates in accordance with the decisions of the appropriate State agency which may have regulatory authority.

(4) Run for a period of time which is at least equal to the repayment period of the loan. State Directors may approve contracts for shorter periods of time if the supplier cannot legally contract for such period, or if the owner and supplier find it impossible or impractical to negotiate a contract for the maximum period permissible under State law, provided:

(i) The supplier is subject to regulations of the Federal Energy Regulatory Commission or other Federal or State agency whose jurisdiction can be expected to prevent unwarranted curtailment of supply; or

(ii) The contract contains adequate provisions for renewal; or

(iii) A determination is made that in the event the contract is terminated, there are or will be other adequate sources available to the owner that can feasibly be developed or purchased.

(5) Set out in detail the amount of connection or demand charges, if any, to be made by the supplier as a condition to making the service available to the owner. However, the payment of such charges from loan funds shall not be approved unless FmHA determines that it is more feasible and economical for the owner to pay such a connection charge than it is for the owner to provide the necessary supply by other means.

(6) Provide for a pledge of the contract to FmHA as part of the security for the loan.

(7) Not contain provisions for:

(i) Construction of facilities which will be owned by the supplier. This does not preclude the use of money paid as a connection charge for construction to be done by the supplier.

(ii) Options for the future sale or transfer. This does not preclude an agreement recognizing that the supplier

and owner may at some future date agree to a sale of all or a portion of the facility.

(g) *Sewage treatment contracts.* Owners preparing to enter into a contract with private or public sources to treat sewage shall have written contracts for such service and all such contracts are subject to FmHA concurrence. Paragraph (f) of this section should be used as a guide to prepare sewage treatment contracts.

(h) *Performing construction.* Owners are encouraged to accomplish construction through contracts with recognized contractors. Owners may accomplish construction by using their own personnel and equipment provided the owners possess the necessary skills, abilities and resources to perform the work and provided a licensed engineer or architect prepares design drawings and specifications and inspects construction and furnishes inspection reports as required by paragraph (o) of this section. For other than utility-type facilities, inspection services may be provided by individuals as approved by the FmHA State Director. In either case, the requirements of paragraph (j) of this section apply. Payments for construction will be handled under § 1942.17(p)(5) of this part.

(i) *Owner's contractual responsibility.* This subpart does not relieve the owner of any contractual responsibilities under its contract. The owner is responsible for the settlement of all contractural and administrative issues arising out of procurements entered into in support of a loan or grant. These include, but are not limited to: source evaluation, protests, disputes, and claims. Matters concerning violation of laws are to be referred to the local, State, or Federal authority as may have jurisdiction.

(j) *Owner's procurement regulations.* Owner's procurement regulations must comply with State and local laws, rules and regulations, and the following standards:

(1) *Code of conduct.* Owners shall maintain a written code or standards of conduct which shall govern the performance of their officers, employees or agents engaged in the award and administration of contracts supported by FmHA funds. No employee, officer or agent of the owner shall participate in the selection, award, or administration of a contract supported by FmHA funds if a conflict of interest, real or apparent, would be involved. Examples of such conflicts would arise when: the employee, officer or agent; any member of their immediate family; their partner; or an organization which employs, or is about to employ, any of the above; has a financial or other interest in the firm selected for the award.

(i) The owner's officers, employees or agents shall neither solicit nor accept gratuities, favors or anything of monetary value from contractors, potential contractors, or parties of subagreements.

(ii) To the extent permitted by State or local law or regulations, the owner's standards of conduct shall provide for penalties, sanctions, or other disciplinary actions for violations of such standards by the owner's officers, employees, agents, or by contractors or their agents.

(2) *Maximum open and free competition.* All procurement transactions, regardless of whether by sealed bids or by negotiation and without regard to dollar value, shall be conducted in a manner that provides maximum open and free competition. Procurement procedures shall not restrict or eliminate competition. Examples of what are considered to be restrictive of competition include, but are not limited to: placing unreasonable requirements on firms in order for them to qualify to do business; noncompetitive practices between firms; organizational conflicts of interest; and unnecessary experience and bonding requirements. In specifying material(s), the owner and its consultant will consider all materials normally suitable for the project commensurate with sound engineering practices and project requirements. Acceptable materials should be specified in accordance with paragraphs (j)(4)(i) and (j)(4)(ii) of this section to assure proper installation and to avoid uncertainty and misunderstanding. Where materials which would normally be suitable are not included for bidding, the owner and its consultant must be prepared to justify the selection of the material(s) specified.

(3) *Owner's review.* Proposed procurement actions shall be reviewed by the owner's officials to avoid the purchase of unnecessary or duplicate items. Consideration should be given to consolidation or separation of procurement items to obtain a more economical purchase. Where appropriate, an analysis shall be made of lease versus purchase alternatives, and any other appropriate analysis to determine which approach would be the most economical. To foster greater economy and efficiency, owners are encouraged to enter into State and local intergovernmental agreements for procurement or use of common goods and services.

(4) *Solicitation of offers,* whether by competitive sealed bids or competitive negotiation, shall:

(i) Incorporate a clear and accurate description of the technical requirements for the material, product, or service to be procured. The description shall not, in competitive procurements, contain features which unduly restrict competition. The description may include a statement of the qualitative nature of the material, product or service to be procured, and when necessary shall set forth those minimum essential characteristics and standards to which it must conform if it is to satisfy its intended use. Detailed product specifications should be avoided if at all possible. When it is impractical or uneconomical to make a clear and accurate description of the technical requirements, a "brand name or equal" description may be used to define the performance or other salient requirements of a procurement. The specific features of the named brands which must be met by offerors shall be clearly stated.

(ii) Clearly specify all requirements which offerors must fulfill and all other factors to be used in evaluating bids or proposals.

(5) *Small, minority, and women's businesses and labor surplus area firms.* (i) affirmative steps should be taken to assure that small and minority businesses are utilized when possible as sources of supplies, equipment, construction and services. Affirmative steps shall include the following:

(A) Include qualified small and minority businesses on solicitation lists.

(B) Assure that small and minority businesses are solicited whenever they are potential sources.

(C) When economically feasible, divide total requirements into smaller tasks or quantities so as to permit maximum small and minority business participation.

(D) Where the requirement permits, establish delivery schedules which will encourage participation by small and minority businesses.

(E) Use the services and assistance of the Small Business Administration and the Office of Minority Business Enterprise of the Department of Commerce.

(F) If any subcontracts are to be let, require the prime contractor to take the affirmative steps in paragraphs (j)(5)(i)(A) through (E) of this section.

(ii) Owners shall take similar appropriate affirmative action in support of women's businesses.

(iii) Owners are encouraged to procure goods and services from labor surplus areas.

(iv) Owners shall submit a written statement or other evidence to FmHA of the steps taken to comply with paragraphs (j)(5)(i) (A) through (F), (j)(5)(ii), and (j)(5)(iii) of this section.

(6) *Contract pricing.* Cost plus a percentage of cost method of contracting shall not be used.

(7) *Unacceptable bidders.* The following will not be allowed to bid on, or negotiate for, a contract or subcontract related to the construction of the project:

(i) An engineer or architect as an individual or firm who has prepared plans and specifications or who will be responsible for monitoring the construction;

(ii) Any firm or corporation in which the owner's architect or engineer is an officer, employee, or holds or controls a substantial interest;

(iii) The governing body's officers, employees, or agents;

(iv) Any member of the immediate family or partners in paragraphs (j)(7)(i), (j)(7)(ii), or (j)(7)(iii) of this section; or

(v) An organization which employs, or is about to employ, any person in paragraph (j)(7)(i), (j)(7)(ii), (j)(7)(iii) or (j)(7)(iv) of this section.

(8) *Contract award.* Contracts shall be made only with responsible parties possessing the potential ability to perform successfully under the terms and conditions of a proposed procurement. Consideration shall include but not be limited to matters such as integrity, record of past performance, financial and technical resources, and accessibility to other necessary resources. Contracts shall not be made with parties who are suspended or debarred by FmHA under Part 1924 Subpart E of this chapter.

(k) *Procurement methods.* Procurement shall be made by one of the following methods: small purchase procedures; competitive sealed bids (formal advertising); competitive negotiation; or noncompetitive negotiation. Competitive sealed bids (formal advertising) is the preferred procurement method for construction contracts.

(1) *Small purchase procedures.* Small purchase procedures are those relatively simple and informal procurement methods that are sound and appropriate for a procurement of services, supplies or other property, costing in the aggregate not more than $10,000. If small purchase procedures are used for a procurement, written price or rate quotations shall be obtained from an adequate number of qualified sources.

(2) *Competitive sealed bids.* In competitive sealed bids (formal advertising), sealed bids are publicly solicited and a firm-fixed-price contract (lump sum or unit price) is awarded to the responsible bidder whose bid, conforming with all the material terms and conditions of the invitation for bids, is lowest, price and other factors considered. When using this method the following shall apply:

(i) At a sufficient time prior to the date set for opening of bids, bids shall be solicited from an adequate number of qualified sources. In addition, the invitation shall be publicly advertised.

(ii) The invitation for bids, including specifications and perinent attachments, shall clearly define the items or services needed in order for the bidders to properly respond to the invitation under paragraph (j)(4) of this section.

(iii) All bids shall be opened publicly at the time and place stated in the invitation for bids.

(iv) A firm-fixed-price contract award shall be made by written notice to that responsible bidder whose bid, conforming to the invitation for bids, is lowest. When specified in the bidding documents, factors such as discounts and transportation costs shall be considered in determining which bid is lowest.

(v) Any or all bids may be rejected by the owner when it is in their best interest.

(3) *Competitive negotiation.* In competitive negotiations, proposals are requested from a number of sources and the Request for Proposal is publicized. Negotiations are normally conducted with more than one of the sources submitting offers. Competitive negotiation may be used if conditions are not appropriate for the use of formal advertising and where discussions and bargaining with a view to reaching agreement on the technical quality, price, other terms of the proposed contract and specifications may be necessary. If competitive negotiation is used for a procurement, the following requirements shall apply:

(i) Proposals shall be solicited from an adequate number of qualified sources to permit reasonable competition consistent with the nature and requirements of the procurement. The Request for Proposal shall be publicized and reasonable requests by other sources to compete shall be honored to the maximum extent practicable.

(ii) The Request for Proposal shall identify all significant evaluation factors, including price or cost where required, and their relative importance.

(iii) The owner shall provide mechanisms for technical evaluation of the proposals received, determination of responsible offerors for the purpose of written or oral discussions, and selection for contract award.

(iv) Award may be made to the responsible offeror whose proposal will be most advantageous to the owner, price and other factors considered. Unsuccessful offerors should be promptly notified.

(v) Owners may utilize competitive negotiation procedures for procurement of architectural/engineering and other professional services, whereby competitors' qualifications are evaluated and the most qualified competitor is selected, subject to negotiations of fair and reasonable compensation.

(4) *Noncompetitive negotiation.* Noncompetitive negotiation is procurement through solicitation of a proposal from only one source, or after solicitation of a number of sources competition is determined inadequate. Noncompetitive negotiation may be used when the award of a contract is not feasible under small purchase, competitive sealed bids (formal advertising) or competitive negotiation procedures. When the amount of noncompetitive construction contracts exceeds $100,000 National Office concurrence must be obtained in accordance with § 1942.9(b) of this subpart. Circumstances under which a contract may be awarded by noncompetitive negotiations are limited to the following:

(i) The item is available only from a single source; or

(ii) There exists a public exigency or emergency and the urgency for the requirement will not permit a delay incident to competitive solicitation; or

(iii) After solicitation of a number of sources, competition is determined inadequate; or

(iv) No acceptable bids have been received after formal advertising; or

(v) The procurement of architectural/engineering and other professional services.

(5) *Additional procurement methods.* Additional innovative procurement methods may be used by the owner with prior written approval of the FmHA National Office.

(l) *Contracting methods.* The services of the consulting engineer or architect and the general construction contractor shall normally be procured from unrelated sources in accordance with paragraph (j)(7) of this section. Procurement methods which combine or rearrange design, inspection or construction services (such as design/build or construction management) may

be used with FmHA written approval. If the contract amount exceeds $100,000, National Office prior concurrence must be obtained under § 1942.9(b) of this subpart. This method cannot be used when an FmHA grant is involved. The owner should request FmHA approval by providing at least the following information to FmHA:

(1) The owner's written request to use an unconventional contracting method with a description of the proposed method.

(2) A proposed scope of work describing in clear, concise terms the technical requirements for the contract. It should include items such as:

(i) A nontechnical statement summarizing the work to be performed by the contractor and the results expected.

(ii) The sequence in which the work is to be performed and a proposed construction schedule.

(3) A proposed firm-fixed-price contract for the entire project which provides that the contractor shall be responsible for:

(i) Any extra cost which may result from errors or omissions in the services provided under the contract.

(ii) Compliance with all Federal, State, and local requirements effective on the contract execution date.

(4) Where noncompetitive negotiation is proposed, an evaluation of the contractor's performance on previous similar projects in which the contractor acted in a similar capacity.

(5) A detailed listing and cost estimate of equipment and supplies not included in the construction contract but which are necessary to properly operate the facility.

(6) Evidence that a qualified construction inspector who is independent of the contractor has or will be hired.

(7) Preliminary plans and outline specifications. However, final plans and specifications must be completed and reviewed by FmHA prior to the start of construction.

(8) The owner's attorney's opinion and comments regarding the legal adequacy of the proposed contract documents and evidence that the owner has the legal authority to enter into and fulfill the contract.

(m) *Contracts awarded prior to preapplications.* Owners awarding construction or other procurement contracts prior to filing a pre-application with FmHA must comply with the following:

(1) *Evidence.* Provide conclusive evidence that the contract was entered into without intent to circumvent the requirements of FmHA regulations. The evidence will consist of at least the following:

(i) The lapse of a reasonable period of time between the date of contract award and the date of filing the preapplication which clearly indicates an irreconcilable failure of previous financial arrangements; or

(ii) A written statement explaining initial plans for financing the project and reasons for failure to obtain the planned credit.

(2) *Modifications.* Modify the outstanding contract to conform with the provisions of this subpart. Where this is not possible, modifications will be made to the extent practicable and, as a minimum, the contract must comply with all State and local laws and regulations as well as statutory requirements and executive orders related to the FmHA financing. When all construction is complete and it is impracticable to modify the contracts, the owner must provide the certification required by paragraph (m)(4) of this section.

(3) *Consultant's certification.* Provide a certification by an engineer or architect that any construction performed complies fully with the plans and specifications.

(4) *Owner's certification.* Provide a certification by the owner that the contractor has complied with all statutory and executive requirements related to FmHA financing for construction already performed even though the requirements may not have been included in the contract documents.

(n) *Contract provisions.* In addition to provisions defining a sound and complete contract, any recipient of FmHA funds shall include the following contract provisions or conditions in all contracts:

(1) *Remedies.* Contracts other than small purchases shall contain provisions or conditions which will allow for administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as may be appropriate. A realistic liquidated damage provision should also be included.

(2) *Termination.* All contracts exceeding $10,000, shall contain provisions for termination by the owner including the manner by which it will be affected and the basis for settlement. In addition, such contracts shall describe conditions under which the contract may be terminated for default as well as conditions when the contract may be terminated because of circumstances beyond the control of the contractor.

(3) *Surety.* In all contracts for construction or facility improvements awarded exceeding $100,000, the owner shall require bonds, a bank letter of credit or cash deposit in escrow assuring performance and payment, each in the amount of 100 percent of the contract cost. The surety will normally be in the form of performance bonds and payment bonds; however, when other methods of surety may be necessary, bid documents must contain provisions for such alternative types of surety. The use of surety other than performance bonds and payment bonds requires concurrence by the National Office after submission of a justification by the State Director together with the proposed form of escrow agreement or letter of credit. For contracts of lesser amounts, the owner may require surety. When a surety is not provided, contractors will furnish evidence of payment in full for all materials, labor, and any other items procured under the contract. Form FmHA 424–10, "Release by Claimants," and Form FmHA 424–9, "Certificate of Contractor's Release," may be obtained at the local FmHA office and used for this purpose. The United States, acting through the Farmers Home Administration, will be named as co-obligee on all surety unless prohibited by State law. Companies providing performance bonds and payment bonds must hold a certificate of authority as an acceptable surety on Federal bonds as listed in Treasury Circular 570 as amended and be legally doing business in the State where the facility is located.

(4) *Equal Employment Opportunity.* All contracts awarded in excess of $10,000 by owners shall contain a provision requiring compliance with Executive Order 11246, entitled, "Equal Employment Opportunity," as amended by Executive Order 11375, and as supplemented by Department of Labor regulations 41 CFR Part 60.

(5) *Anti-kickback.* All contracts for construction shall include a provision for compliance with the Copeland "Anti-Kickback" Act (18 U.S.C. 874). This Act provides that each contractor shall be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which they are otherwise entitled. The owner shall report all suspected or reported violations to FmHA.

(6) *Records.* All negotiated contracts (except those of $2,500 or less) awarded by owners shall include a provision to the effect that the owner, FmHA, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and

records of the contractor which are directly pertinent to a specific Federal loan program for the purpose of making audits, examinations, excerpts, and transcriptions. Owners shall require contractors to maintain all required records for three years after owners make final payments and all other pending matters are closed.

(7) *State Energy Conservation Plan.* Contracts shall recognize mandatory standards and policies relating to energy efficiency which are contained in the State energy conservation plan issued in compliance with the Energy Policy and Conservation Act (Pub. L. 94–163).

(8) *Change orders.* The construction contract shall require that all contract change orders be approved in writing by FmHA.

(9) *FmHA concurrence.* All contracts must contain a provision that they shall not be effective unless and until the FmHA State Director or designee concurs in writing.

(10) *Retainage.* All construction contracts shall contain adequate provisions for retainage. No payments will be made that would deplete the retainage nor place in escrow any funds that are required for retainage nor invest the retainage for the benefit of the contractor. The retainage shall not be less than an amount equal to 10 percent of an approved partial payment estimate until 50 percent of the work has been completed. If the job is proceeding satisfactory at 50 percent completion, further partial payments may be made in full, however, previously retained amounts shall not be paid until construction is substantially complete. Additional amounts may be retained if the job is not proceeding satisfactorily, but in no event shall the total retainage be more than 10 percent of the value of the work completed.

(11) *Other compliance requirements.* Contracts in excess of $100,000 shall contain a provision which requires compliance with all applicable standards, orders, or requirements issued under Section 306 of the Clean Air Act (42 U.S.C. 1857(h)), Section 508 of the Clean Water Act (33 U.S.C. 1368), Executive Order 11738, and Environmental Protection Agency (EPA) regulations 40 CFR Part 15, which prohibit the use under non-exempt Federal contracts, grants or loans of facilities included on the EPA List of Violating Facilities. The provision shall require reporting of violations to FmHA and to the U.S. Environmental Protection Agency, Assistant Administrator for Enforcement. Solicitations and contract provisions shall include the requirements of 40 CFR Part 15.4(c) as set forth in Guide 18 of this subpart which is available in all FmHA offices.

(o) *Contract administration.* Owners shall be responsible for maintaining a contract administration system to monitor the contractors' performance and compliance with the terms, conditions, and specifications of the contracts.

(1) *Preconstruction conference.* Prior to beginning construction, the owner will schedule a preconstruction conference where FmHA will review the planned development with the owner, its architect or engineer, resident inspector, attorney, contractor(s), and other interested parties. The conference will thoroughly cover applicable items included in Form FmHA 424.16, "Record of Preconstruction Conference," and the discussion and agreements will be documented. Form FmHA 424–16 may be used for this purpose.

(2) *Monitoring reports.* Each owner will be required to monitor and provide reports to FmHA on actual performance during construction for each project financed, or to be financed, in whole or in part with FmHA funds to include:

(i) A comparison of actual accomplishments with the construction schedule established for the period. The partial payment estimate may be used for this purpose.

(ii) A narrative statement giving full explanation of the following:

(A) Reasons why established goals were not met.

(B) Analysis and explanation of cost overruns or high unit costs and how payment is to be made for the same.

(iii) If events occur between reports which have a significant impact upon the project, the owner will notify FmHA as soon as any of the following conditions are met:

(A) Problems, delays, or adverse conditions which will materially affect the ability to attain program objectives or prevent the meeting of project work units by established time periods. This disclosure shall be accompanied by a statement of the action taken, or contemplated, and any Federal assistance needed to resolve the situation.

(B) Favorable developments or events which enable meeting time schedules and goals sooner than anticipated or producing more work units than originally projected or which will result in cost underruns or lower unit costs than originally planned and which may result in less FmHA assistance.

(3) *Inspection.* Full-time resident inspection is required for all construction unless a written exception is made by FmHA upon written request of the owner. Unless otherwise agreed, the resident inspector will be provided by the consulting architect/engineer. Prior to the preconstruction conference, the architect/engineer will submit a resume of qualifications of the resident inspector to the owner and to FmHA for acceptance in writing. If the owner provides the resident inspector, it must submit a resume of the inspector's qualifications to the project architect/engineer and FmHA for acceptance in writing prior to the preconstruction conference. The resident inspector will work under the general supervision of the project architect/engineer. A guide format for preparing daily inspection reports (Guide 11 of this subpart) and Form FmHA 424–18, "Partial Payment Estimate," are available on request from FmHA.

(4) *Inspector's daily diary.* The resident inspector will maintain a record of the daily construction progress in the form of a daily diary and daily inspection reports as follows:

(i) A complete set of all daily construction records will be maintained and the original set furnished to the owner upon completion of construction.

(ii) All entries shall be legible and shall be made in ink.

(iii) Daily entries shall include but not be limited to the date, weather conditions, number and classification of personnel working on the site, equipment being used to perform the work, persons visiting the site, accounts of substantive discussions, instructions given to the contractors, directions received, all significant or unusual happenings involving the work, any delays, and daily work accomplished.

(iv) The daily entries shall be made available to FmHA personnel and will be reviewed during project inspections.

(5) *Prefinal inspections.* A prefinal inspection will be made by the owner, resident inspector, project architect or engineer, representatives of other agencies involved, the District Director and a FmHA State Office staff representative, preferably the State Staff architect or engineer. Prefinal inspections may be made without FmHA State Office staff participation if the State Director or a designee determines that the facility does not utilize complicated construction techniques, materials or equipment for facilities such as small fire stations, storage buildings or minor utility extensions, and that an experienced District Office staff representative will be present. The inspection results will be recorded on Form FmHA 424–12, "Inspection Report," and a copy provided to all appropriate parties.

(6) *Final inspection.* A final inspection will be made by FmHA before final payment is made.

(7) *Change is development plans.*

(i) Changes in development plans may be approved by FmHA when requested by owners, provided:

(A) Funds are available to cover any additional costs; and

(B) The change is for an authorized loan purpose; and

(C) It will not adversely affect the soundness of the facility operation or FmHA's security; and

(D) The change is within the scope of the contract.

(ii) Changes will be recorded on Form FmHA 424–7, "Contract Change Order," or, other similar forms may be used with the prior approval of the State Director or designee. Regardless of the form, change orders must be approved by the FmHA State Director or a designated representative.

(iii) Changes should be accomplished only after FmHA approval on all changes which affect the work and shall be authorized only by means of contract change order. The change order will include items such as:

(A) Any changes in labor and material and their respective cost.

(B) Changes in facility design.

(C) Any decrease or increase in quantities based on final measurements that are different from those shown in the bidding schedule.

(D) Any increase or decrease in the time to complete the project.

(iv) All changes shall be recorded on chronologically numbered contract change orders as they occur. Change orders will not be included in payment estimates until approved by all parties.

**§ 1942.19 Information pertaining to preparation of notes or bonds and bond transcript documents for public body applicants.**

(a) *General.* This section includes information for use by public body applicants in the preparation and issuance of evidence of debt (bonds, notes, or debt instruments, herein referred to as bonds). This section is made available to applicants as appropriate for application processing and loan docket preparation.

(b) *Policies related to use of bond counsel.* Preparation of the bonds and the bond transcript documents will be the responsibility of the applicant. Public body applicants will obtain the services and opinion of recognized bond counsel with respect to the validity of a bond issue, except as provided in (b) (1) through (3) below. The applicant normally will be represented by a local attorney who will obtain the assistance of a recognized bond counsel firm which has experience in municipal financing with such investors as investment dealers, banks, and insurance companies.

(1) *Issues of $250,000 or less.* At the option of the applicant for issues of $250,000 or less, bond counsel may be used for the issuance of a final opinion only and not for the preparation of the bond transcript and other documents when the applicant, FmHA, and bond counsel have agreed in advance as to the method of preparation of the bond transcript documents. Under such circumstances the applicant will be responsible for the preparation of the bond transcript documents.

(2) *Issues of $50,000 or less.* At the option of the applicant and with the prior approval of the FmHA State Director, the applicant need not use bond counsel if:

(i) The amount of the issue does not exceed $50,000 and the applicant recognizes and accepts the fact that processing the application may require additional legal and administrative time.

(ii) There is a significant cost saving to the applicant particularly with reference to total legal fees after determining what bond counsel would charge as compared with what the local attorney will charge without bond counsel.

(iii) The local attorney is able and experienced in handling this type of legal work.

(iv) The applicant understands that, if it is required by FmHA to refinance its loan pursuant to the statutory refinancing requirements, it will probably have to obtain at its expense a bond counsel's opinion at that time.

(v) All bonds will be prepared in accordance with this regulation and will conform as nearly as possible to the preferred methods of preparation stated in paragraph (e) of this section but still be consistent with State law.

(vi) Many matters necessary to comply with FmHA requirements such as land rights, easements, and organizational documents will be handled by the applicant's local attorney. Specific closing instructions will be issued by the Office of the General Counsel of the U.S. Department of Agriculture for the guidance of FmHA.

(3) *For loans of less than $500,000.* The applicant shall not be required to use bond counsel in a straight mortgage-note situation where competitive bidding is not required for the sale of the debt instrument, unless a complicated financial situation exists with the applicant. In addition, if there is a known backlog in a particular OGC regional office the applicant will be advised of such backlog and it will be suggested to the applicant that the appointment of bond counsel may be more expeditious. However, it will be the decision of the applicant whether or not to appoint bond counsel. The applicant must comply with (b)(2) (iii) through (vi) of this section.

(c) *Bond transcript documents.* Any questions with respect to FmHA requirements should be discusesd with the FmHA representatives. The bond counsel (or local counsel where no bond counsel is involved) is required to furnish at least two complete sets of the following to the applicant, who will furnish one complete set to FmHA:

(1) Copies of all organizational documents.

(2) Copies of general incumbency certificate.

(3) Certified copies of minutes or excerpts therefrom of all meetings of the applicant's governing body at which action was taken in connection with the authorization and issuance of the bonds.

(4) Certified copies of documents evidencing that the applicant has complied fully with all statutory requirements incident to calling and holding of a favorable bond election, if such an election is necessary in connection with bond issuance.

(5) Certified copies of the resolution or ordinances or other documents, such as the bond authorizing resolutions or ordinance and any resolution establishing rates and regulating the use of the improvement, if such documents are not included in the minutes furnished.

(6) Copies of official Notice of Sale and affidavit of publication of Notice of Sale where a public sale is required by State statute.

(7) Specimen bond, with any attached coupons.

(8) Attorney's no-litigation certificate.

(9) Certified copies of resolutions or other documents pertaining to the bond award.

(10) Any additional or supporting documents required by bond counsel.

(11) For loans involving multiple advances of FmHA loan funds a preliminary approving opinion of bond counsel (or local counsel if no bond counsel is involved) if a final unqualified opinion cannot be obtained until all funds are advanced. The preliminary opinion for the entire issue shall be delivered on or before the first advance of loan funds and state that the applicant has the legal authority to issue the bonds, construct, operate and maintain the facility, and repay the loan subject only to changes during the

advance of funds such as litigation resulting from the failure to advance loan funds, and receipt of closing certrificates.

(12) Preliminary approving opinion, if any, and final unqualified approving opinion of recognized bond counsel (or local counsel if no bond counsel is involved) including opinion regarding interest on bonds being exempt from Federal and any State income taxes. On approval of the Administrator, a final opinion may be qualified to the extent that litigation is pending relating to Indian claims that may affect title to land or validity of the obligation. It is permissible for such opinions to contain language referring to the last sentence of Section 306(a)(1) or to Section 309A(h) of the Consolidated Farm and Rural Development Act [7 U.S.C. 1926(a)(1) or 1929a(h)], and providing that if the bonds evidencing the indebtedness in question are required by the Federal Government and sold on an insured basis from the Agriculture Credit Insurance Fund, or the Rural Development Insurance Fund, the interest on such bonds will be included in gross income for the purpose of the Federal income tax statutes.

(d) *Interim financing from commercial sources during construction period for loans of $50,000 or more.* In all cases where it is possible for funds to be borrowed at current market interest rates on an interim basis from commercial sources, such interim financing will be obtained so as to preclude the necessity for multiple advances of FmHA funds.

(e) *Permanent instruments for FmHA loans to repay interim commercial financing.* FmHA loans will be evidenced by the following types of instruments chosen in accordance with the following order of preference:

(1) *First preference—Form FmHA 440-22, "Promissory Note (Association or Organization)".* If legally permissible use Form FmHA 440-22 for insured loans.

(2) *Second preference—single instruments with amortized installments.* If Form FmHA 440.22 is not legally permissible, use a single instrument providing for amortized installments. Show the full amount of the loan on the face of the document and provide for entering the date and amount of each FmHA advance on the reverse thereof or on an attachment to the instrument. Form FmHA 440-22 should be followed to the extent possible. When principal payment is deferred, no attempt should be made to compute in dollar terms the amount of interest due on these installment dates. Rather the instrument should provide that "interest only" is due on these dates. The appropriate amortized installment computed as follows will be shown due on the installment date thereafter.

(i) Annual payments—Subtract the due date of the *last annual interest only* installment from the due date of the final installment to determine the number of annual payments applicable. When there are no interest only installments, the number of annual payments will equal the number of years over which the loan is amortized. Then multiply the amount of the note by the applicable amortization factor shown in FmHA Amortization Tables and round to the next higher dollar. Example of Computation of Annual Payment:

Date of Loan Closing: 7-5-1976
Amount of Loan: $100,000.00
Interest Rate: 5%
Amortization Period: 40 years
Interest Only Installments: 7-5-1977 and 7-5-1978
First Regular Installment: 7-5-1979
Final Installment: 7-5-2016
Computation:
2016 − 1978 = 38 annual payments
$100,000.00 × .05929 = $5,929.00 annual payment due

(ii) Semiannual payments—Multiply by two the number of years between the due date of the *last annual interest only* installment and the due date of the final installment to determine the correct number of semiannual periods applicable. When there are no interest only installments, multiply by two the number of years over which the loan is amortized. Then multiply the amount of the note by the applicable amortization factor shown in FmHA Amortization Tables and round to the next higher dollar. Example of Computation of Semiannual Payment:

Date of Loan Closing: 7-5-1976
Amount of Loan: $100,000.00
Interest Rate: 5%
Amortization Period: 40 years
Interest Only Installments: 7-5-1977 and 7-5-1978
First Regular Installment: 7-5-1979
Final Installment: 7-5-2016
Computation:
2016 − 1978 = 38 × 2 = 76 semiannual periods
$100,000.00 × .02952 = $2,952.00 semiannual payment due

(iii) Monthly payments—Multiply by twelve the number of years between the due date of the *last annual interest only* installment and the final installment to determine the number of monthly payments applicable. When there are no interest only installments, multiply by twelve the number of years over which the loan is amortized. Then multiply the amount of the note by the applicable amortization factor shown in FmHA Amortization Tables and round to the next higher dollar. Example of Computation of Monthly Payment:

Date of Loan Closing: 7-5-1976
Amount of Loan: $100,000.00
Interest Rate: 5%
Amortization Period: 40 years
Interest Only Installments: 7-5-1977 and 7-5-1978
First Regular Installment: 7-5-1979
Final Installment: 7-5-2016
Computation:
2016 − 1978 = 38 × 12 = 456 monthly payments
$100,000.00 × .00491 = $491.00 monthly payment due

(3) *Third preference—single instrument with installments of principal plus interest.* If a single instrument with amortized installments is not legally permissible, use a single instrument providing for installments of principal plus interest accrued on the unmatured principal balance. The principal should be in an amount best adapted to making principal retirement and interest payments which closely approximate equal installments of combined interest and principal as required by the first two preferences.

(i) The repayment terms concerning interest only installments described in paragraph (e)(2) of this section, "Second perference" applies.

(ii) The instrument shall contain in substance the following provisions:

(A) A statement of principal maturities and due dates.

(B) Payments made on indebtedness evidenced by this instrument shall be applied to the interest due through the next installment due date and the balance to principal in accordance with the terms of the bond. Payments on delinquent accounts will be applied in the following sequence:

(*1*) Billed delinquent interest,
(*2*) Past due interest installments,
(*3*) Past due principal installments,
(*4*) Interest installment due, and
(*5*) Principal installment due.

Extra payments and payments made from security depleting sources shall be applied to the principal last to come due or as specified in the bond instrument.

(4) *Fourth preference—serial bonds with installments of principal plus interest.* If instruments described under the first, second, and third preferences are not legally permissible, *use serial bonds with a bond or bonds delivered in the amount of each advance. Bonds will be delivered in the order of their numbers.* Such bonds will conform with the minimum requirements of paragraph

(h) of this section. Rules for application of payments on serial bonds will be the same as those for principal installment single bonds as set out in the preceding paragraph (e)(3) of this section.

(f) *Multiple advances of FmHA funds using permanent instruments.* Where interim financing from commercial sources is not available, FmHA loan proceeds will be disbursed on an "as needed by borrower" basis in amounts not to exceed the amount needed during 30-day periods.

(g) *Multiple advances of FmHA funds using temporary debt instrument.* When none of the instruments described in paragraph (e) of this section are legally permissible or practical, a bond anticipation note or similar temporary debt instrument may be used. The debt instrument will provide for multiple advance of FmHA loan funds and will be for the full amount of the FmHA loan. The instrument will be prepared by bond counsel (or local counsel if bond counsel is not involved) and approved by the State Director and OGC. At the same time FmHA delivers the last advance, the borrower will deliver the permanent bond instrument and the canceled temporary instrument will be returned to the borrower. The approved debt instrument will show at least the following:

(1) The date from which each advance will bear interest.

(2) The interest rate.

(3) A payment schedule providing for interest on outstanding principal at least annually.

(4) A maturity date which shall be no earlier than the anticipated issuance date of the permanent instrument(s).

(h) *Minimum bond specifications.* The provisions of this paragraph are minimum specifications only, and must be followed to the extent legally permissible.

(1) *Type and denominations.* Bond resolutions or ordinances will provide that the instrument(s) be either a bond representing the total amount of the indebtedness or serial bonds in denominations customarily accepted in municipal financing (ordinarily in multiples of not less than $1000). Single bonds may provide for repayment of principal plus interest or amortized installments; amortized installments are preferable from the standpoint of FmHA. Coupon bonds will not be used unless required by State statute.

(i) To compute the value of each coupon when the bond denomination is consistent:

(A) Multiply the amount of the loan or advance by the interest rate and divide the product by 365 days.

(B) Multiply the daily accrual factor determined in (A) by the number of days from the date of advance or last installment date to the next installment date.

(C) Divide the interest computed in (B) by the number of bonds securing the advance; this is the individual coupon amount.

(ii) to compute the value of each coupon when the bond denomination varies:

(A) Multiply the denomination of the bond by the interest rate and divide the product by 365 days.

(B) Multiply the daily accrual factor determined in (A) by the number of days from the date of advance or last installment date to the next installment due date; this is the individual coupon amount.

(2) *Bond registration.* Bonds will contain provisions permitting registration as to both principal and interest. Bonds purchased by FmHA will be registered in the name, of "United States of America, Farmers Home Administration," and will remain so registered at all time while the bonds are held or insured by the United States. The address of FmHA for registration purposes will be that of the FmHA Finance Office.

(3) *Size and quality.* Size of bonds and coupons should conform to standard practice. Paper must be of sufficient quality to prevent deterioration through ordinary handling over the life of the loan.

(4) *Date of bond.* Bonds will preferably be dated as of the day of delivery, however, may be dated another date at the option of the borrower and subject to approval by FmHA. If the date of delivery is other than the date of the bond, the date of delivery will be stated in the bond. In all cases, interest will accrue from the date of delivery of the funds.

(5) *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.

(6) *Place of payment.* Payments on bonds purchased by FmHA should be submitted to the FmHA District Office by the borrower. The District Office will then remit the payments to the Finance Office or deposit them in a Treasury General Account in accordance with Subpart B of Part 1951 of this chapter.

(7) *Redemptions.* Bonds should contain customary redemption provisions, subject, however, to unlimited right of redemption without premium of any bonds held by FmHA except to the extent limited by the provisions under the "Third Preference" and "Fourth Preference" in paragraph (e) of this section.

(8) *Additional revenue bonds.* Parity bonds may be issued to complete the project. Otherwise, parity bonds may not be issued unless the net revenues (that is, unless otherwise defined by the State statute, gross revenues less essential operation and maintenance expense) for the fiscal year preceding the year in which such parity bonds are to be issued, were 120 percent of the average annual debt service requirements on all bonds then outstanding and those to be issued; provided, that this limitation may be waived or modified by the written consent of bondholders representing 75 percent of the then outstanding principal indebtedness. Junior and subordinate bonds may be issued in accordance with the loan agreement.

(9) *Scheduling of FmHA payments when joint financing is involved.* In all cases in which FmHA is participating with another lender in the joint financing of the project to supply funds required by one applicant, the FmHA payments of principal and interest should approximate amortized installments.

(10) *Precautions.* The following types of provisions in debt instruments should be avoided.

(i) Provisions for the holder to manually post each payment to the instrument.

(ii) Provisions for returning the permanent or temporary debt instrument to the borrower in order that it, rather than FmHA, may post the date and amount of each advance or repayment on the instrument.

(iii) Defeasance provisions in loan or bond resolutions.

(iv) Provisions that amend convenants contained in Forms FmHA 1942–47, "Loan Resolution (Public Bodies)," or FmHA 1942–9, "Loan Resolution (Security Agreement)."

(11) *Multiple Loan Instruments.* The following will be adhered to when preparing debt instruments:

(i) When more than one loan type is used in financing a project, each type of loan will be evidenced by a separate

debt instrument or series of debt instruments.

(ii) Loan funds obligated in different fiscal years and those obligated with different interest rates or terms in the same fiscal year will be evidenced by separate debt instruments.

(iii) Loan funds obligated for the same loan type in the same fiscal year at the same interest rate and term may be combined in the same debt instrument; provided the borrower has been notified on Form FmHA 1940–1, "Request for Obligation of Funds", of the action.

(i) *Bidding by FmHA.* Bonds offered for public sale shall be offered in accordance with State law, in such a manner to encourage public bidding. FmHA will not submit a bid at the advertised sale unless required by State law, nor will reference to FmHA's rates and terms be included. If no acceptable bid is received, FmHA will negotiate the purchase of the bonds.

**§ 1942.20 Community Facility Guides.**

(a) The following documents are attached and made part of this subpart and may be used by FmHA officials in administering this program.

(1) Guide 1 and 1a—Guide Letter for Use in Informing Private Lender of FmHA's Commitment.

(2) Guide 2—Water Users Agreement.

(3) Guide 3—Service Declination Statement.

(4) Guide 4—Bylaws.

(5) Guide 5—Financial Feasibility Report.

(6) Guide 6—Preliminary Architectural Feasibility Report.

(7) Guide 7—Preliminary Engineering Report Water Facility.

(8) Guide 8—Preliminary Engineering Report Sewerage Systems.

(9) Guide 9—Preliminary Engineering Report Solid Waste Disposal Systems.

(10) Guide 10—Preliminary Engineering Report Storm Waste-Water Disposal.

(11) Guide 11—Daily Inspection Report.

(12) Guide 12—Memorandum of Understanding Between the Economic Development Administration—Department of Commerce and the Farmers Home Administration—Department of Agriculture Pertaining to EDA Public Works Projects Assisted by an FmHA Loan.

(13) Guide 13—Memorandum of Understanding Between the Economic Development Administration—Department of Commerce and the Farmers Home Administration—Department of Agriculture Regarding Supplementary Grant Assistance for the Construction of Public Works and Development Facilities.

(14) Guide 14—Legal Services Agreement.

(15) Guide 15—Community Facility Borrower's Application.

(16) Guide 16—Community Facility Loan Docket.

(17) Guide 17—Construction Contract Documents—Short Form.

(18) Guide 18—FmHA Supplemental General Conditions.

(19) Guide 19—Construction Contract Documents.

(20) Guide 20—Agreement for Engineering Services (FmHA/EPA Jointly Funded Projects).

(21) Guide 21—Review of Audit Reports.

(22) Guide 22—Delinquent Accounts Positive Action Plan.

(23) Guide 23—Agreement for Joint Use of Electric System Poles.

(24) Guide 24—Minimum Suggested Contents of Management Agreements.

(25) Guide 25—Joint Policy Statement Between EPA and FmHA.

(26) Guide 26—Community Programs Project Selection Criteria.

(b) These guides are for use by FmHA officials, applicants and applicant's officials and/or agents on certain matters related to the planning, development, and operation of essential community facilities which involve the use of loans and/or grants from FmHA. This includes activities related to applying for and obtaining such financial assistance. These guides are not published in the **Federal Register**, however, they are available in any FmHA office.

**§§ 1942.21–1942.49 [Reserved]**

**§ 1942.50 OMB control number.**

The collection of information requirements in this regulation has been approved by the Office of Management and Budget and assigned OMB control number 0575–0015.

**Subpart G—Industrial Development Grants**

**§ 1942.322 [Amended]**

5. In § 1942.322, paragraph (b), remove the words "§ 1942.20 of" from the first sentence.

**Subpart H—Development Grants for Community Domestic Water and Waste Disposal Systems**

**§ 1942.368 [Amended]**

6. In § 1942.368, paragraph (c) and in Exhibit D, paragraph XVIII (c), change the reference from § 1942.5(d)(8)" to "§ 1942.5(d)(6)."

**Subpart I—Resource Conservation and Development (RCD) loans and Watershed (WS) loans and Watershed Advances**

7. In § 1942.409, paragraphs (a), (e) and (f) are revised to read as follows:

**§ 1942.409 Security, feasibility, evidence of debt, title, insurance and other requirements.**

(a) *Security*—WS loans, WS advances and RCD loans will be secured in accordance with applicable provision of 1942.17(g).

* * * * *

(e) *National flood insurance*—The requirements of the National Flood Insurance Act of 1968 as amended by the Flood Disaster Protection Act of 1973 will be complied with in accordance with the applicable provisions of FmHA Instruction 1901–L. Also see § 1942.18(d)(1)(i).

(f) *Borrower contracts and bonds.* See § 1942.18 (e), (i) and (n)(3) of Subpart A of Part 1942 for applicable provisions.

* * * * *

(7 U.S.C. 1989; 7 CFR 2.23; 7 CFR 2.70)

Dated: October 25, 1984.

**Dwight O. Calhoun,**

*Acting Administrator, Farmers Home Administration.*

[FR Doc. 85–4106 Filed 2–21–85; 8:45 am]

BILLING CODE 3410–07–M

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**Animal and Plant Health Inspection Service**

**9 CFR Part 94**

**[Docket No. 84–115]**

**Change in Disease Status of Great Britain Because of Viscerotropic Velogenic Newcastle Disease**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Interim rule.

**SUMMARY:** This document amends the regulations concerning the importation into the United States of carcasses of certain birds and poultry, and parts or products thereof, and of certain eggs by adding Great Britain (England, Scotland, Wales, and the Isle of Man) to the list of countries declared to be free of viscerotropic velogenic Newcastle disease (VVND). It has been determined that VVND has now been eradicated from Great Britain. The effect of this action is to relieve certain restrictions on the importation into the United States from Great Britain of carcasses of certain birds and poultry, and parts or products thereof, and of certain eggs.

**DATES:** Effective date February 19, 1985. Written comments must be received on or before April 23, 1985.

**ADDRESSES:** Written comments should be submitted to Thomas O. Gessel, Director, Regulatory Coordination Staff, APHIS, USDA, Room 728, Federal Building, Hyattsville, MD 20782. Written comments may be inspected at Room 728 of the Federal Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

**FOR FURTHER INFORMATION CONTACT:** Dr. Samuel S. Richeson, Import-Export Animals and Products Staff, VS, APHIS, USDA, Room 843, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–8172.

**SUPPLEMENTARY INFORMATION:**

**Background**

The regulations in 9 CFR Part 94 (the regulations) regulate the importation into the United States of specified animals and animal products in order to prevent the introduction into the United States of various diseases, including viscerotropic velogenic Newcastle disease (VVND). VVND is a communicable viral disease affecting all species of poultry and birds.

Section 94.6(a)(1) of the regulations provides that VVND is considered to exist in all countries of the world, except those countries listed in § 94.6(a)(2). Prior to the effective date of this document, Great Britain (England, Scotland, Wales and the Isle of Man) was not listed as a country considered to be free of VVND. However, Great Britain has requested that the Department amend the regulations to include Great Britain in the list of countries considered to be free of VVND.

Based on extensive surveys conducted by the government of Great Britain, it has been determined that VVND has been eradicated from Great Britian, and that there is no reason to believe that VVND exists in Great Britain. Further, Great Britain has an effective program (including ongoing surveys, and quarantine requirements on the importation of birds and poultry) for helping to ensure that VVND does not become established in Great Britain. Therefore, this document adds Great Britain to the list of countries in § 94.6(a)(2) considered to be free of VVND.

As a result of this action, the restrictions of § 94.6 no longer apply to the importation of carcasses of certain birds and poultry, or parts of products thereof, or of certain eggs other than hatchings eggs (the regulations in 9 CFR Part 94 do not apply to hatching eggs), which originate in Great Britain and are shipped to the United States directly from Great Britain.

**Emergency Action**

Dr. J. K. Atwell, Deputy Administrator of the Animal and Plant Health Inspection Service for Veterinary Services, has determined that an emergency situation exists which warrants publication of this interim rule without prior opportunity for a public comment period. Great Britain has been found to be free of VVND. Therefore, these amendments should be made effective immediately in order to relieve unnecessary restrictions on the importation of carcasses of certain birds and poultry, and parts or products thereof, and of certain eggs into the United States from Great Britain.

Therefore, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this emergency action is unnecessary and contrary to the public interest, and good cause is found for making this emergency action effective upon signature. Comments have been solicited for 60 days after publication of this document, and a final document discussing comments received and any amendments required will be published in the **Federal Register.**

**Executive Order 12291 and Regulatory Flexibility Act**

This action has been reviewed in accordance with Executive Order 12291 and has been determined to be not a "major rule." The Department has determined that this rule will not have a significant annual effect on the economy; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will have no 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.

For this rulemaking action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

It is anticipated that the amounts of carcasses of poultry and birds, or parts or products thereof, or eggs that will be imported into the United States from Great Britain as a result of this action will be less than one percent of the amounts of these items utilized in the United States annually. Further, the importation of any of these items from Great Britain is not the primary activity of any business in the United States.

Under the circumstances explained above, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

**List of Subjects in 9 CFR Part 94**

Animal diseases, imports, livestock and livestock products, meat and meat products, milk, poultry and poultry products, Exotic Newcastle Disease.

## PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), NEWCASTLE DISEASE (AVIAN PNEUMOENCEPHALITIS), AFRICAN SWINE FEVER, AND HOG CHOLERA: PROHIBITED AND RESTRICTED IMPORTATIONS

**§ 94.6 [Amended]**

Accordingly, 9 CFR Part 94 is amended by adding "Great Britain (England, Scotland, Wales, and the Isle of Man)," immediately after "Finland" in paragraph (a)(2) of § 94.6

Authority: Sec. 2, 32 Stat. 792, as amended; sec. 306, 46 Stat. 689, as amended; secs. 2, 3, 4, 11, 76 Stat. 129, 130, 132; 19 U.S.C. 1306; 21 U.S.C. 111, 134a, 134b, 134c, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Done at Washington, D.C., this 19th day of February, 1985.

J.K. Atwell,

*Deputy Administrator, Veterinary Services.*

[FR Doc. 85–4320 Filed 2–21–85; 8:45 am]

BILLING CODE 3410-34-M

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**9 CFR Part 94**

**[Docket No. 84–116]**

## Swine, Pork and Pork Products Imported from Great Britain

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Interim rule.

**SUMMARY:** This document amends the regulations concerning the importation into the United States of swine, pork, and pork products by adding Great Britain (England, Scotland, Wales, and the Isle of Man) to the list of countries declared to be free of swine vesicular disease (SVD). It has been determined that SVD has now been eradicated from Great Britain. This document also amends the regulations to add Great Britain to the list of countries free of SVD which are subject to special restrictions on the importation of their pork and pork products into the United States. This is necessary to protect

against the introduction into the United States of certain diseases. The overall effect of this action is to relieve certain restrictions on the importation into the United States of swine, pork, and pork products from Great Britain.

**DATES:** Effective date February 19, 1985. Written comments must be received on or before April 23, 1985.

**ADDRESSES:** Written comments should be submitted to Thomas O. Gessel, Director, Regulatory Coordination Staff, APHIS, USDA, Room 728, Federal Building, Hyattsville, MD 20782. Written comments may be inspected at Room 728 of the Federal Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

**FOR FURTHER INFORMATION CONTACT:** Dr. Samuel S. Richeson, Import-Export Animals and Products Staff, VS, APHIS, USDA, Room 843, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-8172.

**SUPPLEMENTARY INFORMATION:**

**Background**

The regulations in 9 CFR Part 94 (the regulations) regulate the importation into the United States of specified animals and animal products in order to prevent the introduction into the United States of various diseases, including swine vesicular disease (SVD). SVD is an acute, highly infectious viral disease of swine. It is characterized by vesicular lesions and subsequently by erosions of the epithelium of the mouth, nares, snout, and feet.

Section 94.12(a) of the regulations provides that SVD is considered to exist in all countries of the world, except those countries listed in § 94.12(a). Prior to the effective date of this document, Great Britain (England, Scotland, Wales and the Isle of Man) was not listed as a country considered to be free of SVD. However, Great Britain recently requested that the Department amend the regulations to include Great Britain in the list of countries considered to be free of SVD.

Based on surveys conducted by the government of Great Britain, it has been determined that SVD has been eradicated from Great Britain, and that there is no reason to believe that SVD exists in Great Britain. The last outbreak of SVD reported in Great Britain was in 1982. The affected animals were promptly destroyed and there have been no cases of SVD reported in Great Britain since 1982. Therefore, this document adds Great Britain to the list of countries in § 94.12(a) considered to be free of SVD.

This document also adds Great Britain to the list in § 94.13 of countries free of SVD which are subject to special restrictions on the importation of their pork and pork products into the United States. Section 94.13 of the regulations imposes restrictions on the importation into the United States of pork and pork products from countries listed in that section which are declared to be free of SVD in § 94.12(a); and which either supplement their national pork supply by the importation of fresh, chilled, or frozen pork from countries where SVD or other vesicular diseases, such as foot-and-mouth disease, are considered to exist; or which have a common border with such countries; or which have certain trade practices that are less restrictive than are acceptable to the United States. Great Britain supplements its national pork supply by the importation of fresh, chilled, or frozen pork from countries where a vesicular disease is considered to exist. Thus, without compliance with the special restrictions in § 94.13, the pork or pork products produced in Great Britain may be commingled with fresh, chilled, or frozen meat of animals from a country where a vesicular disease is considered to exist. Shipment of such commingled pork or pork products into the United States could present an undue risk of the introduction of a vesicular disease.

The overall effect of this action is to relieve certain restrictions set forth in § 94.12 and 94.14 on the importation into the United States of swine, pork, and pork products from Great Britain.

**Emergency Action**

Dr. John K. Atwell, Deputy Administrator of the Animal and Plant Health Inspection Service for Veterinary Services, has determined that an emergency situation exists which warrants publication of this interim rule without prior opportunity for public comment.

Great Britain has been found to be free of swine vesicular disease. Therefore, these amendments should be made effective immediately in order to relieve unnecessary restrictions on the importation of swine, pork, and pork products into the United States from Great Britain.

Therefore, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this emergency action are unnecessary and contrary to the public interest, and good cause is found for making this emergency action effective upon signature. Comments have been solicited for 60 days after publication of this document and a final document discussing comments received and any amendments required will be published in the **Federal Register.**

**Executive Order 12291 and Regulatory Flexibility Act**

This action has been reviewed in accordance with Executive Order 12291 and has been determined to be not a "major rule." The Department has determined that this rule will not have a significant annual effect on the economy; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will have no 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.

For this rulemaking action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

It is anticipated that the amount of swine, pork, or pork products imported into the United States from Great Britain as a result of this action will be less than one percent of the amount of these items imported into the United States annually. Further, the importation of any of these items from Great Britain is not the primary business activity of any business in the United States.

Under the circumstances explained above, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

**List of Subjects in 9 CFR Part 94**

Animal diseases, Imports, Livestock and livestock products, Meat and meat products, Milk, Poultry and poultry products, Swine Vesicular Disease.

## PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), NEWCASTLE DISEASE (AVIAN PNEUMOENCEPHALITIS), AFRICAN SWINE FEVER, AND HOG CHOLERA: PROHIBITED AND RESTRICTED IMPORTATIONS

Accordingly, 9 CFR Part 94 is amended as follows:

1. Paragraph (a) of § 94.12 is revised to read:

**§ 94.12 Pork and pork products from countries where swine vesicular disease exists.**

(a) Swine vesicular disease is considered to exist in all countries of the world except Australia, Bahama Islands, Bulgaria, Canada, Central American

countries, Denmark, Dominican Republic, Finland, Great Britain (England, Scotland, Wales, and the Isle of Man), Greenland, Haiti, Hungary, Iceland, Luxembourg, Mexico, New Zealand, Northern Ireland, Norway, Panama, Republic of Ireland, Rumania, Sweden, Switzerland, Trust Territories of the Pacific Islands, and Yugoslavia.

* * * * *

**§ 94.13 [Amended]**

2. In the first sentence of § 94.13, "Bahama Islands, Luxembourg, Hungary, Yugoslavia, Switzerland, and Bulgaria" is amended to read "Bahama Islands, Bulgaria, Great Britain (England, Scotland, Wales, and the Isle of Man), Hungary, Luxembourg, Switzerland, and Yugoslavia".

**Authority:** Sec. 2, 32 Stat. 792, as amended; sec. 306, 46 Stat. 689, as amended; secs. 2, 3, 4, 11, 76 Stat. 129, 130, 132; 19 U.S.C. 1306; 21 U.S.C. 111, 134a, 134b, 134c, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

Done at Washington, D.C., this 19th day of February, 1985.

J.K. Atwell,

*Deputy Administrator, Veterinary Services.*

[FR Doc. 85-4321 Filed 2-21-85; 8:45 am]

BILLING CODE 3410-34-M

## FARM CREDIT ADMINISTRATION

### 12 CFR Part 602

### Releasing Information

**AGENCY:** Farm Credit Administration.

**ACTION:** Final rule.

**SUMMARY:** The Farm Credit Administration ("FCA"), by its Federal Farm Credit Board ("Federal Board"), adopts amendments to existing regulations relating to testimony concerning official matters and production of official documents of the FCA in legal proceedings in which the FCA is not a named party. The amended regulations set forth requirements and procedures applicable to FCA employees and third parties in such matters. The amendments delete §§ 602.225 and 602.230 and add Subpart C to Part 602 of Chapter VI of Title 12 of the Code of Federal Regulations.

**EFFECTIVE DATE:** March 25, 1985.

**FOR FURTHER INFORMATION CONTACT:** Kathleen M. Mullarkey, Office of General Counsel, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102-5090, (703) 883-4020.

**SUPPLEMENTARY INFORMATION:** On August 6, 1984, FCA noticed and published for public comment proposed amendments to 12 CFR Part 602 (49 FR 31293-31295) which deleted §§ 602.225 and 602.230 and added Subpart C. The amended regulations prescribe the policies and procedures to be followed with respect to testimony concerning official matters and production of official documents of the FCA in legal proceedings in which the FCA is not a named party.

Seven parties commented on the proposed regulations, representing seven Farm Credit Districts. After careful consideration of all comments received, the Federal Board adopted final regulations in the course of its October 1984 meeting.

The comments received are as follows. Several parties recommended that the language "legal proceedings not involving the Farm Credit Administration" be clarified since, while it may not be a named party, the FCA could be "involved" in litigation. The Federal Board agreed with this suggestion and the regulations have been changed to indicate that the regulations apply to legal proceedings in which the FCA is not a named party.

One commentator expressed some concern with the provision in § 602.285 that testimony by FCA employees will be made available only through depositions or written interrogatories, since there may be some difficulty in obtaining a deposition subpoena. The Federal Board declined to change this section because it does not believe that there are any obstacles that would prevent a party from obtaining a deposition subpoena from the appropriate court.

One party suggested that § 602.286(c) be clarified to make clear whether the section is applicable to "anyone" or those persons making a request for documents pursuant to the regulations. The Federal Board did not make any changes to this section since it believes that it is clear that the section applies only to those persons who request documents under the regulations.

It was recommended that § 602.287(f), relating to costs that will be assessed upon production of the requested documents, be amended to require payment of fees in advance. The Federal Board rejected this suggestion because it is administratively more efficient to send the documents and the bill together.

One party expressed concern that § 602.288 may place FCA employees in the position of being held in contempt of court for refusing to produce documents or give testimony in the absence of authorization from the Governor of the FCA, the head of the agency. The Federal Board believes that Government employees are afforded adequate protection by various judicial decisions that have clearly indicated that a Government employee acting on orders of the agency head cannot be held in contempt of court for refusing to turn over agency documents or give testimony and that any order of a court relating to release of official information must be directed to the head of the agency.

Several comments were received regarding § 602.289, which requires that a third party who is served with a subpoena for FCA documents notify the FCA General Counsel, inform the party issuing the subpoena or the court of the procedures set forth in the regulations for obtaining FCA documents, and decline to produce the documents in the absence of the FCA's authorization. It was suggested that this section be amended to remove the requirement that the party refuse to comply with any court order requiring production. The Federal Board agreed with this recommendation and the regulations have been modified to require that the third party notify the FCA of receipt of the subpoena and object to releasing the documents on the basis that release must be sought from the FCA. An additional comment was received with respect to this section suggesting that the regulations set forth criteria on when a credit review is "generated" or "adopted" by the FCA so third parties will know which credit reviews come within the requirements of § 602.289. The Federal Board did not think it necessary to set forth such criteria in the regulation since the adoption of any bank credit review by FCA will be done expressly in writing so that a third party will be on notice when a credit review comes within § 602.289. Also, since the term "generated" is self-explanatory, covering any report prepared by the FCA, there was no need to amend the regulations to further define this term.

One party suggested that the FCA consider including a requirement in the regulations that the FCA notify a Farm Credit System bank or association whose documents are involved of any request received pursuant to these regulations. The Federal Board felt that it was not necessary to include such a requirement in the regulations. However, the FCA does intend to notify the Farm Credit bank or association involved of its decision to release

documents after the decision has been made and offer the institution the opportunity to obtain copies of the released documents, subject to the same conditions imposed upon the requesting party.

Two commentators expressed concern about the broad nature and generality of the regulations and the possibility that the regulations shift the discovery process from a judicial forum to an administrative process. The Federal Board believes that these comments are based on a misunderstanding of the intent of the regulations and the procedures contained therein. The regulations are intended to enable the head of the agency to control the dissemination of official information. The procedures set forth in the regulations are separate from any determination of the discoverability of FCA documents under State or Federal rules of procedure. However, the procedures set forth in the regulations must be followed before a party subpoenas any FCA document or employee or presents the issue to a court for resolution. If a party follows the administrative process and is not satisfied with the information received, the discovery process then comes into play.

One party commented on the possibility that the regulations might cause the FCA to be joined as a defendant in a lawsuit in which it would not otherwise be joined so that a party could obtain necessary documents and testimony. The Federal Board found no reason to believe that the existence of these regulations will entangle the FCA in a lawsuit in which it would not otherwise have been named simply to obtain documents from FCA. Accordingly, no changes relating to this comment were made to the regulations.

**List of Subjects in 12 CFR Part 602**

Archives and records, Freedom of Information, Information, Records.

For reasons set out in the preamble, Part 602 of Chapter VI, Title 12 of the Code of Federal Regulations, is amended as follows:

1. By revising the table of contents for Part 602 to read as follows:

## PART 602—RELEASING INFORMATION

**Subpart A—Information and Records Generally**

Sec.
602.200 General rule.
602.205 Reports of Farm Credit examiners.
602.210 Lists of borrowers.
602.215 Data regarding borrowers and loan applicants.
602.220 Waiver of restrictions.
602.235 Information regarding personnel.
602.245 Official records generally.

**Subpart B—Availability of Records of the Farm Credit Administration**

602.250 Official records of the Farm Credit Administration.
602.251 Current index.
602.255 Identification of records requested.
602.260 Request for records.
602.261 Response to requests for records.
602.265 Fees for provision of records.

**Subpart C—Testimony and Production of Documents in Legal Proceedings in Which the Farm Credit Administration Is Not a Named Party**

602.280 General purposes.
602.281 Definitions.
602.282 General policy.
602.283 Request for testimony or production of documents.
602.284 Scope of permissible testimony.
602.285 Manner in which testimony is given.
602.286 Manner in which documents will be produced.
602.287 Fees.
602.288 Responses to demands served on FCA employees.
602.289 Responses to demands served on non-FCA employees or entities.

Authority: Secs. 5.9, 5.12, 5.18, Pub. L. 92-181, 85 Stat. 619, 620, 621, 12 U.S.C. §§ 2243, 2246, 2252.

**§ 602.225 [Removed]**

2. By removing § 602.225.

**§ 602.230 [Removed]**

3. By removing § 602.230.

4. By adding a new Subpart C to read as follows:

## Subpart C—Testimony and Production of Documents in Legal Proceedings in Which the Farm Credit Administration Is Not a Named Party

**§ 602.280 General purposes.**

The purposes of these rules are to maintain the confidentiality of official documents and information of the Farm Credit Administration, conserve the time of Farm Credit Administration employees for their official duties, maintain the impartial position of the Farm Credit Administration in litigation in which the Farm Credit Administration is not a named party, and enable the Governor to determine when to authorize testimony and to produce documents in legal proceedings in which the Farm Credit Administration is not a named party. This Subpart sets forth the procedures to be followed with respect to testimony concerning official matters and production of official documents of the Farm Credit Administration in legal proceedings in which the Farm Credit Administration is not a named party. This Subpart in no way affects the rights and procedures governing public access to official documents pursuant to the Freedom of Information Act or the Privacy Act. *See* 12 CFR Parts 602, Subpart B and 603.

**§ 602.281 Definitions.**

For the purpose of this Subpart:

(a) "FCA" means the Farm Credit Administration.

(b) "Governor" means the Governor of the FCA or his or her designee.

(c) "General Counsel" means the General Counsel of the FCA or his or her designee.

(d) "Official" means concerning the authorized business of the FCA.

(e) "Legal proceeding" means any admininstrative, civil, or criminal proceeding, including a discovery proceeding therein, before a court of law, administrative board or commission, hearing officer, or other body in which the FCA is not a named party or in which the FCA has not instituted the administrative investigation or administrative hearing.

(f) "Document" means any record or paper, including but not limited to a report, credit review, audit, letter, telegram, memorandum, study, calendar and diary entry, log, graph, pamphlet, note, chart, tabulation, analysis, statistical or information accumulation, any kind of record of meetings and conversations, film impression, magnetic tape, or any electronic media, disk, film or mechanical reproduction that is generated, obtained or adopted by the FCA in connection with the conduct of its official business.

(g) "Employee" means any officer, former officer, employee or former employee of the FCA, any member or former member of the Federal Farm Credit Board, any receiver appointed by the FCA, or any agent or independent contractor acting on behalf of the FCA, even though the appointment or contract has terminated.

(h) "Demand" means any order, subpoena or other legal process for testimony or documents.

(i) "FCA Counsel" means the General Counsel or his or her designee, a Department of Justice attorney, or counsel authorized by the FCA to act on behalf of the FCA or an employee.

(j) "Court" means an entity conducting a legal proceeding.

(k) "Person" means any individual, or any agency, corporation, partnership, trust, association, joint venture, pool, syndicate, sole proprietorship,

unincorporated organization, or any other form of entity not specifically listed herein but does not include the FCA or any FCA employee.

**§ 602.282 General policy.**

It is the policy of the FCA that official documents will not be voluntarily produced and that FCA employees will not voluntarily appear as witnesses in any legal proceeding. Under appropriate circumstances, the Governor may grant exceptions in writing to this policy when the Governor determines that the disclosure of official documents or testimony would be in the best interest of the FCA or in the public interest.

**§ 602.283 Request for testimony or production of documents.**

(a) No FCA employee shall give testimony concerning official matters nor produce any official documents in any legal proceeding without the prior written authorization of the Governor.

(b) If testimony by an FCA employee concerning official matters or the production of official documents is desired, the requesting party or his or her counsel shall submit a letter to the Governor setting forth the title of the case, the forum, the requesting party's interest in the case, a summary of the issues in the litigation, the reasons for the request, and a showing that the desired testimony, documents, or information are not reasonably available from any other source. If an appearance or testimony is requested, the letter shall also set forth the intended use of the testimony, a general summary of the scope of the testimony requested, and a showing that no document could be provided and used in lieu of the testimony or other appearance requested.

(c) The General Counsel is authorized to consult with the requesting party or his or her counsel to (1) refine and limit the request so that compliance is less burdensome, or (2) obtain information necessary to make the determination described in section 602–282 of this Subpart. Failure of the requesting party or his or her counsel to cooperate in good faith with the General Counsel to enable the Governor to make an informed determination under this Subpart may serve as the basis for a determination not to comply with the request.

**§ 602–284 Scope of permissible testimony.**

(a) The scope of permissible testimony by an FCA employee is limited to that set forth in the written authorization granted that employee by the Governor.

(b) FCA employees are not authorized to give opinion testimony. The FCA, as the regulatory agency charged with the responsibility of examining and auditing, supervising and regulating the banks and associations and other institutions organized or chartered under the Farm Credit Act of 1971, as amended, relies on the ability of its employees to gather full and complete information in order to carry out its statutory responsibilities. The use of FCA employees to give opinion testimony would hamper the FCA's ability to carry out its statutory responsibilities and would cause a serious administrative burden on the FCA's staff.

**§ 602.285 Manner in which testimony is given.**

(a) Authorized testimony of FCA employees will be made available only through depositions or written interrogatories. FCA employees are not authorized to appear and testify in court or to give interviews prior to a deposition or otherwise.

(b) Where, in response to a request, the Governor determines that circumstances warrant authorizing testimony by an FCA employee, the requesting party shall cause a subpoena to be served on the employee in accordance with applicable Federal or State rules of procedure, with a copy of the subpoena sent by registered mail to the General Counsel.

(c) Normally, authorized depositions will be taken at the FCA office to which the employee is assigned, and at a time arranged with the employee that is reasonably fixed to avoid substantial interference with the performance of the employee's duties.

(d) Upon completion of the deposition of an FCA employee, a copy of the transcript of the testimony shall be furnished at the expense of the party requesting the deposition to the General Counsel for the FCA's files.

**§ 602.286 Manner in which documents will be produced.**

(a) An FCA employee's authorization to produce official documents is limited to the authority granted that employee by the Governor.

(b) Prior to the release of any official documents authorized by the Governor to be released, the requesting party shall obtain a protective order satisfactory in form to the FCA from the court before which the action is pending to preserve the confidentiality of the documents subsequently produced.

(c) Certified or authenticated copies of official FCA documents authorized by the Governor to be released under this Subpart will be provided upon request.

**§ 602.287 Fees.**

Unless waived or reduced, the following fees shall be charged for documents produced by the FCA in connection with requests subject to this subpart:

(a) *Searches for documents.* $1.50 for each one-quarter hour (or fraction thereof) per employee for time spent by clerical personnel in excess of the first quarter hour and $3.15 for each one-quarter hour (or fraction thereof) per employee for time spent by professional or managerial personnel in excess of the first quarter hour in locating, examining, preparing or copying the documents, and for transportation of personnel and documents necessary to the search.

(b) *Copying of documents.* Ten cents per copy of each page made by photocopy or similar process. Normally, only one copy will be provided. Additional copies will be provided only upon a showing of demonstrated need.

(c) *Certification or authentication of documents.* $3.00 per certification or authentication.

(d) *Computer searches.* Services of personnel in the nature of a computer search shall be charged for at rates prescribed in paragraph (a) of this section. A charge shall be made for the computer time involved, based upon the prevailing level of costs to the FCA and upon the particular types of computer and associated equipment and the amount of time that such equipment is utilized. A charge shall also be made for any substantial amount of special supplies or materials used to contain, present, or make available the output of computers, based upon prevailing levels of costs to the FCA and upon the type and amount of such supplies or materials that are used.

(e) *Other costs.* When other services and materials not specifically identified in this section are requested and provided, their actual cost to the FCA shall be charged.

(f) *Payment of fees.* A bill will be forwarded to the requesting party upon completion of the production. Payment shall be made by check or money order payable to the FCA.

**§ 602.288 Responses to demands served on FCA employees.**

(a) Any FCA employee who is served with a demand in a legal proceeding shall immediately notify the General Counsel of such service, of the testimony or documents described in the demand and of all relevant facts.

(b) When authorization to testify or to produce documents has not been granted by the Governor, FCA counsel shall provide the party issuing the demand or the court with a copy of the regulations contained in this Subpart and shall inform the party issuing the demand or the court that the employee upon whom the demand has been made is prohibited from testifying or producing documents without the prior approval of the Governor.

(c) If the court rules that the demand must be complied with irrespective of instructions from the Governor not to produce the documents or disclose the information sought, the FCA employee upon whom the demand has been made shall respectfully decline to comply with the demand.

(d) A determination under this subpart to comply or not to comply with any demand shall not constitute an assertion or waiver of privilege, lack of relevance, technical deficiencies or any other ground for noncompliance. The FCA reserves the right to oppose any demand on any legal ground independent of its determination under this subpart.

**§ 602.289 Responses to demands served on non-FCA employees or entities.**

(a) FCA reports of examination or audits, or credit reviews generated or adopted by the FCA, or any documents related thereto are the property of the FCA and are not to be disclosed to any person without the FCA's consent.

(b) If any person who has possession of an FCA report of examination or audit, or a credit review generated or adopted by the FCA, or any documents related thereto is served with a demand in a legal proceeding directing that person to produce such FCA documents or to testify with respect thereto, such person shall immediately notify the FCA General Counsel of such service, of the testimony and documents described in the demand and of all relevant facts. Such person shall also object to the production of such documents or information contained therein on the basis that the documents are the property of the FCA and cannot be released without FCA's consent and that their production must be sought from the FCA following the procedures set forth in §§ 602.283 (b) and (c), and 602.286(b) of this subpart.

Donald E. Wilkinson,

*Governor.*

[FR Doc. 85-3907 Filed 2-21-85; 8:45 am]

BILLING CODE 6705-01-M

## DEPARTMENT OF ENERGY

## Federal Energy Regulatory Commission

## 18 CFR Parts 270, 271, 272, and 273

**[Docket No. RM84-14-021 through 024, Order No. 406-B]**

## Deregulation and Other Pricing Changes on January 1, 1985, Under the Natural Gas Policy Act

Issued: February 15, 1985.

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Order denying rehearing and clarifying previous order.

**SUMMARY:** On December 21, 1984, the Federal Energy Regulatory Commission (Commission) issued Order No. 406-A, denying rehearing in part and granting rehearing in part in Docket No. RM84-14-001 *et al.* Order No. 406-A stated that certain intrastate gas contracts deregulated under section 121(a)(3) because the price is over $1.00 per MMBtu, are subject to a new ceiling price if the gas is priced under an indefinite price escalator provision. The Commission received two petitions for rehearing and one petition for rehearing or clarification of that part of the final rule. For the reasons detailed in this order, the Commission is denying the petitions for rehearing of Order 406-A, and granting clarification.

**FOR FURTHER INFORMATION CONTACT:** Peter J. Roidakis, (202) 357-8307 or Elisabeth Pendley, (202) 357-8476, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, Washington, D.C. 20426.

Before Commissioners: Raymond J. O'Connor, Chairman; Georgiana Sheldon, A. G. Sousa, Oliver G. Richard III and Charles G. Stalon.

## Order Denying Applications for Rehearing and Clarifying Previous Order

### I. Introduction

The Federal Energy Regulatory Commission (Commission) is denying applications for rehearing of Order No. 406-A,[1] which amended Order No. 406.[2] Order No. 406-A stated, among other things, that certain intrastate gas contracts that are deregulated under section 121(a)(3) of the Natural Gas Policy Act of 1978 (NGPA) are subject to a price limitation if the gas is priced under an indefinite price escalator provision. The Commission received three timely applications for rehearing or clarification of this issue.[3] For the reasons stated below and those set forth in the final rule and the first order on rehearing, this order denies rehearing and clarifies the previous order.

### II. Background

On January 1, 1985, NGPA section 121 deregulated the prices for substantial amounts of intrastate and interstate gas. Section 121(a) eliminates price controls for "new natural gas" defined in section 102(c)[4] and certain gas produced from "new, onshore production wells" under section 103.[5] Section 121(a)(3) also deregulates the price of intrastate gas under section 105 or 106(b), if the price paid for the last deliveries of such natural gas occurring on December 31, 1984, (or, if no actual deliveries occurred on that date, the price that would have been paid for deliveries) is higher than $1.00 per MMBtu.

Section 121(e), however, imposes a limitation on the price that may be collected under indefinite price escalator clauses in certain intrastate contracts otherwise deregulated by section 121(a)(3).[6]

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[1] Deregulation and Other Pricing Changes on January 1, 1985, Under the Natural Gas Policy Act, 49 FR 50637 (Dec. 31, 1984) (Order denying rehearing in part, granting rehearing in part, denying stay and making technical corrections).

[2] Deregulation and Other Pricing Changes on January 1, 1985, Under the Natural Gas Policy Act, 49 FR 46874 (Nov. 29, 1984) (Final rule).

[3] National Fuel Gas Distribution Corporation, RM84-14-022, January 16, 1985; Grace Petroleum Corporation, RM84-14-023, January 18, 1985; Shell Offshore Inc. and Shell Western E&P Inc. (Shell), RM84-14-024, January 22, 1985.

On December 20, 1984, in Docket No. RM84-14-021, Kepco, Inc. filed an untimely request for partial rehearing and partial stay of Order No. 406. Kepco's filing raised issues addressed by the Commission's final rule and previous order on rehearing. Thus, no action on Kepco's petition is necessary.

[4] "New natural gas" under section 102(c) covers three types of gas: (1) Gas produced from the Outer Continental Shelf under a lease entered into, on or after April 20, 1977; (2) gas produced from an onshore well on which surface drilling began on or after February 19, 1977, or the depth was increased by 1,000 feet on or after that date, and which is at least 2.5 miles from the nearest marker well or which is 1,000 feet deeper than the deepest completion location of any marker well within 2.5 miles; and (3) gas produced from a reservoir from which natural gas was not produced in commercial quantities before April 20, 1977, subject to certain exclusions.

[5] "New onshore production wells" under section 103(c) are onshore wells on which surface drilling began on or after February 19, 1977, and from which gas is produced from a proration unit that meets certain requirements. Section 121 deregulates on January 1, 1985, the price of gas produced from section 103 wells where the gas was not committed or dedicated to interstate commerce on April 20, 1977, and is produced from a completion location deeper than 5,000 feet.

[6] *See* 15 U.S.C. 3331(a)(3) (1982).

In general, Order No. 406 stated (1) that jurisdictional agency determinations are still necessary for section 102 and section 103 gas after January 1, 1985; (2) that first sellers may make interim collections at the agreed upon deregulated price; (3) that gas which qualifies for both a regulated and a deregulated category will be deregulated; (4) that contract prices for intrastate contracts that are above $1.00 per MMBtu by virtue of a definite price clause would not be subject to the price limitation on indefinite price escalator clauses imposed by section 121(e).

Order No. 406–A denied rehearing on all issues raised by petitioners except the one concerning intrastate contracts and the $1.00 MMBtu threshold. With respect to this one issue, Order No. 406 had provided that "where an intrastate contract contained both a fixed price term and an indefinite price term, and both were over $1.00 per MMBtu . . . the section 105(b)(3)(A) limitation would *not* apply," [7] even if the December 31, 1984, price was actually computed under the indefinite price clause. Order No. 406–A, however, granted rehearing on this issue and concluded that the section 121(e) and section 105(b)(3)(A) limitation applies to *any* indefinite price escalator clause in an existing or successor intrastate contract that was, or would have been, used to determine a contract price in excess of $1.00 per MMBtu on December 31, 1984. One petitioner requested rehearing on this issue and two petitioners requested that the Commission clarify certain issues relating to intrastate gas subject to the price limitation on indefinite price escalation clauses.

## III. Discussion

### *A. Determining Whether Certain Intrastate Gas Is Subject to the Price Limitation on Indefinite Price Escalator Clauses*

Shell Offshore Inc. and Shell Western E&P Inc. (Shell) object to the Commission's position in Order No. 406–A regarding when the price limitation on indefinite price escalator clauses would apply and state that the position taken in Order No. 406 was correct. Shell did not, however, raise any arguments in its petition for rehearing. Rather, it relied on arguments raised in its written statement and oral comments at the October 11, 1984, public hearing on the Commission's Notice of Proposed Rulemaking in this docket and on its comments filed October 17, 1984. The Commission has again reviewed Shell's statement and comments and finds that it merely agreed with the Commission's initial interpretation on this issue but made no arguments supporting its position. The Commission therefore reaffirms its position on this issue and denies Shell's application for rehearing. As stated more fully in Order No. 406–A, the text of section 121(e) and the conference report support the Commission's position that the price limitation on indefinite price escalator clauses should apply to any existing or successor intrastate contract otherwise deregulated by section 121(a)(3).

### *B. Application of Section 110 Severance Taxes to Section 105(b)(3)(A)*

One petitioner, Grace Petroleum Corporation (Grace), filed an application in the alternative, either for rehearing or clarification, on the issue of whether severance taxes are recoverable under section 110 of the NGPA in addition to the maximum lawful price established on and after January 1, 1985, pursuant to section 105(b)(3)(A).

The Commission has stated that the allowances under section 110 of the NGPA are available for gas that is regulated but is not available for gas that is deregulated under the NGPA.[8] The Commission stated that this approach is consistent with a decision by Congress to subject a substantial amount of interstate and intrastate gas to market forces after January 1, 1985. The Commission added that it made little economic sense to keep one component of the price of gas subject to a ceiling while deregulating another component, since the seller could compensate for cost limitations on the regulated component by legitimately raising the nonregulated component.

Natural gas priced under a contract subject to section 105(b)(3)(A) is subject to the new price limitation established on and after January 1, 1985, however. Therefore, the contract price is *not* price deregulated.[9] In that case, severance taxes *are* recoverable under section 110 of the NGPA without being in excess of the price limitation. Historically, gas subject to sections 105 and 106(b) was also allowed a reimbursement for severance taxes under section 110.[10] Since this gas remains subject to a price limitation, the Commission believes that it should follow the rule it established for regulated gas, not the one established for deregulated gas.[11]

### *C. Continuing Regulation Under Section 108 for Gas Qualifying Under Section 105(b)(3)(A)*

National Fuel Gas Distribution Corporation (National Fuel) is concerned that Order No. 406–A disallows collection of a section 108 stripper well gas price for section 105 gas that would otherwise be sold subject to the price limitation on indefinite price escalator clauses. Since National Fuel has misconstrued the Commission's position on this issue, the Commission will deny rehearing and clarify its position on this issue.

If natural gas is both stripper well gas and intrastate gas subject to the price limitation on indefinite price escalator clauses, the section 108 stripper well gas price may be collected. Section 105(b)(3)(D) specifically excludes the application of the price limitation on indefinite price escalator clauses found in section 105(b)(3)(A) [12] from stripper well gas.[13] Therefore, this gas may be sold subject to the limitations of section 108. If, at some future time, however, the gas is no longer qualified as production from a section 108 stripper well, then the price limitation on indefinite price escalator clauses in section 105(b)(3)(A) would apply.

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[7] Deregulation and Other Pricing Changes on January 1, 1985, Under the Natural Gas Policy Act, 49 FR 46680 (Nov. 29, 1984) (Final Rule).

[8] See Order No. 406, Deregulation and Other Pricing Changes on January 1, 1985, Under the Natural Gas Policy Act, 49 FR 46874 at 46882 (Nov. 29, 1984) (Final rule) and Order No. 407, Collection of NGPA section 110 Allowances After January 1, 1985, 49 FR 49623 (Dec. 21, 1984) (Final rule).

[9] This is consistent with the Commission's position in Order No. 406–A. In that order, the Commission said that while this gas was deregulated by section 121(a)(3) of the NGPA, it was subject to a price ceiling under section 121(e) if it was priced under an indefinite price escalator clause. If this gas is limited by the price ceiling, then it remains regulated and its first seller may collect certain production-related costs.

[10] *See* Order No. 108–B, 49 FR 17439 (April 24, 1984) ("Since the total proceeds from the sale of gas at any ceiling price (including section 105) are fungible, there are no persuasive reasons to discriminate against section 105 sellers by labeling some of the proceed from the sale of section 105 gas as 'tax reimbursements.' If collection of that ceiling price generates a severance tax liability, then section 110(a)(1) operates to permit the seller to collect a sufficient amount, contract permitting, to reimburse him for that liability.").

[11] The Commission notes that contractual authorization to collect section 110 severance taxes is necessary, however.

[12] The price cap imposed by section 121(e) is calculated using a formula found in section 105(b)(3)(A). The cap is the higher of the contract price on the date of enactment of the NGPA, adjusted for inflation, or the section 102 price with an inflation and growth adjustment.

[13] The Conference Committee Report is even more explicit in stating that section 105 gas otherwise subject to the price limitation on indefinite price escalators, but which is also stripper well gas would not be subject to the limitation on indefinite price escalator clauses, "if such gas were sold subject to the provisions of section 108." S. Rep. No. 1126, 95th Cong., 2d Sess. 83 (1978).

**List of Subjects in 18 CFR Parts 270 Through 273**

Natural gas, incentive prices.

In consideration of the foregoing as well as for the reasons set forth in the final rules in this docket, the Commission denies the applications for rehearing and clarifies the previous order. By the Commission.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 85-4380 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

## DEPARTMENT OF THE TREASURY

### Customs Service

### 19 CFR Parts 171 and 172

[T.D. 85-25]

## Customs Regulations Amendments Relating to District Directors Authority Over Fines, Penalties, and Liquidated Damages Cases

**AGENCY:** Customs Service, Treasury.

**ACTION:** Final rule.

**SUMMARY:** This document amends the Customs Regulations by increasing the authority of district directors of Customs to act on petitions for relief in administrative cases involving penalties, forfeitures, or claims for liquidated damages, incurred for violations of the customs or navigation laws or regulations. The Customs Regulations are also amended to provide that the authority to act on certain supplemental petitions is retained by the Commissioner of Customs. The further delegation of authority will result in more expeditious processing of less complex cases, thereby benefiting the importing and traveling public.

**EFFECTIVE DATE:** March 25, 1985.

**FOR FURTHER INFORMATION CONTACT:** Jeremy Baskin, Miscellaneous Penalties Branch, Office of Regulations and Rulings, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229 (202-566-5746).

**SUPPLEMENTARY INFORMATION:**

### Background

Pursuant to section 618, Tariff Act of 1930, as amended (19 U.S.C. 1618), the Secretary of the Treasury is empowered to mitigate or remit fines, penalties, or forfeitures that are incurred under the customs or navigation laws. Section 623(c), Tariff Act of 1930 (19 U.S.C. 1623(c)) empowers the Secretary to cancel any charge made against a bond for breach of any condition of the bond, upon payment of a lesser amount or penalty or upon such other terms and conditions as the Secretary may deem sufficient. With certain stated exceptions, by paragraph 1(h) of Treasury Department Order No. 165, Revised (T.D. 53654), the Secretary delegated authority to the Commissioner of Customs to act on all cases where the claim for liquidated damages, fine or penalty (including the forfeiture) is not in excess of $100,000. This Order granted full mitigation authority to the Commissioner for specifically listed violations, including all liquidated damages claims.

The Commissioner, by regulation, has delegated some of his mitigation authority to district directors of Customs. Pursuant to § 171.21, Customs Regulations (19 CFR 171.21), district directors are empowered to mitigate or remit fines, penalties, or forfeitures incurred under any law administered by Customs when the total amount of fines or penalties incurred with respect to any one offense, together with the value of any merchandise subject to forfeiture, does not exceed $25,000. Under § 172.21, Customs Regulations (19 CFR 172.21), district directors may cancel claims for liquidated damages arising from breaches of the terms or conditions of any bond when the claim is $50,000 or less. For certain liquidated damages claims the district director is given full authority to act upon the claim, without regard to the amount of the claim. These claims, which include most notably the failure to file timely entry summaries, are outlined in § 172.22, Customs Regulations (19 CFR 172.22).

Pursuant to §§ 171.33 and 172.33, Customs Regulations (19 CFR 171.33, 172.33), regional commissioners of Customs are empowered to consider supplemental petitions for relief in all cases acted upon by the district directors. Such review is mandated if there has been a specific request on the part of the petitioner for reconsideration by the regional commissioner, or if the district director believes no additional relief is warranted, or if the petitioner is not satisfied with the additional relief granted by the district director.

Over the years it became clear that district directors were able to handle many of the less complex cases competently and more expeditiously than Customs Headquarters. Therefore, by notice published in the **Federal Register** on July 17, 1984 (49 FR 28883), it was proposed to amend Parts 171 and 172, Customs Regulations, to increase the district directors' authority. It was proposed that district directors be allowed to decide cases in which the liability was $100,000 or less, except with respect to violations of section 592, Tariff Act of 1930, as amended (19 U.S.C. 1592), in which the jurisdictional amount was to remain at $25,000 or less. It was also proposed that supplemental petition review authority be retained by the Commissioner if the amount of the liability was between $25,000 and $100,000 (inclusive) with respect to penalty and forfeiture cases, and between $50,000 and $100,000 (inclusive) with respect to liquidated damages cases. Regional commissioners were to have this review authority if the liability was either $25,000 or less in penalty and forfeiture cases, or $50,000 or less in liquidated damages cases.

Four comments were received in response to the notice. Three supported the granting of further mitigation authority and two also supported the retention of existing supplemental petition review authority by Customs Headquarters. A discussion of the specific comments and our responses follow.

### Discussion of Comments

*Comment:* The proposed delegation of further mitigation authority to district directors should not except cases arising under 19 U.S.C. 1592.

*Response:* We disagree. Because of the inherently complex nature of these cases, the frequent representation of alleged violators by experienced Customs counsel, and the availability of expertise at the Customs Headquarters level, it has been determined that the existing delegations of authority in these cases should be retained.

*Comment:* Since district directors are to be given mitigation authority in cases in which the liability is under $100,000, regional commissioners should be given the same authority for supplemental petition review.

*Response:* We disagree. Retention of supplemental petition review authority by Headquarters in fines, penalty, or forfeiture cases in which the liability is between $25,000 and $100,000 is essential to our functional responsibility for the fines, penalties and forfeitures program. Monitoring and oversight of Customs field operations are the central points of this functional responsibility. We have found that retaining review of such cases in the $25,000-$100,000 range is an effective method of implementing this monitoring and oversight responsibility. Also, retention of current supplemental petition review authority ensures Headquarters review of cases in which unique or precedential issues might arise.

*Comment:* One commenter is concerned that the proposed delegation

of further authority to district directors would result in a greater lack of consistency in decisions made by field offices. That commenter supports the increase in authority only if it is accompanied by an increase in training and monitoring of field personnel by Headquarters.

*Response:* As stated in the notice proposing the delegation of further mitigation authority, this delegation will be accompanied by a program for increased monitoring of the disposition of cases within field offices, as well as an expanded training program for fines and penalties personnel in the field offices. Also, it should be noted that a new Fines, Penalties and Forfeitures Handbook, which will provide comprehensive mitigation guidelines for all violations, will be published as a guide for field personnel.

Upon consideration of all comments received, and further review of the matter, it has been determined advisable to adopt the amendments as proposed.

**Executive Order 12291**

These amendments do not meet the criteria for a "major rule" as defined by section 1(b) of E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

**Regulatory Flexibility Analysis**

Pursuant to the provisions of section 605(b) of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 et seq.), it is hereby certified that the amendments set forth in this document will not have a significant economic impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

**Drafting Information**

The principal author of this document was Susan Terranova, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs Offices participated in its development.

**List of Subjects**

*19 CFR Part 171*

Administrative practice and procedure, Law enforcement, Penalties, Seizures and forfeitures.

*19 CFR Part 172*

Administrative practice and procedure, Penalties.

**Amendments to the Regulations**

Parts 171 and 172, Customs Regulations (19 CFR Parts 171, 172), are amended as set forth below.

**Alfred R. De Angelus,**

*Acting Commissioner of Customs.*

Approved: February 4, 1985.

**John M. Walker, Jr.,**

*Assistant Secretary of the Treasury.*

## PART 171—FINES, PENALTIES, AND FOREITURES

1. Section 171.21 is revised to read as follows:

**§ 171.21 Petitions acted on by district director.**

The district director may mitigate or remit fines, penalties, and forfeitures incurred under any law administered by Customs, with the exception of penalties or forfeitures incurred under the provisions of section 592, Tariff Act of 1930, as amended (19 U.S.C. 1592), on such terms and conditions as, under the law and in view of the circumstances, he shall deem appropriate, when the total amount of the fines and penalties incurred with respect to any one offense, together with the total value of any merchandise or other article subject to forfeiture or to a claim for forfeiture value, does not exceed $100,000. The district director may mitigate or remit fines, penalties, or forfeitures incurred under 19 U.S.C. 1592 when the total amount of those fines, penalties or forfeitures does not exceed $25,000.

2. Section 171.33(b)(1) is revised to read as follows:

**§ 171.33 Supplemental petitions for relief.**

* * * * *

(b) *Consideration*—(1) *Decisions of the district director.* Where the district director has the authority to grant relief in accordance with the provisions of § 171.21 and 171.22, he may grant additional relief if he believes it is warranted. If there has been a specific request on the part of the petitioner for review by the regional commissioner or Commissioner of Customs, or if the district director believes no additional relief is warranted, or if the petitioner is not satisfied with the additional relief granted by the district director, the supplemental petition, together with all pertinent documents, shall be forwarded to the regional commissioner of the region in which the district lies if the amount of the liability is $25,000 or less, or to the Commissioner of Customs if the amount of the liability is more than $25,000 but does not exceed $100,000, for reconsideration and disposition of the case, except as provided in § 171.22(c).

(R.S. 251, as amended, R.S. 5294, as amended, sec. 9, 24 Stat. 81, as amended, secs. 618, 623, 624, 641, 46 Stat. 757, as amended, 759, as amended (19 U.S.C. 66, 1618, 1623, 1624, 1641, 46 U.S.C. 7, 320))

## PART 172—LIQUIDATED DAMAGES

1. Section 172.21 is revised to read as follows:

**§ 172.21 Petitions acted on by district director of Customs.**

The district director may cancel any claim for liquidated damages incurred on such terms and conditions as, under the law and in view of the circumstances, he shall deem appropriate when the claim is $100,000 or less.

2. Section 172.33(b)(1) is revised to read as follows:

**§ 172.33 Supplemental petitions for relief.**

* * * * *

(b) *Consideration*—(1) *Decisions of the district director.* Where the district director has authority to grant relief in accordance with the provisions of § 172.21 and 172.22, he may grant additional relief if he believes it is warranted. If there has been a specific request on the part of the petitioner for review by the regional commissioner or Commissioner of Customs, or if the petitioner is not satisfied with the additional relief granted by the district director, the supplemental petition, together with all pertinent documents, shall be forwarded to the regional commissioner of the region in which the district lies if the amount of the liability is $50,000 or less, or to the Commissioner of Customs if the amount of the liability is more than $50,000 but does not exceed $100,000, for reconsideration and disposition of the case, except as provided in § 172.22(d)(3).

* * * * *

(R.S. 251, as amended, R.S. 5294, as amended, sec. 9, 24 Stat. 81, as amended, secs. 618, 623, 624, 641, 46 Stat. 757, as amended, 759, as amended (19 U.S.C. 66, 1618, 1623, 1624, 1641, 46 U.S.C. 7, 320))

[FR Doc. 85-4378 Filed 2-21-85; 8:45 am]

BILLING CODE 4820-02-M

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**Office of the Secretary**

**Office of the Assistant Secretary for Housing—Federal Housing Commissioner**

**Office of the Assistant Secretary for Public and Indian Housing**

**24 CFR Part 232**

**[Docket No. N-85-1501]**

**Announcement of Effective Dates for Recently Published Final Rules**

*Correction*

In FR Doc. 85-4047, appearing on page 6937, in the issue of Tuesday, February 19, 1985, in the third column, in paragraph number "2", in the second line, "221, 238" should read "221, 232, 238".

BILLING CODE 1505-01-M

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

**[Region II Docket No. 44; A-2-FRL-2782-2]**

**Approval and Promulgation of Implementation Plans; Commonwealth of Puerto Rico Lead Plan**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** As proposed in the Federal Register on July 2, 1984 (49 FR 27174), this action approves the Commonwealth of Puerto Rico Implementation Plan for lead. The Environmental Protection Agency has found that the Puerto Rico lead plan meets all applicable requirements under section 110 of the Clean Air Act and 40 CFR Part 51, "Requirements for preparation, adoption and submittal of implementation plans," and is, therefore, approvable. The Puerto Rico plan provides for attainment and maintenance of the national ambient air quality standards for lead throughout the Commonwealth.

**EFFECTIVE DATE:** This action will be effective on March 25, 1985.

**ADDRESSES:** Copies of the plan and the accompanying support documents are available for inspection during normal business hours at the following locations:

Environmental Protection Agency, Air Programs Branch, Region II Office, Room 1005, Jacob K. Javits Federal Building, 26 Federal Plaza, New York, New York 10278

Environmental Protection Agency, Public Information Reference Unit, 401 M Street, SW., Washington, DC 20460

Office of the Federal Register, Room 8401, 1100 L Street, NW., Washington, D.C.

Commonwealth of Puerto Rico, Environmental Quality Board, 204 Del Parque Street, Santurce, Puerto Rico 00910

**FOR FURTHER INFORMATION CONTACT:** William S. Baker, Chief, Air Programs Branch, U.S. Environmental Protection Agency, Region II, Jacob K. Javits Federal Building, 26 Federal Plaza, New York, New York 10278, (212) 264-2517

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On October 5, 1978 (43 FR 46246), the Environmental Protection Agency (EPA) promulgated at 40 CFR 50.12 national ambient air quality standards for lead. Both the primary and secondary standards were set at a concentration of 1.5 micrograms of lead per cubic meter of air, averaged over a calendar quarter. As required by section 110 of the Clean Air Act and the October 5, 1978 promulgation, it was necessary for the Commonwealth of Puerto Rico to submit a plan that provides for attainment and maintenance of the lead standards.

The general requirements for a lead plan are outlined in section 110 of the Clean Air Act and EPA regulations at 40 CFR Part 51, Subpart B. Specific requirements for developing a lead plan are the submission of air quality data, emissions data, an air quality modeling analysis, control strategies for each area exceeding the standards, a demonstration that the standards will be attained within the time frame specified by the Clean Air Act, and provisions for maintenance of the standards.

On March 16, 1984 the Chairman of the Puerto Rico Environmental Quality Board submitted to EPA a draft plan for the attainment and maintenance of the air quality standards for lead. A public hearing on this plan was held on June 6, 1984.

EPA evaluated this draft plan and, on July 2, 1984 (49 FR 27174), proposed its approval. However, this notice of proposed rulemaking pointed out that final approval would be contingent upon the adoption of the plan, including a program for the review of new or modified sources of lead. No comments were received in response to either the Commonwealth's public hearing or EPA's notice of proposed rulemaking. In a letter dated September 28, 1984 the Chairman of the Puerto Rico Environmental Quality Board submitted the final plan to EPA.

**II. The New Source Review Program for Lead**

As noted in EPA's July 2, 1984 notice of proposed rulemaking, EQB submitted as a part of its draft lead plan proposed revisions to Rule 102 of the Puerto Rico Regulations for the Control of Atmospheric Pollution. These proposed revisions were found to address adequately EPA's requirements for new source review, but required final adoption. In a December 12, 1984 letter to EPA, EQB provided the following assurances with regard to these revisions:

(1) A schedule, with interim milestones, for adopting the new source review regulations prior to March 31, 1985.

(2) A certification that if any new stationary source of lead that has a potential to emit five tons per year or more is foreseen to be built, such source will be reviewed and the permit to construct denied if the source is found to cause a violation of the lead standard.

**III. EPA's Final Action**

Based on its review of the Commonwealth of Puerto Rico lead plan, EPA finds that the Commonwealth's submittal adequately provides for the attainment of the air quality standards for lead and provides for the maintenance of these standards in all areas of the Commonwealth. Therefore, EPA is approving the Commonwealth of Puerto Rico's lead implementation plan.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review must be filed in the United States Court of Appeals for the appropriate circuit within 60 days of today. This action may not be challenged later in proceedings to enforce its requirements. (Sec. 307(b)(2).)

**List of Subjects in 40 CFR Part 52**

Air pollution control, Incorporation by Reference, Lead, Particulate matter, Intergovernmental relations.

**Note.**—Incorporation by Reference of the Implementation Plan for the Commonwealth of Puerto Rico was approved by the Director of the Federal Register on July 1, 1982.

(Secs. 110 and 301 of the Clean Air Act, as amended (42 U.S.C. 7410 and 7601))

Dated: February 15, 1985.

**Lee M. Thomas,**

*Administrator, Environmental Protection Agency.*

## PART 52—[AMENDED]

Title 40, Chapter I, Subchapter C, Part 52, *Code of Federal Regulations* is amended as follows:

### Subpart BBB—Puerto Rico

1. Section 52.2720 is amended by adding a new paragraph (c)(32) as follows:

**§ 52.2720 Identification of plans.**

* * * * *

(c) * * *

(32) An Implementation Plan for attainment of the lead standard was submitted on September 28, 1984 by the Chairman of the Puerto Rico Environmental Quality Board. On December 12, 1984, the Chairman submitted a schedule for establishing a program to review new sources of lead.

* * * * *

2. Section 52.2723 is amended by adding to the table a new column for the pollutant lead, "Pb," as follows:

**§ 52.2723 Attainment dates for national standards.**

* * * * *

| Air quality control region and nonattainment area | Pollutant | |
|---|---|---|
| | | Pb |
| Catano air basin * * * | | a |
| Guayanilla air basin * * * | | a |
| Remainder of Puerto Rico AQCR * * * | | a |

* * * * *

[FR Doc. 85-4365 Filed 2-21-85; 8:45 am]

BILLING CODE 6560-50-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 2, 21, 74, 78, 94, and 95

[Gen. Docket No. 82-334; FCC 85-49]

### Establishment of a Spectrum Utilization Policy for the Fixed and Mobile Services' Use of Certain Bands Between 947 MHz and 40 GHz

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Commission has adopted a *Second Report and Order* regarding use of the 31.0 to 31.3 GHz band. Existing technical standards are modified and a prior frequency coordination requirement is eliminated. Fixed and mobile operations will be licensed; however, no protection from harmful interference will be afforded. This action is in response to suggestions from the public for a frequency allocation with greatly reduced licensing and coordination requirements. It should encourage development of equipment and lead to expanded use of the band.

**EFFECTIVE DATE:** March 18, 1985.

**ADDRESS:** Federal Communications Commission, 1919 M Street, NW, Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Donald Draper Campbell, Office of Science and Technology, Spectrum Management Division, Frequency Allocations Branch, 202-653-8171.

**SUPPLEMENTARY INFORMATION:**

**List of Subjects**

*47 CFR Part 2*

Allocations.

*47 CFR Part 21*

Communication common carriers Point-to-point microwave Transmission.

*47 CFR Part 74*

Point-to-point microwave.

*47 CFR Part 78*

Point-to-point microwave.

*47 CFR Part 94*

Point-to-point microwave.

*47 CFR Part 95*

Point-to-point microwave.

**Second Report and Order**

In the Matter of Establishment of a spectrum utilization policy for the fixed and mobile services' use of certain bands between 947 MHz and 40 GHz. (Gen. Doc. 82-334).

Adopted: January 29, 1985.
Released: February 8, 1985.
By the Commission.

**Purpose**

1. In this *Second Report and Order* (*2nd R&O*) we are considering one issue raised in the *Notice of Proposed Rule Making* but not completed in the *First Report and Order* in this proceeding. This issue concerns the use of the 31 GHz (31.0-31.3 GHz) band.

**Background**

2. On January 13, 1983, the Commission adopted and released a *Notice of Proposed Rulemaking* (*NPRM*) in this proceeding, 48 FR 6730 (1983), proposing spectrum allocations and standards for certain microwave bands. Although a major purpose of this proposal was to develop provisions for the reaccommodation of users in the 12 GHz band (12.2-12.7 GHz) that might need to relocate to other spectrum because of the reallocation for a Direct Broadcasting Satellite service, other issues were addressed. One such issue was the future use of the 31 GHz band.

3. On September 9, 1983 the Commission adopted a *First Report and Order* (*1st R&O*) in General Docket 82-334, 48 FR 50722 (1983) that provided spectrum for the reaccommodation of existing 12 GHz fixed microwave users. In adopting the *1st R&O*, the Commission stated that a number of the issues raised in the *NPRM* would be addressed in a later phase of this proceeding. In this *2nd R&O* we are adopting rules which will permit expanded use of, and access to, the 31 GHz band by Commission licensees.[1]

**Proposals Regarding 31 GHz**

4. In the *NPRM* the Commission proposed the following for the 31 GHz band:

(1) Establish channeling plans based on 12.5 MHz and 25.0 MHz bandwidths,

(2) Place no restriction on the type of emission which may be employed,

(3) Require transmitters to maintain a frequency stability of 0.003% or better,

(4) Limit the transmitter output power to 0.05 W (both fixed and mobile operations),

(5) Place no limitations on equivalent isotropically radiated power (EIRP),

(6) Require a minimum front-to-back ratio of 38 dBi and 4 degree beamwidth for antennas, and

(7) Permit access to this spectrum by an entities, including individuals for personal communication.

We also stated that while licensing would be required no interference protection would be afforded to fixed and mobile stations operating in this band.

5. This proposal for the 31 GHz band was designed to satisfy various types of short range, fixed and mobile communications requirements. For example, an individual who wants to install a remote video security system or a private earth station could make use of this band. Also, a common carrier could utilize this band to establish a temporary radio link to bypass an existing cable facility which has been disrupted. A broadcaster or cablecaster who needs to establish a radio link between a television camera and a mobile relay station could equally find this band valuable. The proposal was

[1] The 31.0 to 31.3 GHz band is currently allocated on a primary basis to non-government Fixed and Mobile Services and on a secondary basis to both the government and non-government Standard Frequency and Time Signal-Satellite Service.

based on suggestions from commenters to the *Notice of Inquiry* in this proceeding who stated that there is a need for a spectrum allocation having greatly reduced licensing and coordination requirements.

**Comments**

6. Five parties commented on the 31 GHz band proposals. The comments can be divided according to two issues: technical standards and access provisions. With respect to the technical issues, Harris Corporation supported the Commission proposals for 31 GHz. Hughes Microwave stated that the use of the 31 GHz band should be limited to inexpensive, low performance equipment. M/A–COM, on the other hand, recommended that the frequency stability be relaxed to 0.03% and the channel bandwidth be widened to 50 MHz to support FM-video and to be consistent with the relaxed frequency stability. M/A–COM indicated that these changes would not cause any loss of frequency use since there is to be no coordination in this band.

7. Both CBS, Inc. (CBS) and Los Angeles County Department of Communications (Los Angeles) raised questions about access to the band. CBS stated individuals *per se* should not be authorized in the 31 GHz band but should be given access to spectrum above 40 GHz. While Los Angeles did not address the issue of individuals' access to the 31 GHz band, it did state that since public safety services may use the 31 GHz band, some technical standards and administrative procedures are needed to protect licensed services. Further, Los Angeles suggested that safety-of-life use should be a first priority.

**Discussion**

8. CBS did not provide any supporting documentation on why individuals should not be permitted access to this spectrum other than to state that inclusion of individuals may create congestion and strain the Commission's resources to enforce transmission standards. Likewise, Los Angeles did not support, with specific data, its contention that priority access should be given to the licensing of public safety operations at 31 GHz.

9. The Commission does not find merit in the positions of CBS and Los Angeles. As CBS correctly notes in its comments, the Commission is trying to find spectrum for those who do not fall within the traditional service categories, but yet have unfulfilled communication requirements. We continue to feel that this 300 megahertz at 31 GHz is an appropriate location for use by individuals. One of the driving forces behind this proceeding is the reduction or elimination of "type of entity" barriers, except perhaps where some special conditions exist. At present, individuals, in their own right, do not have access to spectrum allocated to the fixed or mobile services above 1 GHz. There are a number of potential applications where individuals have a need to communicate on either a one-way or two-way basis which are not practical by other means, i.e. wire. For instance, if an individual owns a receive-only earth station which could not be located next to his home, that person might want to install an interconnecting point-to-point microwave link. The Commission's Rules do not prohibit an individual to be the licensee of a transmitting or receiving earth station. Another example would be the operation of a remote video security system. There are no doubt numerous other applications where the needs of an individual could be fulfilled if individuals had access to this spectrum.

10. In the *NPRM* the Commission proposed to permit both fixed and mobile operations in the 31GHz band on a co-equal non-protected basis; that is, a licensee could not object to harmful interference being caused by any other licensed operation.[2] No specific data has been presented to indicate that it would not be in the public interest to adopt this approach. The probability of causing or receiving harmful interference at 31 GHz will be small because (a) free space and atmospheric attenuation is high, (b) transmitter power is limited to 0.05 W, and (c) a minimum front-to-back antenna gain of 38 dB is required. All of these factors, plus the expected geographic diversity of use, should limit the potential for harmful interference. If an entity does not feel that its operations can exist in an environment where there is a potential for harmful interference, then it should operate in other bands where protection is provided, e.g. 18 and 22 GHz. The Commission does not believe that there is sufficient justification to prioritize the licensing of any operation in this band, given the access approach discussed above. Therefore, the public interest would not be served by adopting Los Angeles' request to give preference to public safety applications.

11. As noted above, one commenter stated that the technical operating parameters should be relaxed from what was proposed in the *NPRM*. There was no specific objection by other parties. The Commission feels that it is appropriate to relax the frequency tolerance from 0.003% to 0.03%, to drop the proposed 12.5 MHz channeling plan, and to provide a 50 MHz channeling plan. Therefore, we are adopting in this *2nd R&O* technical standards for this band that provide for:

(a) Channeling plan based on 25 and 50 MHz bandwidths,

(b) No restriction on the type of emission which may be employed,

(c) Transmitters to maintain frequency stability of 0.03% or better,

(d) The maximum transmitter output power of 0.05 W (both fixed and mobile operations),

(e) No limitations on EIRP, and

(f) A minimum front-to-back ratio of 38 dBi and a 4 degree beamwidth for antennas.

We believe that the adoption of these standards will encourage the development of equipment for this band which is currently unused. Equipment manufacturers who feel inclined to develop equipment with a tighter tolerance will reap some benefit from using the 25 MHz channeling plan.

12. Stations will be licensed for either fixed or mobile operations.[3] Applications for fixed operations will specify the coordinates of both the transmitting and receiving stations. Applications for mobile operations will specify an area of operation. If a transmitting or receiving station is to be a permanent facility, its coordinates will be given plus a radius of operation (in kilometers). If, on the other hand, both transmitting and receiving stations will be mobile, the area of operation specified can be either a circle (defined by a point and radius) or rectangular box (defined by longitude and latitude of the sides of the rectangle).

13. The current practice is to require transmitters designed exclusively for fixed point-to-point operation to be authorized under the notification procedure. However, transmitters designed for mobile operation are authorized under the type acceptance procedure. At 31 GHz, we are permitting both fixed and mobile operation. Due to the higher frequency involved, the low

[2] "Harmful Interference: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radiocommunication service operating in accordance with these [international Radio] Regulations." (§ 2.1 Terms and Definitions.)

[3] Canadian and Mexican facilities will be afforded protection from harmful interference. Prior to licensing of domestic 31 GHz facilities located either north of Line A or west of Line C (see § 2.1 for definition of Lines A and C), those proposals will be coordinated with Canada by the Commission.

power level restriction, and the lack of any protection against harmful interference from other users, we have chosen, in this instance, to require notification for all forms of operation.

14. In this *2nd R&O* we have adopted rules which permit expanded use of, and access to, the 31 GHz band by Commission licensees. These rules include permitting individuals access to the band for the transmission of personal communication and new technical standards which will encourage the development of equipment.

**Final Regulatory Flexibility Analysis**

15. This proceeding increases the options available for the sharing of the 31 GHz band by all types of entities, including individuals. No comments were received which addressed issues specifically related to the Initial Regulatory Flexibility Analysis. The proposed rules were developed to minimize the regulatory burden on all users of this spectrum, including small businesses. Since no alternative regulatory approaches were suggested in the comments to further reduce the anticipated burden on small businesses, we see no need to modify the regulatory structure proposed in the *NPRM*.

**Administrative**

16. Accordingly, it is ordered, that pursuant to the authority of Sections 4(i), 301 and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 4(i), 301 and 303(r), that Parts 2, 21, 74, 78, 90, 94 and 95 of Chapter I of Title 47 of the Code of Federal Regulations are amended as specified in the Appendix. These amendments become effective March 18, 1985.

17. For further general information contact Donald Draper Campbell, (202–653–8171). With respect to common carrier issues contact Stephen Thompson (202–634–1854), for private radio issues contact Frederick Day (202–634–2443), for broadcast auxiliary issues contact James Durst (202–634–6307), for cable television issues contact John Wong (202–254–3420) and for general mobile radio issues contact John B. Johnston (202–632–4964).

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

Federal Communications Commission.

**William J. Tricarico,**

*Secretary.*

**Appendix**

Chapter I, Parts 2, 21, 74, 78, 90, 94 and 95 of Title 47 of the Code of Federal Regulations is amended as follows:

## PART 2—ALLOCATIONS, ASSIGNMENT, AND USE OF RADIO FREQUENCIES

1. Section 2.106 is amended by revising column (6) of the Table between 31.0 and 31.3 GHz as follows:

**§ 2.106 Table of frequency allocations.**

* * * * *

AUXILIARY BROADCASTING (74)

DOMESTIC PUBLIC FIXED (21)

CABLE TELEVISION RELAY (78)

GENERAL MOBILE RADIO (95)

PRIVATE OPERATIONAL-FIXED MICROWAVE (94)

* * * * *

## PART 21—DOMESTIC PUBLIC FIXED RADIO SERVICE

1. Section 21.100 is amended by adding new paragraph (b) as follows:

**§ 21.100 Frequencies.**

(a) * * *

(b) The provisions of this section do not apply to operations in the band 31.0 to 31.3 GHz. Operations in this band are unprotected and subject to harmful interference from other licensed operations in this band.

* * * * *

2. Section 21.107 is amended by revising all entries above 10,000 MHz in the Table in paragraph (b) as follows:

**§ 21.107 Transmitter power.**

(a) * * *

(b) * * *

| Frequency range (MHz) | Rated power output (watts) |
|---|---|
| * * * * * | |
| 10,000 to 31,000 | [1] [2] 10.0 |
| 31,000 to 31,300 | 0.05 |
| Above 31,300 | [1] 10.0 |
| * * * * * | |

3. Section 21.108 is amended by revising paragraph (c) as follows:

**§ 21.108 Antennas**

(a) * * *

* * * * *

(c) Fixed stations (other than temporary fixed stations, Multipoint Distribution Service stations, and Digital Termination Service nodal stations) operating at 2,500 MHz or higher shall employ transmitting and receiving antennas meeting the appropriate performance Standard A indicated below, except that in areas not subjected to frequency congestion antennas meeting performance Standard B may be used subject to the liabilities set forth in § 21.109(c).

ANTENNA STANDARDS

| Frequency (MHz) | Category | Maximum beam-width to 3 dB points (included angle in degrees) | Minimum antenna gain (dBi) | Minimum radiation suppression to angle in degrees from centerline of main beam in decibels | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | 5° to 10° | 10° to 15° | 15° to 20° | 20° to 30° | 30° to 100° | 100° to 140° | 140° to 180° |
| 2,500 to 5,000 | A | n/a | 36.0 | 23 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 36.0 | 20 | 24 | 28 | 32 | 32 | 32 | 32 |
| 5,000 to 10,565 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 10,615 to 10,680 | A | n/a | [2] 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | [2] 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 17,700 to 18,820 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 18,920 to 19,700 | A | n/a | [2] 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | [2] 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 21,200 to 23,600 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 31,000 to 31,300 | n/a | [1] 4.0 | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| Above 31,300 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |

[1] Digital Termination User Station antennas shall meet performance Standard B and have a minimum antenna gain of 34 dBi.

[2] The minimum front-to-back ratio shall be 38 dBi.

Note.—Stations must employ an antenna that meets the performance standards for category A, except that in areas not subject to frequency congestion antennas meeting standards for category B may be employed. Note, however, that the Commission may require the use of a high performance antenna where interference problems can be resolved by the use of such antennas.

* * * * *

4. Section 21.120 is amended by adding a sentence to the end of paragraph (a) as follows:

**§ 21.120 Authorization of transmitters.**

(a) * * * Transmitters designed for use in the 31.0 to 31.3 GHz band shall be authorized under the notification procedure.

* * * * *

5. Section 21.701 is amended by replacing the phrase "31,000- 31,200 MHz [4]" with the phrase "31,000- 31,300 MHz [15]" in the Table in paragraph (a); adding note [15] to the Table in paragraph (a); and adding new paragraph (e) as follows:

**§ 21.701 Frequencies**

(a) * * *

* * * * *

[15] Frequencies in this band are co-equally shared with stations in the Auxiliary Broadcasting (Part 74), Cable Television Relay (Part 78), Private Operational-Fixed Microwave (Part 94) and General Mobile Radio (Part 95) Services.

* * * * *

(e) 31.0 to 31.3 GHz. These frequencies are shared on a co-equal basis with other stations in the fixed and mobile services (see Parts 21, 74, 94, and 95). No interference protection is afforded to fixed or mobile stations operating in this band.

(1) 25 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,012.5 | 31,162.5 |
| 31,037.5 | 31,187.5 |
| 31,062.5 | 31,212.5 |
| 31,087.5 | 31,237.5 |
| 31,112.5 | 31,262.5 |
| 31,137.5 | 31,287.5 |

(2) 50 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,025.0 | 31,175.0 |
| 31,075.0 | 31,225.0 |
| 31,125.0 | 31,275.0 |

6. Section 21.703 is amended by revising all entries between 29,500 and 38,600 MHz in the Table in paragraph (g) as follows:

**§ 21.703 Bandwidth and emission limitations.**

* * * * *

(g) * * *

| Frequency range (MHz) | Maximum authorized bandwidth (MHz) |
|---|---|
| * * * * * | |
| 31,000 to 31,300 | 25 or 50. |
| * * * * * | |

7. Section 21.801 is amended by revising the Table in paragraph (a); adding note [6] to the Table in paragraph (a); revising the Table in paragraph (d); adding note [9] to the Table in paragraph (a); and adding new paragraph (e) as follows:

**§ 21.801 Frequencies.**

(a) * * *

6,425 to 6,525 MHz [6]
11,700 to 12,000 MHz [3]
13,200 to 13,250 MHz [1]
21,200 to 22,000 MHz [1, 2, 4, 5]
22,000 to 23,600 MHz [1, 2, 5]
31,000 to 31,300 MHz [6]

* * * * *

[6] Frequencies in this band are co-equally shared with stations in the Auxiliary Broadcasting (Part 74), Cable Television Relay (Part 78), and Private Operational-Fixed Microwave (Part 94) and General Mobile Radio (Part 95) Services.

(b) * * *

(c) * * *

(d) * * *

3,700 to 4,200 MHz [1, 9]
5,925 to 6,425 MHz [1, 5]
10,700 to 11,700 MHz [1, 6]
13,200 to 13,250 MHz [2]
21,200 to 22,000 MHz [2, 4, 7, 9]
22,000 to 23,600 MHz [2, 6, 9]
31,000 to 31,300 MHz [9]

* * * * *

[9] Frequencies in this band are co-equally shared with stations in the Auxiliary Broadcasting (Part 74), Cable Television Relay (Part 78), Private Operational-Fixed Microwave (Part 94) and General Mobile Radio (Part 95) Services.

(e) *31.0 to 31.3 GHz.* These frequencies are shared on a co-equal basis with other stations in the fixed and mobile services (see Parts 74, 78, 94, and 95). No interference protection is afforded to fixed or mobile stations operating in this band.

(1) 25 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,012.5 | 31,162.5 |
| 31,037.5 | 31,187.5 |
| 31,062.5 | 31,212.5 |
| 31,087.5 | 31,237.5 |
| 31,112.5 | 31,262.5 |
| 31,137.5 | 31,287.5 |

(2) 50 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,025.0 | 31,175.0 |
| 31,075.0 | 31,225.0 |
| 31,125.0 | 31,275.0 |

* * * * *

8. Section 21.804 is amended by adding a new entry in the Table in paragraph (d) as follows:

**§ 21.804 Bandwidth and emission limitations.**

* * * * *

(d) * * *

| Frequency range (MHz) | Maximum authorized bandwidth (MHz) |
|---|---|
| * * * * * | |
| 31,000 to 31,300 | 25 or 50. |
| * * * * * | |

## PART 74—EXPERIMENTAL, AUXILIARY AND SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTION SERVICES

1. Section 74.502 is amended by redesignating paragraphs (c) and (d) as paragraphs (d) and (e) respectively; and by adding new paragraph (c) as follows:

**§ 74.502 Frequency assignment.**

(a) * * *

* * * * *

(c) *31.0 to 31.3 GHz.* The following frequencies are available for assignment to aural broadcast STL and intercity relay stations. These frequencies are shared on a co-equal basis with other stations in the fixed and mobile services (see Parts 21, 78, 94 and 95). Applicants may use either a two-way link or one or both frequencies of a frequency pair for one-way links. No interference protection is afforded to fixed or mobile stations operating in this band.

(1) 25 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,012.5 | 31,162.5 |
| 31,037.5 | 31,187.5 |
| 31,062.5 | 31,212.5 |
| 31,087.5 | 31,237.5 |
| 31,112.5 | 31,262.5 |
| 31,137.5 | 31,287.5 |

(2) 50 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,025.0 | 31,175.0 |
| 31,075.0 | 31,225.0 |
| 31,125.0 | 31,275.0 |

* * * * *

2. Section 74.534 is amended by revising paragraph (b) as follows:

**§ 74.534 Power limitations.**

(a) * * *

(b) For stations operating in bands above 17.7 GHz, the transmitter output power shall be limited to that necessary to accomplish the function of the system. Further, the output power of a transmitter on any authorized frequency shall not exceed the following:

(1) *

| Frequency band (GHz) | Maximum transmitter output power (watts)[1] |
|---|---|
| 17.7 to 19.7 | 10.0 |
| 31.0 to 31.3 | 0.05 |

[1] Peak envelope power.

(2)

| Frequency band (GHz) | Maximum allowable EIRP (dBW) |
|---|---|
| 17.7 to 18.6 | +55.0 |
| 18.6 to 18.8 | +35.0 |
| 18.8 to 19.7 | +35.0 |
| 31.0 to 31.3 | No limit |

* * * * *

3. Section 74.536 is amended by revising paragraph (b), including the Table, as follows:

**§ 74.536 Directional antenna required.**

(a) * * *

(b) An aural broadcast STL or intercity relay station operating in either the 18 or 31 GHz band shall employ transmitting and receiving antennas meeting the appropriate performance Standard A indicated below, subject to paragraph (c) of this section.

ANTENNA STANDARDS

| Frequency (MHz) | Category | Maximum beamwidth to 3 dB points (included angle in degrees) | Minimum antenna gain (dBi) | Minimum radiation suppression to angle in degrees from centerline of main beam in decibels | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | 5° to 10° | 10° to 15°K | 15° to 20° | 20° to 30° | 30° to 100° | 100° to 140° | 140° to 180° |
| 17,700 to 19,700 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 31,000 to 31,300 | n/a | [1]4.0 | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |

[1] The minimum front-to-back ratio shall be 38 dBi.

Note.—Stations must employ an antenna that meets the performance standards for category A, except that in areas not subject to frequency congestion antennas meeting standards for category B may be employed. Note, however, that the Commission may require the use of a high performance antenna where interference problems can be resolved by the use of such antennas.

* * * * *

4. Section 74.550 is amended by adding a sentence to the end of the paragraph as follows:

**§ 74.550 Equipment authorization.**

* * * Transmitters designed for use in the 31.0 to 31.3 GHz band shall be authorized under the notification procedure.

5. Section 74.561 is amended by revising paragraph (b) as follows:

**§ 74.561 Frequency tolerance.**

(a) * * *

(b) In the bands above 17.7 GHz, the operating frequency of the transmitter shall be maintained in accordance with the following table:

| Frequency band (GHz) | Tolerance as percentage of assigned frequency |
|---|---|
| 17.7 to 19.7 | 0.003 |
| 31.0 to 31.3 | 0.03 |

6. Section 74.602 is amended by adding new paragraph (j) as follows:

**§ 74.602 Frequency assignment.**

* * * * *

(j) *31.0 to 31.3 GHz.* The following frequencies are available for assignment to television STL, television relay stations and television translator relay stations. The provisions of § 74.604 do not apply to the use of these frequencies. These frequencies are shared on a coequal basis with other stations in the fixed and mobile services (see Parts 21, 78, 94 and 95). Applicants may use either a two-way link or one or both frequencies of a frequency pair for one-way links. No interference protection is afforded to fixed or mobile stations operating in this band.

(1) 25 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,012.5 | 31,162.5 |
| 31,037.5 | 31,187.5 |
| 31,062.5 | 31,212.5 |
| 31,087.5 | 31,237.5 |
| 31,112.5 | 31,262.5 |
| 31,137.5 | 31,287.5 |

(2) 50 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,025.0 | 31,175.0 |
| 31,075.0 | 31,225.0 |
| 31,125.0 | 31,275.0 |

7. Section 74.636 is amended by revising paragraph (b) as follows:

**§ 74.636 Power limitations.**

(a) * * *

(b) For stations operating in bands 17.7–19.7 and 31.0–31.3 GHz, the transmitter output power shall be limited to that necessary to accomplish the function of the system. Further, the output power of a transmitter on any authorized frequency shall not exceed the following:

(1)

| Frequency band (GHz) | Maximum transmitter output power (watts)[1] |
|---|---|
| 17.7 to 19.7 | 10.0 |
| 31.0 to 31.3 | 0.05 |

[1] Peak envelope power.

(2)

| Frequency band (GHz) | Maximum allowable EIRP (dBW) |
|---|---|
| 17.7 to 18.6 | +55.0 |
| 18.6 to 18.8 | +35.0 |
| 18.8 to 19.7 | +55.0 |
| 31.0 to 31.3 | No limit |

**§ 74.637 [Amended]**

8. Section 74.637 is amended by replacing the phrase "17,700–19,700 MHz band" with the phrase "17,700–19,700 MHz and 31,000–31,300 HMz bands".

9. Section 74.641 is amended by revising the introductory text of paragraph (a) and the table in paragraph (a)(1) as follows:

**§ 74.641 Antenna systems.**

(a) For fixed stations operating in the 12.7–13.2 and 17.7–19.7 GHz bands, and for fixed and mobile stations operating in the 31.0–31.3 GHz bands, the following standards apply:

(1) * * *

ANTENNA STANDARDS

| Frequency (MHz) | Category | Maximum beam-width to 3 dB points (included angle in degrees) | Minimum antenna gain (dBi) | Minimum radiation suppression to angle in degrees from centerline of main beam in decibles | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | 5° to 10° | 10° to 15° | 15° to 20° | 20° to 30° | 30° to 100° | 100° to 140° | 140° to 180° |
| 12,700 to 13,250 | A | 1.0 | n/a | 23 | 28 | 35 | 39 | 41 | 42 | 50 |
| | B | 2.0 | n/a | 20 | 25 | 28 | 30 | 32 | 37 | 47 |
| 17,700 to 19,700 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 31,000 to 31,300 | n/a | [1]4.0 | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |

[1] The minimum front-to back ratio shall be 38 dBi.

NOTE.—Stations must employ an antenna that meets the performance standards for category A, except that in areas not subject to frequency congestion antennas meeting standards for category B may be employed. Note, however, that the Commission may require that use of a high performance antenna where interference problems can be resolved by the use of such antennas.

* * * * *

10. Section 74.655 is amended by adding a sentence to the end of paragraph (a) as follows:

**§74.655 Authorization of equipment.**

(a) * * * Transmitters designed for use in the 31.0 to 31.3 GHz band shall be authorized under the notification procedure.

* * * * *

11. Section 74.661 is amended by revising paragraph (e) as follows:

**§74.661 Frequency tolerance.**

* * * * *

(e) In the bands between 17.7 and 31.3 GHz, the operating frequency of the transmitter shall be maintained in accordance with the following table:

| Frequency band (GHz) | Tolerance as percentage of assigned frequency |
|---|---|
| 17.7 to 19.7 | 0.003 |
| 31.0 to 31.3 | 0.03 |

## PART 78—CABLE TELEVISION RELAY SERVICE

1. Section 78.18 is amended by a new paragraph (a)(5) as follows:

**§78.18 Frequency assignments**

(a) * * *

* * * * *

(5) *31.0 to 31.3 GHz.* These frequencies are shared on a co-equal basis with other stations in the fixed and mobile services (see Parts 21, 74, 94 and 95). No interference protection is afforded to fixed or mobile stations operating in this band.

(1) 25 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,012.5 | 31,162.5 |
| 31,037.5 | 31,187.5 |
| 31,062.5 | 31,212.5 |
| 31,087.5 | 31,237.5 |
| 31,112.5 | 31,262.5 |
| 31,137.5 | 31,287.5 |

(2) 50 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,025.0 | 31,175.0 |
| 31,075.0 | 31,225.0 |
| 31,125.0 | 31,275.0 |

* * * * *

2. Section 78.101 is amended revising paragraph (d) as follows:

**§78.101 Power limitations.**

* * * * *

(d) For stations operating in bands above 17.7 GHz, the transmitter output shall be limited to that necessary to accomplish the function of the system. Further, the output power of a transmitter on any authorized frequency shall not exceed the following:

(1)

| Frequency band (GHz) | Maximum transmitter output power (watts) [1] |
|---|---|
| 17.7 to 19.7 | 10.0 |
| 31.0 to 31.3 | 0.05 |

[1] Peak envelope power.

(2)

| Frequency band (GHz) | Maximum allowable EIRP (dBW) |
|---|---|
| 17.7 to 18.6 | +55.0 |
| 18.6 to 18.8 | +35.0 |
| 18.8 to 19.7 | +55.0 |
| 31.0 to 31.3 | no limit |

3. Section 78.105 is amended by revising the introductory text of paragraph (a) and the table in paragraph (a)(1) as follows:

**§78.105 Antenna systems.**

(a) For fixed stations operating in the 12.7–13.2 and 17.7–19.07 GHz bands, and for fixed and mobile stations operating in the 31.0–31.3 GHz bands, the following standards apply:

(1) * * *

ANTENNA STANDARDS

| Frequency (MHz) | Category | Maximum beam-width to 3 dB points (included angle in degrees) | Minimum antenna gain (dBi) | Minimum radiation suppression to angle in degrees from centerline of main beam in decibels | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | 5° to 10° | 10° to 15° | 15° to 20° | 20° to 30° | 30° to 100° | 100° to 140° | 140° to 180° |
| 12,700 to 13,250 | A | 1.0 | n/a | 23 | 28 | 35 | 39 | 41 | 42 | 50 |
| | B | 2.0 | n/a | 20 | 25 | 28 | 30 | 32 | 37 | 47 |
| 17,700 to 19,700 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 31,000 to 31,300 | n/a | [1]4.0 | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| 38,600 to 40,000 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |

[1] The minimum front-to-back ratio shall be 38 dBi.

Note.—Stations must employ an antenna that meets the performance standards for category A, except that in areas not subject to frequency congestion antennas meeting standards for category B may be employed. Note, however, that the Commission may require the use of a high performance antenna where interference problems can be resolved by the use of such antennas.

* * * * *

4. Section 78.107 is amended by adding a sentence to the end of paragraph (b) as follows:

**§78.107 Equipment and installation.**

(a) * * *

(b) * * * Transmitters designed for use in the 31.0 to 31.3 GHz band shall be authorized under the notification procedure.

* * * * *

## PART 94—PRIVATE OPERATIONAL-FIXED MICROWAVE SERVICE

1. Section 94.61 is amended by revising the entries between 23,600 and

38,600 MHz in the Table and by adding a new footnote (2) in paragraph (b) as follows:

**§ 94.61 Applicability**

(a) * * *

(b) Frequencies in the following bands are available for assignment to stations in the Private Operational-Fixed Service:

| FREQUENCY BAND (MHz) | |
|---|---|
| * * * * * | |
| 31,000 to 31,300 | ([2], [3]) |
| * * * * * | |

[3] Frequencies in this band are co-equally shared with stations in the Domestic Public Fixed (Part 21), Auxiliary Broadcasting (Part 74), Cable Television Relay (Part 78) and General Mobile Radio (Part 95) Services.

**§ 94.63 [Amended]**

2. Section 94.63 is amended by deleting the phrase "31,000–31,200 MHz" in paragraph (a).

3. Section 94.65 is amended by removing paragraph (k) and by adding new paragraphs (k) and (l), as follows:

**§ 94.65 Frequencies**

* * * * *

(k) *31.0 to 31.3 GHz.* These frequencies are shared on a coequal basis with other stations in the fixed and mobile services (see Parts 21, 74, 78 and 95). No interference protection is afforded to fixed or mobile stations operating in this band.

(1) 25 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,012.5 | 31,162.5 |
| 31,037.5 | 31,187.5 |
| 31,062.5 | 31,212.5 |
| 31,087.5 | 31,237.5 |
| 31,112.5 | 31,262.5 |
| 31,137.5 | 31,287.5 |

(2) 50 MHz authorized bandwidth channels, 150 MHz separation.

| Transmit (receive) (MHz) | Receive (transmit) (MHz) |
|---|---|
| 31,025.0 | 31,175.0 |
| 31,075.0 | 31,225.0 |
| 31,125.0 | 31,275.0 |

(l) Except as provided for in § 94.91 and § 94.65(k), frequencies in bands authorized above 21.2 GHz are not paired and will be as specified in the authorization.

4. Section 94.67 is amended by revising the Table in paragraph (a) between 19,700 and 40,000 MHz as follows:

**§ 94.67 Frequency tolerance.**

(a) * * *

| Frequency Band (MHz) | Tolerance as percentage of assigned frequency |
|---|---|
| * * * * * | |
| 21,200 to 23,600 | * 0.03 |
| 31,000 to 31,300 | 0.03 |
| 31,300 to 40,000 | 0.03 |
| * * * * * | |

5. Section 94.71 is amended by revising the Table in paragraph (b) between 23,600 and 38,600 MHz as follows:

**§ 94.71 Emission and bandwidth limitations.**

(a) * * *

(b) * * *

| Frequency Band (MHz) | Maximum authorized bandwidth |
|---|---|
| * * * * * | |
| 31,000 to 31,300 | 25 or 50 MHz. |
| * * * * * | |

6. Section 94.73 is amended by revising the Table in paragraph (a)(1) between 12,200 and 40,000 MHz; and by revising the Table in paragraph (a)(2) between 19,700 and 40,000 MHz as follows:

**§ 94.73 Power limitations.**

(a) * * *

(1) * * *

| Frequency Band (MHz) | Maximum transmitter output power (watts) |
|---|---|
| * * * * * | |
| 12,100–31,000 | * 10.0 |
| 31,000–31,300 | 0.05 |
| 31,300–40,000 | 10.0 |
| * * * * * | |

(2) * * *

| Frequency Band (MHz) | Maximum allowable EIRP (dBW) [1] |
|---|---|
| * * * * * | |
| 19,700–31,000 | * +40.0 |
| 31,000–31,300 | No limit |
| 31,300–40,000 | +40.0 |
| * * * * * | |

7. Section 94.75 is amended by revising the Table and notes in paragraph (b) as follows:

**§ 94.75 Antenna Limitations.**

* * * * *

(b) * * *

ANTENNA STANDARDS

| Frequency (MHz) | Category | Maximum beamwidth to 3 dB points (included angle in degrees) | Minimum antenna gain (dBi) | Minimum radiation suppression to angle in degrees from centerline of main beam in decibels | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | 5° to 10° | 10° to 15° | 15° to 20° | 20° to 30° | 30° to 100° | 100° to 140° | 140° to 180° |
| 952 to 960 [1] [4] | A | 14.0 | n/a | | 6 | 11 | 14 | 17 | 20 | 24 |
| | B | 20.0 | n/a | | | 6 | 10 | 13 | 15 | 20 |
| 1,850 to 2,690 [5] | A | 5.0 | n/a | 12 | 18 | 22 | 25 | 29 | 33 | 39 |
| | B | 8.0 | n/a | 5 | 18 | 20 | 20 | 25 | 28 | 36 |
| 6,525 to 6,875 | A | 1.5 | n/a | 26 | 29 | 32 | 34 | 38 | 41 | 49 |
| | B | 2.0 | n/a | 21 | 25 | 29 | 32 | 35 | 39 | 45 |
| 10,550 to 10,680 [5] | A | n/a | 36.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 36.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 12,200 to 13,250 [6] | A | 1.0 | n/a | 23 | 28 | 35 | 39 | 41 | 42 | 50 |
| | B | 2.0 | n/a | 20 | 25 | 28 | 30 | 32 | 37 | 47 |
| 17,700 to 19,700 [5] | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 21,200 to 23,600 [5] | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 31,000 to 31,300 | n/a | [7] 4.0 | n/a | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| 27,500 to 29,500 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |
| 38,600 to 40,000 | A | n/a | 38.0 | 25 | 29 | 33 | 36 | 42 | 55 | 55 |
| | B | n/a | 38.0 | 20 | 24 | 28 | 32 | 35 | 36 | 36 |

[1] Except for frequencies listed in § 94.65(a)(1) where omnidirectional antennas may be used.

[2] Except for 2,150 to 2,150 MHz, where the maximum beamwidth is 360° and except for frequencies in the 2,500 to 2,690 MHz band where standards contained in Subpart I, Part 74, of this chapter apply.

[3] Except as provided in § 94.199 for Digital Termination System antennas.

[4] Antennas used at outlying stations as part of a central protection alarm system need conform to only the following 2 standards: (1) the minimum on-beams forward gain must be at least 10 dBi, and (2) the minimum front-to-back ratio must be at least 20 dB.

[5] Except as provided in § 94.91.

[6] Except as provided in § 94.90, or for the band 13,200 to 13,250 MHz, as provided in the developmental authorization.

[7] The minimum front-to-back ratio shall be 38 dBi.

Note.—Stations must employ an antenna that meets the performance standards for category A, except that in areas not subject to frequency congestion antennas meeting standards for category B may be employed. None, however, that the Commission may require the use of a high performance antenna where interference problems can be resolved by the use of such antennas.

* * * * *

8. Section 94.81 is amended by adding a sentence to the end of the paragraph (b) as follows:

**§ 94.81 Authorization of microwave equipment.**

(a) * * *

(b) * * * Transmitters designed for use in the 31.0 to 31.3 GHz band shall be authorized under the notification procedure.

## PART 95—GENERAL MOBILE RADIO SERVICE

1. Section 95.1 is amended by designating the paragraph as paragraph (a) and adding new paragraph (b) as follows:

**§ 95.1 The General Mobile Rado Service (GMRS).**

(a) * * *

(b) Any entity eligible for licensing under this subpart is eligible to obtain an authorization in the 31.0 to 31.3 GHz band for personal communications, provided that the technical standards applicable to the band (as set out in Part 94) are observed. (Individuals applying for stations in the 31.0 to 31.3 GHz band for personal communications shall use application Form 402.)

[FR Doc. 85-4028 Filed 2-21-85; 8:45 am]
BILLING CODE 6712-01-M

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

### 49 CFR Part 501

### Organization and Delegation of Powers and Duties

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

**ACTION:** Final rule.

**SUMMARY:** This notice amends the Code of Federal Regulations' provisions on delegation of authority, to incorporate new delegations of authority arising from enactment of the Motor Vehicle Theft Law Enforcement Act of 1984.

**EFFECTIVE DATE:** February 22, 1985.

**FOR FURTHER INFORMATION CONTACT:** Stephen P. Wood, Assistant Chief Counsel for Rulemaking, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, D.C. 20590 (202-426-2992).

**SUPPLEMENTARY INFORMATION:** This notice amends Part 501 of Title 49, Code of Federal Regulations, to reflect assignments of new duties and powers within the NHTSA, resulting from the passage of the Motor Vehicle Theft Law Enforcement Act of 1984 (Pub. L. 98-547; 15 U.S.C. 2021 *et seq.*). Sec. 101(a) of Pub. L. 98-547 amends the Motor Vehicle Information and Cost Savings Act (15 U.S.C. 1901 *et seq.*) by adding a new Title VI. The powers and duties for administering the new Title are automatically delegated by the Secretary of Transportation to the Administrator of the NHTSA by the terms of 49 CFR 1.50(f). This notice delegates powers and duties from the Administrator to other officials within the agency. In addition, it corrects typographical errors in the CFR.

The amendments set forth below relate solely to the organization and assignment of duties within the agency, and have no substantive regulatory effect. Notice and public procedure are, therefore, not required, and the amendment may be made effective in less than 30 days after publication.

**List of Subject in 49 CFR Part 501**

Authority delegations, Organization and functions.

## PART 501—[AMENDED]

In consideration of the foregoing, Part 501 of Title 49, Code of Federal Regulations, is amended as set forth below:

1. Section 501.2(f) is revised to read as follows:

**§ 501.2 General.**

* * * * *

(f) Carry out the functions vested in the Secretary by the Motor Vehicle Information and Cost Savings Act, as amended (15 U.S.C. 1901 et seq.) except section 512.

* * * * *

2. Section 501.3(c) (1) and (2) are revised to read:

**§ 501.3 Organization and general responsibilities.**

* * * * *

(c) *Associate Administrators*—(1) *Associate Administrator for Rulemaking.* As the principal advisor to the Administrator on all matters as they relate to the setting of standards and regulations, administers the programs of the administration to develop and promulgate Federal standards and regulations dealing with the crash protection, crash survivability, crash avoidance of motor vehicles, the issuance of mandatory fuel economy and theft prevention standards and related procedural regulations, and the development of consumer information and regulations dealing with the crash protection and survivability characteristics, damageability, crash avoidance, ease of diagnosis and repair of motor vehicles.

(2) *Associate Administrator for Enforcement.* As the principal advisor to the Administrator on all matters as they relate to the enforcement of motor vehicle safety, fuel economy, theft prevention, and damageability laws and standards, administers programs of the administration to ensure compliance with Federal laws, standards and regulations pertinent to vehicle safety, fuel economy, theft prevention, damageability, consumer information and odometer fraud.

3. Section 501.8(d)(2), introductory text of (f), (f)(2) and (g) are revised to read:

**§ 501.8 Delegations.**

* * * * *

(d) * * *

(2) Establish the legal sufficiency of all investigations conducted under the authority of the National Traffic and Motor Vehicle Safety Act of 1966, as amended (80 Stat. 718; 15 U.S.C. 1381 *et seq.*) and under the authority of titles I, IV, and VI of the Motor Vehicle Information and Cost Savings Act of 1972, as amended (86 Stat. 947; 15 U.S.C. 1901 *et seq.*), and to compromise any civil penalty or monetary settlement resulting therefrom in an amount of $5,000 or less.

* * * * *

(f) *Associate Administrator for Rulemaking.* Except for those portions that have been reserved to the Administrator, the Associate Administrator for Rulemaking is delegated authority to exercise the powers and perform the duties of the Administrator with respect to the setting of motor vehicle safety and theft prevention standards, average fuel economy standards, procedural regulations, and the development of consumer information and regulations authorized under:

* * * * *

(2) Titles I, II, V and VI of the Motor Vehicle Information and Cost Savings Act, as amended (86 Stat. 947; 15 U.S.C. 1901 *et seq.*).

(g) *Associate Administrator for Enforcement.* Except for those portions that have been reserved to the Administrator, delegated to the Chief Counsel, or delegated to the Executive Secretary, the Associate Administrator for Enforcement is delegated authority to exercise the powers and perform the duties of the Administrator with respect to administering the NHTSA enforcement program for all laws, standards, and regulations pertinent to

vehicle safety, fuel economy, theft prevention, damageability, consumer information and odometer fraud, authorized under the National Traffic and Motor Vehicle Safety Act of 1966, as amended (80 Stat. 718; 15 U.S.C. 1381 *et seq.*), and the Motor Vehicle Information and Cost Savings Act of 1972, as amended (86 Stat. 947; 15 U.S.C. 1901).

(Delegation at 49 CFR Part 1.50.)

Issued on February 14, 1985.

**Diane K. Steed,**

*Administrator.*

[FR Doc. 85-4204 Filed 2-21-85; 8:45 am]

BILLING CODE 4910-59-M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Parts 611 and 655

**[Document No. 31220-244]**

### Foreign Fishing and Atlantic Mackerel, Squid, and Butterfish Fisheries

**AGENCY:** National Marine Fisheries Service (NMFS), NOAA, Commerce.

**ACTION:** Notice of inseason allocation of reserve.

**SUMMARY:** NOAA issues this notice to allocate 13,941 metric tons (mt) of Atlantic mackerel reserve to the total allowable level of foreign fishing (TALFF). This action is allowed by regulations implementing the Fishery Management Plan for the Atlantic Mackerel, Squid, and Butterfish Fisheries (FMP). The intended effect of the allocation is to promote full utilization of the optimum yield by all harvesters of this fishery.

**EFFECTIVE DATE:** February 22, 1985.

**FOR FURTHER INFORMATION CONTACT:** Salvatore A. Testaverde, 617-281-3600, extension 273.

**SUPPLEMENTARY INFORMATION:** Final initial specifications for the Atlantic mackerel, squid, and butterfish fisheries for the fishing year 1984-1985, effective March 30, 1984 (49 FR 13373, April 4, 1984), established a 28,500 mt reserve of mackerel. Regulations at 50 CFR Part 655 provide a mechanism to allocate all or part of the Atlantic mackerel reserve to TALFF during each fishing year. A complete discussion of these procedures is found in the supplementary information section of the notice of proposed allocation of reserve (50 FR 1890, January 14, 1985) and is not repeated here. No comments were received during the 15-day comment period provided by the proposed allocation. Therefore, the Secretary allocates a partial amount of the reserve, 13,941 mt, to the TALFF, which now will total 42,531 mt (includes 90 mt of bycatch adjustment).

Bycatch TALFF specifications for *Loligo*, *Illex*, and butterfish, will also increase, each by one percent, as follows: *Loligo*—from 12,250 mt to 12,389 mt, *Illex*—from 3,150 mt to 3,289 mt, and butterfish—from 1,111 mt to 1,250 mt.

REVISED SPECIFICATIONS FOR FISHING YEAR APRIL 1, 1984, THROUGH MARCH 31, 1985

[In metric tons (mt)]

| | *Loligo* squid | | *Illex* squid | | Butterfish | | Atlantic mackerel | |
|---|---|---|---|---|---|---|---|---|
| | Initial specifications | Adjusted specifications | Initial specifications | Adjusted specifications | Initial specifications | Adjusted specifications | Initial specifications | Adjusted specifications |
| MAX OY* | 44,000 | | 30,000 | | *16,000 | | | |
| ABC | 44,000 | | 30,000 | | 16,000 | | | |
| AC | | | | | | | 87,000 | |
| IOY | 21,125 | 30,264 | 15,750 | 16,789 | *16,000 | | [3] 83,500 | |
| DAH | 17,875 | | 13,500 | | 11,000 | | [4] 26,500 | |
| DAP | 13,000 | | 5,000 | | 11,000 | | 73,300 | |
| JVP[5] | 4,875 | | 8,500 | | | | 13,400 | |
| Reserve | 0 | 0 | 0 | 0 | 0 | 0 | 28,500 | [7] 14,559 |
| TALFF | 3,250 | 12,389 | 2,250 | 3,289 | [6] 571 | 1,250 | 28,500 | [7] 42,531 |

*Up to figure given.
* These are maximums OYs (as stated in the FMP) to which the IOYs may rise.
[5] Total sum of the initial over-the-side amount. Dose not include 3,625 mt *Loligo* or 9,700 mt *Illex* which will be available depending upon performance of joint ventures.
[3] May be increased by 3,500 mt based upon domestic performance.
[4] Includes 5,800 mt for the recreational fishery.
[6] This amount is increased as unallocated amounts of squid are allocated to TALFF and reserves of hakes and mackerel are allocated to TALFF.
[7] Amounts reflect the January 1985 reallocation of 13, 941 mt of Reserve to TALFF and an additional 90 mt of bycatch adjustment.

### Classification

This action is authorized by 50 CFR Part 655, and complies with Executive Order 12291.

### List of Subjects

*50 CFR Part 611*

Fisheries, Foreign relations, Reporting and recordkeeping requirements.

*50 CFR Part 655*

Fisheries, Reporting and recordkeeping requirements.

(16 U.S.C. 1801 *et seq.*)

Dated: February 19, 1985.

**Joseph W. Angelovic,**

*Deputy Assistant Administrator for Science and Technology, National Marine Fisheries Service.*

[FR Doc. 85-4448 Filed 2-19-85; 4:47 pm]

BILLING CODE 3510-22-M

### 50 CFR Part 671

**[Docket No. 41154-4154]**

### Tanner Crab Off Alaska; Season Closure

**AGENCY:** National Marine Fisheries Service (NMFS), NOAA, Commerce.

**ACTION:** Notice of season closure.

**SUMMARY:** The Director, Alaska Region, NMFS (Regional Director), has determined that the Tanner crab fishery in the Southwest, South Mainland, and Semidi Islands Sections of the Kodiak District of Registration Area J must be closed in order to protect Tanner crab stocks in these sections. The Secretary of Commerce (Secretary) therefore issues this notice of closure to fishing for Tanner crab by vessels of the United States in all three sections. This intended effect is to conserve Tanner crab stocks.

**DATE:** This notice is effective 12:00 noon, Alaska Standard Time (AST), February 19, 1985. Public comments on this notice of closure are invited until March 6, 1985.

**ADDRESS:** Comments should be sent to Robert W. McVey, Director, Alaska Region, National Marine Fisheries Service, P.O. Box 1668, Juneau, Alaska 99802. During the 15-day comment period, the data upon which this notice is based will be available for public inspection during business hours (8:00 a.m. to 4:30 p.m., AST, weekdays) at (1) the NMFS Kodiak Field Office, Gibson Cove, Kodiak, Alaska, and (2) the NMFS Alaska Regional Office, Federal Building, Room 453, 709 West Ninth Street, Juneau, Alaska.

**FOR FURTHER INFORMATION CONTACT:** Raymond E. Baglin (Fishery Management Biologist, Kodiak Field Office, NMFS), 907–486–3298.

**SUPPLEMENTARY INFORMATION:**

## Background

The Fishery Management Plan for the Commercial Tanner Crab Fishery off the Coast of Alaska (FMP), which governs this fishery in the fishery conservation zone under the Magnuson Fishery Conservation and Management Act (Magnuson Act), provides for inseason adjustments of season and area openings and closures. Implementing rules at 50 CFR 671.27(b) specify that notices of these adjustments will be issued by the Secretary under criteria set out in that section.

Section 671.26(f) establishes six districts within Registration Area J in order to prevent overfishing of individual Tanner crab stocks by allowing closure or partial closure of a particular district when the desired harvest level is reached. The Kodiak District is further subdivided into eight sections, also to prevent overfishing of individual Tanner crab stocks. The 1985 fishing season for all sections began on January 15. Reasons for the closures in these sections follow:

### *Southwest Section*

Approximately 14 vessels have delivered an estimated 540,000 pounds of crab through February 10. The catch of crabs per pot was less than 20 at the beginning of the season. It fluctuated from 10 to 40 crabs per pot during January, and has recently declined to less than 5 crabs per pot. The rapid decline in catch per pot and a recent increase in molting crab substantiates that the stock is at a low level and is in poor condition. It is estimated that no more than 1.02 million pounds of Tanner crab from this section should be taken, and that this harvest will be achieved on February 18, 1985, well before the scheduled April 30, 1985, closure date.

### *South Mainland and Semidi Island Sections*

Very few vessels have made deliveries from these two sections. Only 25,000 pounds have been landed from each of these sections through February 10, 1985. The few vessels that fished these sections have already departed due to the low catches obtained. The stocks are insufficient to support fisheries through the closure dates of April 30 for the South Mainland Section and May 15 for the Semidi Island Section.

In light of this information, the Regional Director, in accordance with § 671.27(b), has determined that (1) the actual conditions of Tanner crab stocks in the above sections are substantially different from conditions anticipated at the beginning of the fishing year; and (2) these differences reasonably support the need to protect those Tanner crab stocks by closing the Southwest, South Mainland, and Semidi Island Sections of the Kodiak District as defined in § 671.26(f)(1)(i). These sections are therefore closed to all fishing for Tanner crab until 12:00 noon, Alaska Daylight Time, April 30, 1985 (May 15, 1985, for the Semidi Island Section), at which time the closures of these areas prescribed in § 671.26(f)(2)(i) will begin.

These closures will become effective after this notice is filed for public inspection with the Office of the Federal Register and the closures are publicized for 48 hours through procedures of the Alaska Department of Fish and Game. Public comments on this notice of closure may be submitted to the Regional Director at the address above. If comments are received, the necessity of this closure will be reconsidered and a subsequent notice will be published in the **Federal Register**, either confirming this notice's continued effect, modifying it, or rescinding it.

## Other Matters

Tanner crab stocks in the above sections will be subject to damage by overfishing unless these closures take effect promptly. The Agency therefore finds for good cause that advance opportunity for public comment on this notice is contrary to the public interest and that no delay should occur in its effective date.

This action is taken under the authority of regulations specified at 50 CFR 671.27, and complies with Executive Order 12291. It is not subject to the requirements of the Regulatory Flexibility Act. It does not contain any collection of information requests, as defined in the Paperwork Reduction Act.

## List of Subjects in 50 CFR Part 671

Fisheries.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: February 19, 1985.

**Joseph W Angelovic,**

*Deputy Assistant Administrator for Science and Technology, National Marine Fisheries Service.*

[FR Doc. 85–4449 Filed 2–20–85; 9:48 am]

BILLING CODE 3510-22-M

# Proposed Rules

Federal Register
Vol. 50, No. 36
Friday, February 22, 1985

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.

## FEDERAL TRADE COMMISSION

### 16 CFR Part 13

[File No. 842 3099]

### Associated Dry Goods Corp.; Proposed Consent Agreement With Analysis To Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

**SUMMARY:** In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would require a New York City merchandise retailer, among other things, cease failing to disclose to an applicant who has been denied credit on the basis of information contained in a consumer report (including non-derogatory information or no file response), that the adverse action was based wholly or partly on reported information, and provide rejected applicant with the name and address of the reporting agency. The Order would additionally require that a copy of the letter attached to the Order as Appendix A be completed to include the name and address of the appropriate consumer reporting agency, and mailed within 90 days to those credit applicants who were rejected by Robinson's of Florida or Hahne, divisions of Associated Dry Goods Corporation, between January 1, 1982 and December 31, 1983, on the basis of information submitted by a consumer reporting agency.

**DATE:** Comments must be received on or before April 23, 1985.

**ADDRESS:** Comments should be directed to: FTC/Office of the Secretary, Room 136, 6th St. and Pa. Ave., NW., Washington, D.C. 20580.

**FOR FURTHER INFORMATION CONTACT:** Paul K. Davis, Atlanta Regional Office, FTC, 1718 Peachtree St., Room 1000, Atlanta, GA 30367, (404) 881–4836.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist and an explanation thereof, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(14) of the Commission's Rules of Practice (16 CFR 4.9(b)(14)).

### List of Subjects in 16 CFR Part 13

Consumer credit, Trade practices.

### United States of America Before Federal Trade Commission

[File No. 842 3099]

*Agreement Containing Consent Order To Cease and Desist*

In the Matter of Associated Dry Goods Corporation, a corporation.

The Federal Trade Commission having initiated an investigation of certain acts and practices of Associated Dry Goods Corporation, a corporation, and it now appearing that Associated Dry Goods Corporation, a corporation, hereinafter sometimes referred to as proposed respondent, is willing to enter into an agreement containing an order to cease and desist from the use of the acts and practices being investigated,

It is hereby agreed by and between Associated Dry Goods Corporation, by its duly authorized officer, and its attorney, and counsel for the Federal Trade Commission that:

1. Proposed respondent Associated Dry Goods Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Virginia, with its office and principal place of business located at 417 Fifth Avenue, New York, New York 10016.

Robinson's of Florida ("Robinson's") is a division of proposed respondent. Robinson's principal office and place of business is located at Tyrone Square, St. Petersburg, Florida.

Hahne and Company ("Hahne's") is also a division of proposed respondent. Hahne's principal office and place of business is located at 609 Broad Street, Newark, New Jersey 07101.

2. Proposed respondent admits all the jurisdictional facts set forth in the draft of complaint here attached.

3. Proposed respondent waives:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft of compliant here attached.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent: (1) Issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The

order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this agreement shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the proposed complaint and order contemplated hereby. It understands that once the order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the order. Proposed respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

*Order*

For the purposes of this Order the following definitions are applicable:

A. The terms "consumer," "consumer report," and "consumer reporting agency" shall be defined as provided in Sections 603(b), 603(d), and 603(f), respectively, of the Fair Credit Reporting Act, 15 U.S.C. 1681, 1681a(b), 1681a(d) and 1681a(f) (1970).

B. The term "no file response" shall be defined as a consumer report consisting of a response by a consumer reporting agency to respondent's request for information on a given applicant indicating that the consumer reporting agency has no credit history information in its files under the name and other identifiers supplied.

C. The term "non-derogatory information" shall be defined as information in a consumer report furnished to respondent by a consumer reporting agency, consisting of the presence of new credit accounts with credit histories too short to meet the respondent's criteria for granting credit, insufficient credit history, or insufficient credit file.

I

It is ordered that respondent Associated Dry Goods Corporation, a corporation, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with any application for credit that is primarily for personal, family or household purposes, do forthwith cease and desist from:

1. Failing, whenever credit for personal, family or household purposes involving a consumer is denied wholly or partly because of information contained in a consumer report from a consumer reporting agency (including non-derogatory information or no file response), to disclose to the applicant at the time the adverse action is communicated to the applicant: (a) That the adverse action was based wholly or partly on information contained in such a report and (b) the name and address of the consumer reporting agency making the report.

2. Failing, within ninety (90) days after the date of service of this Order, to mail a copy of the letter attached hereto as Appendix A, completed to provide the name and address of the consumer reporting agency supplying the report, to each applicant who was denied credit by Robinson's of Florida or Hahne's between January 1, 1982, and December 31, 1983, based in whole or in part on information contained in a consumer report from a consumer reporting agency (including applicants denied credit based in whole or in part on non-derogatory information or no file response.) The letter shall be sent by first class mail to the last known address of the applicant which is reflected in respondent's files. *Provided*, however, if the applicant was later extended credit or given the notice required by Section 615(a) of the Fair Credit Reporting Act, a copy of the letter attached as Appendix A need not be sent. Nothing in this Order shall prohibit respondent from adding to Appendix A a paragraph that resolicits the previously rejected applicants.

II

It is further ordered that respondent, its successors, and assigns shall maintain the following:

1. For at least two (2) years, documents that will demonstrate compliance with the requirements of Paragraph I.1. of this Order.

2. For at least three (3) years, documents that will demonstrate compliance with the requirements of Paragraph I.2. of this Order.

Upon request, such documents shall be made available to the Federal Trade Commission for inspection and copying. Such documents shall include, but are not limited to, all credit evaluation criteria instructions given to employees regarding compliance with the provisions of this Order, any notices provided to consumers pursuant to any provisions of this Order, and the complete application file to which they relate.

III

It is further ordered that Robinson's of Florida and Hahne's shall deliver a copy of this Order to all present employees engaged in reviewing or evaluating consumer reports in connection with applications for credit to be used for personal, family or household purposes. In addition, respondent shall deliver a copy of this Order to all present and future Directors of Credit of each division, at least once per year, for a period of four (4) years from the date of this Order.

IV

It is further ordered that respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergency of a successor corporation, the creation or dissolution of subsidiaries or divisions or any other change in the corporation which may affect compliance obligations arising out of the Order. This provision shall remain in effect for a period of four (4) years from the date of this Order.

V

It is further ordered respondent, within one hundred fifty (150) days after service upon it of this Order, shall file with the Commission a report in writing setting forth in detail the manner and form in which it has complied with this Order.

**Appendix A**

Dear Customer:

Our records show that [Division of Associated Dry Goods] denied your application for consumer credit within the last four years. The Fair Credit Reporting Act gives persons denied consumer credit the right to know whether the denial was based on information supplied by a consumer reporting agency and, if so, the name and address of such agency. Credit reports provide a variety of information to creditors, including information about how many and what type of credit accounts you have.

Our records show that we may not have informed you that your [Division of Associated Dry Goods] application was denied because of information contained in a credit report. This report showed either no credit history or an insufficient credit record for you. The consumer reporting agency that furnished the report is:

[Name of Consumer Reporting Agency]——

[Street Address] ——

If you want more information about the federal credit laws, write the Federal Trade

Commission, Division of Credit Practices, Washington, D.C. 20580.

Thank you.

### Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement to a proposed consent order from Associated Dry Goods Corporation (ADG), 417 Fifth Avenue, New York, New York.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The proposed Complaint charges that, in many instances, Associated Dry Goods Corporation, through its divisions Robinson's of Florida and Hahne's, violated section 615(a) of the Fair Credit Reporting Act by failing to advise certain rejected applicants of the name and address of consumer reporting agencies that furnished reports on these applicants. The applicants who were denied credit, but were not given the required FCRA notice, fall into a class having the following characteristics:

1. The applicants were denied credit by either Robinson's of Florida or Hahne's during the two-year period, January 1, 1982, through December 31, 1983; and

2. Each of the rejected applicants was denied credit based in whole or in part on a report furnished by a consumer reporting agency which contained non-derogatory information (*e.g.*, no credit file, insufficient credit history, or insufficient credit file).

To remedy alleged FCRA violations, the proposed consent agreement requires that a letter be sent to those rejected applicants falling into the above class. This letter will advise each rejected applicant of the name and address of the particular consumer reporting agency that supplied the non-derogatory information. Further, Associated Dry Goods Corporation will be enjoined from future violations of Section 615(a) of the Fair Credit Reporting Act.

The intent of the proposed consent order is to remedy past violations and to prevent future violations of the Act.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

**Emily H. Rock,**

*Secretary.*

[FR Doc. 85-4316 Filed 2-21-85; 8:45 am]

BILLING CODE 6750-01-M

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### 16 CFR Part 424

### Retail Food Store Advertising and Marketing Practices

**AGENCY:** Federal Trade Commission.

**ACTION:** Extension of time for comments on advance notice of proposed rulemaking.

**SUMMARY:** The Federal Trade Commission (FTC) is seeking public comment on whether the Rule on Retail Food Store Advertising and Marketing Practices should remain in effect without change, or should be amended of rescinded. The time for comments is hereby extended from February 8, 1985 until March 11, 1985.

**DATE:** Comments should be received no later than March 11, 1985.

**ADDRESSES:** Comments should be sent to: Secretary, Federal Trade Commission, 6th and Pennsylvania Avenue, NW., Washington, D.C. 20580.

**FOR FURTHER INFORMATION CONTACT:** Lewis Franke, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission Washington, D.C. 20580 [Telephone (202) 376-2863] or Michael Lynch, Economist, Bureau of Economics, Federal Trade Commission, Washington, D.C. 20580 [Telephone (202) 634-7869].

**SUPPLEMENTARY INFORMATION:** By **Federal Register** notice of December 10, 1984 (49 FR 48059) the Federal Trade Commission sought public comment on whether the Rule on Retail Food Store Advertising and Marketing Practices should remain in effect without change, or should be amended or rescinded. The original comment period was to end on February 8, 1985.

Because of both formal and informal requests for an extension of time within which to file comments, the Commission has set the date of March 11, 1985 by which time comments should be received.

By direction of the Commission.

**Emily H. Rock,**

*Secretary.*

[FR Doc. 85-4315 Filed 2-21-85; 8:45 am]

BILLING CODE 6750-01-M

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## DELAWARE RIVER BASIN COMMISSION

### 18 CFR Part 410

### Proposed Amendment to Comprehensive Plan and Water Code of the Delaware River Basin

**AGENCY:** Delaware River Basin Commission.

**ACTION:** Proposed rule and public hearing.

**SUMMARY:** Notice is hereby given that the Delaware River Basin Commission will hold a public hearing to receive comments on a proposed amendment to the Commission's Comprehensive Plan and *Water Code of the Delaware River Basin* in relation to well registration. The hearing will be a part of the Commission's regulation business meeting which is open to the public.

The primary objectives of the proposed well registration program are:

1. To provide a means for the acquisition of additional information necessary to more accurately plan and manage water resources in the Basin;

2. To collect and compile uniform and compatible water use and hydrogeologic data for individual wells;

3. To quantify preexisting water users and to identify areas where water demands are increasing; and

4. To minimize well interference issues.

**DATES:** The public hearing is scheduled for Wednesday, March 27, 1985, beginning at 1:30 p.m. Persons wishing to testify at this hearing are requested to register with the Secretary prior to the hearing. The comment closing date will be announced at the hearing.

**ADDRESSES:** Written comments should be submitted to Susan M. Weisman, Delaware River Basin Commission, P.O. Box 7360, West Trenton, New Jersey 08628. The public hearing will be held in the Goddard Conference Room of the Commission's offices at 25 State Police Drive, West Trenton, New Jersey.

**FOR FURTHER INFORMATION CONTACT:** Susan M. Weisman, Commission Secretary, Delaware River Basin Commission, telephone (609) 883-9500.

**SUPPLEMENTARY INFORMATION:** This proposed amendment is one of a number or recommendations presented to the Commission in the *Special Ground Water Study, Basinwide Report and Executive Summary*. Accepted by the Commission on December 15, 1982, the study outlined a program for integrated management of ground water quantity and quality in the Basin. On February 23, 1983, the Commission approved task

descriptions and a schedule for implementation of the study.

The proposed amendment, Recommendation No. 14 of the study, calls for the registration by the four signatory states of all new and existing wells or projects that withdraw 10,000 gallons per day or more during any calendar month.

The subject of the hearing will be as follows:

**Amendment to the Comprehensive Plan Relating to Well Registration Policy, Standards and Criteria**

**List of Subject in 18 CFR Part 410**

Water pollution control.

**PART 410—[AMENDED]**

Article 2 of the *Water Code of the Delaware River Basin* includes Commission policy relating to conservation, development and utilization of Basin water resources. The lack of quantifiable information regarding ground water and the hydrologic system is a long-standing problem which has hindered water management activities throughout the Basin. The Commission is now considering an amendment to the Comprehensive Plan to add well registration policy, standards and criteria as recommended in the Commission's *Special Ground Water Study, Basinwide Report and Executive Summary*. It is proposed to:

1. Amend the Comprehensive Plan and Article 2 of the *Water Code of the Delaware River Basin* which are referenced in 18 CFR Part 410 by the addition of a new section 2.20.7, to read as follows:

*2.20.7 Basinwide well registration standards and criteria.*

A. Policy.—All owners or their agents (e.g., well drillers) of individual wells or groups of wells operated as a system that withdraw an average of 10,000 gallons per day (gpd) or more during any 30-day period from the underground waters of the Basin shall register their wells with the appropriate signatory state.

B. Standards and criteria.—Registration shall be filed on forms, or in accordance with procedures established by the appropriate signatory state. The following data shall constitute suggested information requirements for well registration (Owners or their agents are responsibile for items 1–8; states or the United States Geological Survey (U.S.G.S.) are responsible for items 9–13):

1. Well identification number (owner ID)
2. Well owner's name, address, and telephone number
3. Well location:
   a. State
   b. County
   c. Municipality or nearest town and direction
   d. U.S.G.S. Quadrangle location
4. Well construction information:
   a. Date of well completion
   b. Driller's name, state license number
   c. Diameter of hole (inches)
   d. Depth of hole (ft. below land surface datum)
   e. Depth of completed well (ft. below lsd)
   f. Drilling method
   g. Casing sequence(s)
      —depth of top (ft. below lsd)
      —depth of bottom (ft. below lsd)
      —diameter
      —material
   h. Screen opening sequence(s)
      —depth of top (ft. below lsd)
      —depth of bottom (ft. below lsd)
      —diameter (inches)
      —material
      —type
   i. Grout information
      —grout material
      —grout top (ft. below lsd)
      —grout bottom (ft. below lsd)
   j. Driller's Log
5. Water yielding zones (consolidated-rock aquifers)
   a. depth of top (ft. below lsd)
   b. depth of bottom (ft. below lsd)
6. Driller's Pump Test information:
   a. Date
   b. Static water level (ft. above or below lsd)
   c. Pumping water level (ft. below lsd)
   d. Pumping time (hours and minutes)
   e. Pumping rate (gpm)
   f. Pumping measurement method
7. Use information:
   a. Use type
      —Agriculture (non-irrigation)
      —Commercial
      —Domestic
      —Industrial
      —Irrigation
      —Mining
      —Dewatering
      —Air conditioning, geothermal heat pump
      —Power
         i Fossil-fueled power
         ii Nuclear power
      —Sewage treatment
      —Public water supply
   b. Anticipated or estimated usage (gpd, gpm, or gpy)
   c. Meter type
   d. Pump installation date
   e. Pump capacity (gpm)
   f. Motor capacity (hp)
   g. Pump manufacturer and type
   h. Power source
   i. Intake setting (ft. below lsd)
   j. Current pumping level (if available)
8. Verification: Name, address, date, and telephone number of person supplying data for items 1–7
9. Identification and location
   a. Latitude and longitude (method used)
   b. Major watershed (U.S.G.S. Hydrologic Unit)
   c. Minor watershed
   d. Stream reference and river mile
   e. Identification numbers (Registration ID)
   f. Altitude (ft. above or below mean sea level) (method used)
10. Interpretation
   a. Aquifer and geologic formation
   b. Lithology of aquifer
   c. Depth to bedrock
   d. Bedrock material
   e. Confined or unconfined aquifer
   f. Drawdown
   g. Specific capacity
11. Manner and location of wastewater disposal
12. Water-withdrawal permit data (if available):
   a. Name of permitting agency
   b. Permit number
   c. Permit quantity
   d. Expiration date
13. Verification: Name, agency, address, date, and telephone number of person supplying data for items 9–12

C. Administrative agreements.—Recognizing the existence of ongoing well registration programs in Delaware and New Jersey, and recognizing the major differences among the four signatory states regarding the legal authority and enforcement capability for the conduct of well registration, the Executive Director shall effecutate independent administrative agreements with each state for the conduct of well registration. The administrative agreements shall at a minimum provide for (1) the adoption by each state of the suggested information requirements presented in [B] for registration of *new wells*, producing an average of 10,000 gpd or more during any 30-day period, (2) the identification and automation of well records for all *registered, existing wells* producing an average of 10,000 gpd or more during any 30-day period, and (3) the adoption of procedures for registration of *unregistered, existing wells* producing an average of 10,000 gpd or more during any 30-day period.

(Delaware River Basin Compact (75 Stat. 688))

**Susan M. Weisman,**

*Secretary.*

February 14, 1985.

[FR Doc. 85–4331 Filed 2–21–85; 8:45 am]

BILLING CODE 6360-01-M

## ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Parts 704 and 721**

**[OPTS–82016; FRL–2722–7]**

## Hexachloronorbornadiene; Proposed Submission of Notice of Manufacturer, Import, or Processing and Determination of Significant New Use

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would require certain manufacturers, importers, and processors of hexachloronorbornadiene (HEX-BCH) to submit to EPA a report, under section 8(a) of the Toxic Substances Control Act

(TSCA), and other manufacturers, importers, and processors of HEX-BCH to submit a significant new use notice under section 5(a) of TSCA. The reports and notices would allow EPA to monitor the volume of HEX-BCH manufacture, imported, and processed, the number of individuals exposed to HEX-BCH, the manner of its environmental release, and the method of its disposal. EPA would evaluate the reported information to determine it further regulatory action is needed.

**DATE:** Written comments should be submitted by April 8, 1985.

**ADDRESS:** Since some comments are expected to contain confidential business information (CBI), all comments should be sent in triplicate to: Document Control Officer (TS-793), Office of Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St., SW., Washington, D.C. 20460.

Comments should include the docket control number OPTS-82016. Non-confidential comments and public versions of confidential comments on this proposal will be placed in the rulemaking record and will be available for public inspection. Unit VIII of this preamble contains additional information on submitting comments containing CBI.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator—202-554-1404).

**SUPPLEMENTARY INFORMATION:** OMB Control Number 2070-0038.

## I. Authority

The Agency is proposing this rule pursuant to two sections of TSCA, sections 8(a) and 5(a)(2). Section 8(a) (15 U.S.C. 2607(a)) authorizes EPA to require persons (other than small manufacturers, importers, and processors) who manufacture, import, or process a chemical substance to submit such reports as the Administrator may reasonably require.

Section 5(a)(2) (15 U.S.C. 2604(A)(2)) authorizes EPA to determine that a use of a chemical substance is a significant new use. This determination is made by rule after a consideration of all relevant factors, including those listed in section 5(a)(2). Once a use is determined to be significant new use, persons, must, under section 5(a)(1)(B), submit a notice to EPA at least 90 days before they commence that significant new use.

Persons who intend to export a substance identified in a proposed or final SNUR are subjecte to the export provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR Part 707. Persons who intend to import a substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. The EPA policy in support of the import certification requirements appears at 40 CFR Part 707.

## II. Applicability of General Provisions

In the **Federal Register** of September 5, 1984 (49 FR 35011), EPA promulgated general regulatory provisions applicable to SNURs (40 CFR Part 721, Subpart A). EPA is proposing that these general provisions apply to the SNUR aspect of this rulemaking. The general provisions are discussed in detail in the cited **Federal Register** document and interested persons should refer to that document for further information. General provisions applicable to the section 8(a) aspect of this rulemaking have also been promulgated and are codified at 40 CFR Part 704.

## III. Summary of This Proposed Rule

The chemical substance identified in this proposed rule is 1,2,3,4,7,7 hexachloronorbornadiene (HEX-BCH), Chemical Abstracts Service Registry Number 3389-71-7. EPA is proposing to require certain manufacturers, importers and processors of HEX-BCH to submit to EPA a section 8(a) report, and other manufacturers, importers, and processors of HEX-BCH to submit a significant new use notice.

### *A. Section 8(a) Reporting*

An initial section 8(a) report would be required from those persons (other than small manufacturers, importers, and processors) who manufacture, import, or process, or propose to manufacture, import, or process HEX-BCH for use as an intermediate in the production of isodrin or endrin. These persons would be required to report on such things as the estimated quantities of production, importation, or processing of HEX-BCH; the number of employees exposed to HEX-BCH; and the quantity, content, method of disposal, and disposal site of any wastes generated during the manufacture, import, or processing of HEX-BCH.

Subsequent reporting would be triggered by certain events that are likely to significantly change human or environmental exposures to HEX-BCH and the need for current information. The triggers are based on information submitted in the most recent report (wether it is the initial or a subsequent report). Examples of these triggers are: The actual amount of HEX-BCH manufactured, imported, or processed is greater than or equal to 200 percent of the estimated quantity for that year; an increase of 30 percent or more in the number of employees exposed to HEX-BCH; and a change in the disposal site or method of disposal of the wastes generated from the manufacture, import, or processing of HEX-BCH.

Whenever subsequent reporting is triggered, the respondent would be required to state the reason for submitting a subsequent report and to update all the information provided in the previous report. For instance, if a person proposes to manufacture HEX-BCH for use as an intermediate in the production of isodrin, that person would be required to submit an initial section 8(a) report. One aspect of this report is a 3-year, annual forecast of estimated production. Assume that the manufacturer estimates the production of HEX-BCH at 150 pounds per year for years 1, 2, and 3. If in year 2 the manufacturer actually produced 330 lbs of HEX-BCH (an amount greater than 200 percent of the amount estimated in the initial report), the event would trigger the subsequent reporting requirement. The subsequent report would include the reason for submission (actual production greater than 200 percent of estimated production), and would update the information provided in the previous report (i.e. provide a prospective 3-year, annual forecast of production for years 3 through 5).

Lastly, in order to ensure compliance with the section 8(a) reporting requirements, this rule would establish certification and recordkeeping requirements. Each person that would be required by this rule to submit an 8(a) report would also be required to: (1) Retain documentation of the information contained in each report for 5 years from the date of its submission; and (2) after submitting a report, annually review their activities to determine whether a triggering event has occurred. If a review shows that none of the triggering events have occurred, the person would be required to certify a written statement to this fact; and (3) retain all certified statements for 3 years from the date of their creation.

### *B. Significant New Use Reporting*

Persons (including small manufacturers, importers, and processors) who intend to manufacture, import, or process HEX-BCH for any use other than as an intermediate in the

production of isodrin or endrin would be required to submit a significant new use notice. The notice must be submitted to EPA at least 90 days before the commencement of the manufacture, import, or processing of HEX-BCH and must comply with certain TSCA provisions. The notice is generally subject to the same statutory requirements and procedures as a premanufacture notice (PMN) submitted pursuant to section 5(a)(1)(A). In particular, these include the information submission requirements of section 5(b) and (d)(1), and the exemptions authorized by section 5(h). Also, submitters must use the PMN form number 7710-25. These requirements and procedures were promulgated in the Federal Register of September 5, 1984 and will be codified in 40 CFR Part 721, Subpart A.

Once EPA receives a significant new use notice, EPA has up to 180 days to initiate regulatory action. EPA may act pursuant to section 5(e), 5(f), 6, or 7 to control risks that are or might be presented by the significant new use. If no action is taken, section 5(g) requires the Agency to explain in the Federal Register its reasons for not taking action.

## IV. Discussion of Chemical Substance

1. *Production and use data.* HEX-BCH has recently been manufactured at a rate of 300,000 pounds every 2 to 3 years by one manufacturer at one plant site. All of this production is used to produce isodrin which is an intermediate in the production of endrin. Endrin is a pesticide and when used as a pesticide it is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act. In November of 1984, the sole manufacturer vountarily cancelled its U.S. pesticide registrations of technical endrin and for two of their three endrin formulations. The remaining formulation will be cancelled in August of 1985. However, it is important to note these actions merely curtailed a limited U.S. market for endrin and do not affect a manufacturer's ability to produce HEX-BCH in the U.S. for shipment elsewhere. EPA has identified other possible uses of HEX-BCH, none of which has been commercially practiced.

2. *Human health and environmental effects.* EPA has relatively few data on the human health effects of HEX-BCH. This chemical substance is moderately toxic (rat oral $LD_{50} = 776$ mg/kg), it will affect neuromuscular functions (an indication of neurotoxicity), and, based on its structural similarity to several carcinogenic pesticides that like HEX-BCH contain the hexachloronorbornene moiety, HEX-BCH may be a carcinogen.

There are considerably more data on the environmental effects of HEX-BCH. Studies show that HEX-BCH is persistent, highly toxic to fish, has a high bioconcentration factor, and will tend to partition to soil and sediment.

3. *Past and current exposure data.* Workers at a municipal waste water treatment plant and people residing in close proximity to a waste disposal site have been exposed to HEX-BCH. Past disposal methods for HEX-BCH production wastes included its direct discharge into the municipal waste water system. Workers at the waste water treatment plant were exposed through inhalation to HEX-BCH, and HEX-BCH was detected in their urine. The people residing near the waste disposal site were exposed by drinking well water which contained, among other chemical substances, detectable levels of HEX-BCH. In both instances, the levels of HEX-BCH were considerably less than the levels shown to cause neuromuscular effects. However, if HEX-BCH is a carcinogen the levels take on greater significance.

The sole current manufacturer of HEX-BCH uses a totally enclosed manufacturing process to produce HEX-BCH, and therefore does not expose its employees to this substance. The manufacturer is also now required by the municipal waste water treatment plant to pretreat its production wastes before discharging them to the sewer system. However, the discharge permit does allow some discharge of HEX-BCH. The disposal site has been closed, capped, is on the National Priorities List, and is being evaluated for further cleanup efforts.

4. *Regulatory background.* In December 1983, the Interagency Testing Committee recommended HEX-BCH to EPA for priority consideration in developing a test rule to further characterize the chemical's health effects (48 FR 55674). HEX-BCH was also added to the section 8(a) Preliminary Assessment Information Rule (48 FR 55685) and the section 8(d) Health and Safety Data Reporting Rule (48 FR 55686). In the Federal Register of November 19, 1984 (49 FR 45654), EPA published its decision not to require testing of HEX-BCH. EPA decided that testing was not warranted at that time because of the limited production of and low potential for human exposure to HEX-BCH. Individuals should read the Federal Register document cited above for a complete discussion of EPA's decision.

## V. Reasons for Proposing This Rule

HEX-BCH's known adverse environmental effects and potential adverse human health effects have prompted EPA to develop this rule to monitor the production volume of HEX-BCH and the potential for its exposure to humans and the environment. The proposed section 8(a) initial and subsequent reports will keep EPA reasonably apprised of the production volume of and exposure to HEX-BCH during its use as an intermediate in the production of isodrin or endrin. The subsequent reporting triggers were selected as those instances EPA considers significant enough to prompt another risk assessment. For instance, if a manufacturer should produce an amount of HEX-BCH that is 200 percent greater than a previous estimate this signifies a marked demand for HEX-BCH that is much greater than expected and a potential for increases in exposure to and the discharge of HEX-BCH. The subsequent notice would prompt EPA to review the situation. The proposed significant new use reporting will keep EPA reasonably apprised of the production volume of and exposure to HEX-BCH for any other use.

In the event production of or exposure to HEX-BCH should substantially increase, EPA will reconsider its decision not to promulgate a section 4 test rule and may consider other regulatory action. In addition, if the increase in production of or exposure to HEX-BCH would be attributed to the commencement of a significant new use of HEX-BCH, EPA will have the opportunity to review the use and, if necessary, act to prevent potential adverse environmental or human exposures to HEX-BCH.

The previously promulgated section 8(a) reporting rule for HEX-BCH (48 FR 55685) is insufficient to provide the information or notice EPA now requires. That rule was a one-time reporting requirement that informed EPA of past HEX-BCH production. Therefore, to provide monitoring of the manufacture, import, and processing of HEX-BCH as an intermediate in the production of isodrin and endrin, and to ensure advance notice to EPA and an opportunity to prevent any unreasonable risks in the event HEX-BCH is manufactured, imported, or processed for use other than as an intermediate in the production of isodrin or endrin, EPA is proposing this rule.

## VI. Applicability of Proposal to Uses Occurring Before Promulgations of Final SNUR

EPA believes that the intent of section 5(a)(1)(B) is best served by determining whether a use is a significant new use as of the proposal date of the SNUR rather

than upon promulgation of a final rule. If uses begun during the proposal period of the SNUR were not considered significant new uses, it would be extremely difficult for the Agency to establish SNUR notice requirements. Any person could defeat the SNUR by initiating the proposed significant new uses before the rule becomes final.

EPA recognizes that this interpretation of section 5 may disrupt the commercial activities of persons who begin the manufacture, import, or processing of HEX-BCH for uses other than as an intermediate in the production of isodrin or endrin during the proposal period. However, this proposal puts them on notice of the potential disruption and they proceed at their own risk.

## VII. Economic Analysis

After promulgation of this reporting rule, two types of reporting would be required: section 8(a) reporting and significant new use reporting. An initial section 8(a) report would be required from all persons (other than small businesses) who manufacture, import, or process HEX-BCH for use as an intermediate in the production of isodrin or endrin. Subsequent reporting would be triggered by events likely to significantly change exposures to HEX-BCH or required to correct previously reported information. The Agency estimates that the direct costs of submitting an initial section 8(a) report, keeping documentation of the report, and subsequent certifications range from $453 to $1,615. The costs of subsequent reporting will vary with the amount of information that is included in each report and the number of reports that must be submitted. It is not possible to quantify these costs at present.

Under the significant new use reporting requirement in this rule, all other persons (including small businesses) who intend to manufacture, import, or process HEX-BCH for any use other than as an intermediate in the production of isodrin or endrin must submit a significant new use notice. As a result of this requirement, there are two courses of action for a person who intends to engage in a significant new use: (1) Not manufacture, import, or process HEX-BCH or (2) file a significant new use notice with the Agency. EPA has up to 180 days from receipt of the notice to initiate follow-up regulatory action under section 5 (e) or (f).

The Agency estimates that the direct costs of submitting a significant new use notice range from $1,375 to $7,950. It is not possible to estimate the costs associated with a decision by the company not to engage in a significant new use of HEX-BCH. However, since the direct costs of submitting a notice are relatively minor, the Agency believes that a decision not to engage in a significant new use would be based on the market prospects associated with the significant new use and the anticipation of Agency regulatory actions subsequent to notification.

## VIII. Comments Containing Confidential Business Information

Any person who submits comments claimed as confidential business information must mark the comments as "confidential," "trade secret," or with another appropriate designation. Comments not claimed as confidential at the time of submission will be placed in the public file. Any comments marked as confidential will be treated in accordance with the procedures in 40 CFR Part 2. EPA requests that any party submitting confidential comments prepare and submit a public version of the comments that EPA can place in the public file.

## IX. Judicial Review

When this proposed rule is promulgated, judicial review may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or in the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA intends to promulgate this rule for purposes of judicial review two weeks after publishing the final rule in the **Federal Register**. The effective date will be calculated from the promulgation date.

## X. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPTS–82016). The record includes basic information considered by the Agency in developing this proposed rule. EPA will supplement the record with additional information as it is received. The record now includes the following:

1. Thirteenth Report of the TSCA Interagency Testing Committee to the Administrator, (48 FR 55674).

2. Automatic section 8(a) perliminary assessment information reporting requirement for HEX-BCH, (48 FR 55685); and information reported thereunder.

3. Automatic section 8(d) reporting requirement of health and safety data, (48 FR 55686); and information reported thereunder.

4. Certain pesticide products; intent to cancel registrations (49 FR 42792).

5. EPA's decision not to initiate a test rule for HEX-BCH (49 FR 45654).

6. A chemical hazard information profile for HEX-BCH.

7. Use and substitute analysis of HEX-BCH.

8. Economic Analysis.

EPA will accept additional materials for inclusion in the record at any time between publication of this proposed rule and designation of the complete record. EPA will identify the complete rulemaking record by the date of promulgation. A public version of this record containing sanitized copies from which CBI has been deleted is available for inspection in Rm. E–107, 401 M St., SW., Washington, D.C. 20460, from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays.

## XI. Regulatory Assessment Requirements

### *A. Executive Order 12291*

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this proposed rule is not a "Major" rule because it does not have an effect on the economy of $100 million or more, and it will not have a significant effect on competition, costs, or prices. EPA estimates industry's annual compliance cost to range from $453 to $7,950 depending on whether a section 8(a) report or significant new use notice is required. This regulation was submitted to Office of Management and Budget (OMB) for review under Executive Order 12291.

### *B. Regulatory Flexibility Act*

Under the Regulatory Flexibility Act, 5 U.S.C. 605(b), EPA certifies that this proposed rule, if promulgated, will not have a significant impact on a substantial number of small businesses. The Agency has not determined whether parties affected by this proposed rule are likely to be small businesses. However, EPA believes that few manufacturers, importers, or processors will submit notices. Therefore, although the costs of preparing a notice under this rule might be significant for some businesses, the number of such businesses affected is not expected to be substantial.

### *C. Paperwork Reduction Act*

OMB has approved the information collection requirements contained in this proposed rule for the significant new use reporting under the provisions of the Paperwork Reduction Act of 1980, 44

U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070–0038. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB, marked Attention: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

The information collection requirements in this proposed rule for the section 8(a) reporting have been submitted for OMB approval. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB marked Attention: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

**List of Subjects**

*40 CFR Part 704*

Environmental protection, Hazardous materials, Chemicals, Recordkeeping and reporting requirements.

*40 CFR Part 721*

Environmental protection, Chemicals, Hazardous materials, Recordkeeping and reporting requirements, Significant new uses.

Dated: February 12, 1985.

Lee M. Thomas,

*Acting Administrator.*

**PART 704—[AMENDED]**

Therefore, it is proposed that Parts 704 and 721 of Title 40, Chapter I, be amended as follows:

1. In Part 704:

a. By adding in appropriate alphabetical order the definition for "CAS number", and revising the definition of "propose to manufacture or import" to read as follows:

**§ 704.3 Definitions.**

* * * * *

"CAS Number" means Chemical Abstracts Service Registry Number.

* * * * *

"Propose to manufacture, import, or process" means that a person has made a firm management decision to commit financial resources for the manufacture, import, or processing of the specified chemical.

* * * * *

b. By adding § 704.142 to Subpart D to read as follows:

**§ 704.142 Hexachloronorbornadiene.**

(a) *Definitions.* (1) "Endrin" means the pesticide 2,7,3,6-Dimethanonaphth (2,3-b) oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6,6a,7,7a-octahydro-, (1aalpha, 2beta, 2abeta, 3alpha, 6alpha, 6abeta, 7beta, 7aalpha), CAS Number 72–20–8.

(2) "HEX-BCH" means the chemical substance 1,2,3,4,7,7 hexachloronorbornadiene, CAS Number 3398–71–7.

(3) "Isodrin" means the pesticide 1,4,:5,8-Dimethanoaphthalene, 1,2,3,4,10,10-Hexachloro-1,4,4a,5,8,8a-hexahydro-, (1alpha, 4alpha, 4abeta, 5beta, 8beta, 8abeta), CAS Number 465–73–6.

(4) "Small business" means any manufacturer, importer, or processor who meets either paragraph (a)(4) (i) or (ii) of this section:

(i) A business is small if its total annual sales, when combined with those of its parent (if any), are less than $40 million. However, if the annual manufacture, import, or processing volume of a particular chemical substance at any individual site owned or controlled by the business is greater than 45,400 kilograms (100,000 pounds), the business shall not qualify as small for purposes of reporting on the manufacture, import, or processing of that chemical substance at that site, unless the business qualifies as small under paragraph (a)(4)(ii) of this section.

(ii) A business is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of the particular chemical substance manufactured, imported, or processed by that business.

(iii) For imported mixtures containing HEX-BCH the 45,400 kilograms (100,000 pounds) standard in paragraph (a)(4)(i) of this section applies only to the amount of HEX-BCH in a mixture and not the other components of the mixture.

(5) "8-hour time weighted average" means the cumulative exposure for an 8-hour work shift and shall be computed as follows:

$$E = \frac{C_1T_1 + /c_2T_2 + C_nT_n}{8}$$

where:

E is the equivalent exposure for the working shift.

$C_i$ is the concentration (i.e. part per million) during any period of time ($T_i$) where the concentration remains constant.

$T_i$ is the duration in hours of the exposure at the concentration $C_i$.

(6) "Year" means corporate fiscal year.

(b) *Persons who must report.* (1) Reports must be submitted by: (i) persons who are manufacturing, importing, or processing HEX-BCH for use as an intermediate in the production of isodrin or endrin on or after (insert effective date of final rule); and (ii) persons who propose to manufacture, import, or process HEX-BCH for use as an intermediate in the product of isodrin or endrin, on or after (insert effective date of final rule).

(2) Persons described in paragraph (b)(1) of this section who engage in more than one activity (i.e. manufacture and processing) must sumbit a report for each activity.

(c) *Persons exempt from reporting.* (1) Small businesses.

(2) Persons described in § 704.5 (a) and (c).

(d) *Information to report.* (1) Initial reports must include, to the extent that it is known to or reasonably ascertainable by the person reporting, the following information:

(i) Company name and address.

(ii) Name, address, and telephone number of the principal contact.

(iii) Location of plant site where HEX-BCH is or is proposed to be manufactured, imported, or processed.

(iv) If applicable, the intended date for initiating manufacture, import, or processing of HEX-BCH.

(v) If applicable, the actual quantity (by weight) of HEX-BCH manufactured, imported, or processed during the most recently concluded year.

(vi) The estimated quantity (by weight) of HEX-BCH to be manufacturred, imported, or processed each year during the first three years following the date of the report or the date of the intended start of manufacture, import, or processing, whichever occurs later.

(vii) For each year described in paragraph (d)(1)(vi) of this section: the expected number of employees exposed to HEX-BCH during its manufacture or import, processing, distribution in commerce, use and disposal; the routes of exposure; and the 8-hour time weighted average of exposure. This information is to be reported separately for each activity noted.

(viii) If employees are exposed or expected to be exposed to HEX-BCH, for each reported route of exposure, whether personal protective equipment is used or expected to be used, and a description of the personal protective equipment.

(ix) The quantity, content, method of

disposal, and disposal site of any wastes generated during the manufacture, import, or processing of HEX-BCH.

(2) Subsequent reports must provide, to the extent known to or reasonably ascertainable by the person reporting, the information in paragraph (d)(1) of this section and a statement explaining why the subsequent report is required.

(e) *When to report.* (1) Persons who are manufacturing, importing, or processing HEX-BCH on (effective date of final rule) must submit an initial report to EPA by (30 days after effective date of final rule).

(2) Persons who propose to manufacture, import, or process HEX-BCH on or after (effective date of final rule) must submit an initial report to EPA by (30 days after effective date of final rule) or 15 days after making the management decision described in § 704.3(p), whichever is later in time.

(3) Persons described in paragraph (b) of this section, who have submitted a report described in paragraph (d) of this section, and who know or could reasonably ascertain that based on the most recently submitted report any of the following events have occurred, must submit a subsequent report within 30 days of such event.

(i) The actual quantity (by weight) of HEX-BCH manufactured, imported, or processed is greater than or equal to 200 percent of the estimated value for any year reported pursuant to paragraph (d)(1(vi) of this section.

(ii) The total number of employees exposed to HEX-.BCH is greater than 130 percent of the annual value reported pursuant to paragraph (d)(1)(vii) of this section.

(iii) The route of exposures to HEX-BCH reported pursuant to paragraph (d)(1)(vii) of this section has changed.

(iv) Any 8-hour time weighted average reported pursuant to (d)(1)(vii) of this section has increased by more than 100 percent.

(v) The manufacture, import, or processing of HEX-BCH has moved to a plant site different than that reported pursuant to paragraph (d)(1)(iii) of this section.

(vi) The method of disposal or disposal site reported pursuant to paragraph (d)(1)(ix) has changed.

(vii) Three years have passed since the most recent submission of a report under this paragraph.

(f) *Certification of review.* Each person who has submitted a report under this section must review its activities each year to determine whether any reportable events specified in paragraph (e)(3) of this section has occurred. If a review shows that none of these events has occurred, the person is required to certify this fact in writing.

(g) *Recordkeeping.* Any person subject to the reporting requirements of this section must:

(1) Retain documentation of information contained in their reports. This documentation must be maintained for a period of 5 years from the date of the submission of the report; and

(2) Retain the certification required by paragraph (f) for 3 years from the date of its creation.

(h) *Where to send reports.* Reports must be submitted by certified mail to the United States Environmental Protection Agency, Document Processing Center, P.O. Box 2070, Rockville, MD 20852. ATTN: HEX–BCH Notification.

(Approved by the Office of Management and Budget under control number 2070– )

## PART 721—[AMENDED]

2. In Part 721, by adding § 721.342 to Subpart B to read as follows:

### § 721.342 Hexachloronorbornadiene.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance hexachloronorbornadiene, CAS Number 3389–71–7, is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is: Use other than as as intermediate in the production of isodrin or endrin.

(b) *Specific requirements.* The provisions of subpart A of this Part apply to this section except as modified by this paragraph.

(1) *Definitions.* In addition to the definitions in § 721.3, the following definitions apply:

(i) "Endrin" means the pesticide 2,7:3,6-Dimethanonaphth (2,3-b) oxirene, 3,4,5,6,9,9-hexachloro-1a,2,2a,3,6a,7,7a-octahydro-, (1aalpha, 2beta, 2abeta, 3alpha, 6alpha, 6abeta, 7beta, 7aalpha), CAS Number 72–20–8.

(ii) "Isodrin" means the pesticide 1,4:5,8-Dimethanonaphthalene, 1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-, (1alpha, 4alpha, 4abeta, 5beta, 8beta, 8abeta), CAS Number 465–73–6.

(2) [Reserved]

(Approved by the Office of Management and Budget under control number 2070–0038)

[FR Doc. 85–4237 Filed 2–21–85; 8:45 am]
BILLING CODE 6560–50–M

## GENERAL SERVICES ADMINISTRATION

### 41 CFR Ch. 201

### Amendment of the FIRMR To Revise ADP Performance Validation Provisions

**AGENCY:** Office of Information Resources Management, GSA.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The General Services Administration proposes to amend the FIRMR policy and guidance regarding agency performance validation of proposed ADP equipment systems. The regulation will allow agencies more freedom in selecting and using appropriate ADP equipment validation techniques. The intent is to increase economy and efficiency in the acquisition of Federal ADP equipment systems.

**DATE:** Comments are due March 25, 1985.

**ADDRESS:** Comments should be submitted to the General Services Administration (KMPP), Washington, DC 20405.

**FOR FURTHER INFORMATION CONTACT:** Carolyn A. Thomas, Policy Branch, Office of Information Resources Management, telephone: (202) 566–0194 or FTS, 566–0194. The full text of this proposed rule (Project 84.80A) is available upon request.

**SUPPLEMENTARY INFORMATION:**

1. On October 22, 1982, the General Accounting Office (GAO) issued an audit report entitled, "Benchmarking: Costly and Difficult, But Often Necessary When Buying Computer Equipment or Services" (GAO/AFMD–83–5). The audit found that one of the tools used most commonly for computer system performance validation was the benchmark. It also found the benchmark process to be very costly and that its effectiveness as an evaluation tool was dependent upon the extent to which it could be made representative of projected workload. The audit concluded that in some circumstances, more cost effective evaluation tools are indicated, and recommended a revision to Federal regulations to discourage the use of benchmarking as an evaluation tool for low dollar ADP acquisitions.

2. In September 1982 the General Services Administration (GSA) contracted with the Federal Computer Performance Evaluation and Simulation Center (FEDSIM) for a technical study of alternative performance validation techniques. The FEDSIM study (NA–82060–GSA), completed in May 1984,

generally supported GAO's conclusions and recommendations.

3. GSA proposes to amend several sections of the FIRMR relating to the performance validation of proposed ADP equipment systems. The amendment allows agencies more freedom in selecting and using appropriate ADP equipment capability and performance validation techniques (including benchmarking) based on the risks associated with the technique and how those risks impact the accomplishment of agency mission needs. Solicitation preparation guidance, based on the revised regulatory provisions, will also be published.

4. GSA has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, and therefore a Regulatory Impact Analysis is not required.

**List of Subjects in 41 CFR Chapter 201**

Government information resources activities, Government procurement.

(Sec. 205(c), 64 Stat. 390; 40 U.S.C. 486(c))

Dated: December 27, 1984.

**Francis A. McDonough,**

*Deputy Assistant Administrator for Federal Information Resources Management.*

[FR Doc. 85-4382 Filed 2-21-85; 8:45 am]

BILLING CODE 6820-25-M

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## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

### 49 CFR Parts 390, 391, 392, 393, 394, 395, 396, 397, 398, and 399

[BMCS Notice No. 85-3]

### Motor Carrier Safety Act of 1984; Submission of State Safety Regulations for Review; Initial Guidelines

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Public notice of clarification of guidelines to States.

**SUMMARY:** This notice clarifies the guidelines to States published at 50 FR 1243 on January 10, 1985, which are required by section 207(c) of the Motor Carrier Safety Act of 1984. The compilation of commercial motor vehicle State safety laws and regulations must be submitted by April 30, 1985. The analyses of such laws and regulations can be submitted as soon as practicable after April 30, 1985, but not later than a date which may be established by the Commercial Motor Vehicle Safety Regulatory Review Panel.

**EFFECTIVE DATE:** This notice of clarification is effective on February 22, 1985.

**FOR FURTHER INFORMATION CONTACT:** Mr. J.J. Fulnecky, Bureau of Motor Carrier Safety, (202) 426-0033; or Mr. Thomas P. Holian, Office of the Chief Counsel, (202) 426-0346, Federal Highway Administration, 400 7th Street, SW., Washington, D.C. 20590. Office hours are from 7:45 a.m. to 4:15 p.m. ET, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** On January 10, 1985, FHWA issued initial guidelines required by section 207(c) of the Motor Carrier Safety Act of 1984 (Pub. L. 98-554, 98 Stat. 2829) (the Act) (see 50 FR 1243, January 10, 1985). These guidelines called for the submission by States of compilations and analyses of State laws and regulations pertaining to commercial motor vehicle safety. This information was requested to be submitted by April 30, 1985.

Section 207(a) of the Act required submission of such State laws and regulations by April 30, 1985, to the Secretary and the Commercial Motor Vehicle Safety Regulatory Review Panel (Safety Panel) to be established pursuant to section 209 of the Act. The Safety Panel is to review such State laws and regulations and determine which laws or regulations pertain to commercial motor vehicle safety by April 30, 1986. Section 208(b)(1). States are also directed by section 207(d) of the Act to submit analyses to the Safety Panel of the effect of their laws and regulations, and their comparative stringency relative to the Federal regulations, as soon as practicable but not later than such time as the Safety Panel may establish. Within 12 months after the Safety Panel determines a State law or regulation pertains to commercial motor vehicle safety (i.e., by April 30, 1987), the Safety Panel shall determine whether the State law or regulation so identified has the same effect as; is less stringent than; is additional to or more stringent than the Federal regulation. Upon notification by the Safety Panel of its determinations, the Secretary will initiate rulemaking to determine which State laws and regulations may remain in effect after October 30, 1989. Section 208(a). This rulemaking is to be completed within 18 months of receiving the Safety Panel's determinations. Section 208(c)(5)(A). Thus, this rulemaking is scheduled to be completed by October 30, 1988. Any person (including any State) may petition for a waiver of a determination by the Secretary. Section 208(d)(1).

In our initial guidelines, we requested States to submit their analyses regarding their laws and regulations together with their compilations of such laws and regulations by April 30, 1985, in order to facilitate the work of the Safety Panel. We are aware, however, that it will take time for States to complete both the compilations and analyses of their laws and regulations pertaining to commercial motor vehicle safety. We are also mindful of the fact that pursuant to section 206 of the Act changes in the Federal rules will be proposed and made within 18 months of the enactment of the Act (i.e., by April 30, 1986). Thus, the Safety Panel cannot meaningfully analyze the relative stringency of the State laws and regulations until changes in the Federal regulations have been made. Therefore, we request States to submit their laws and regulations (see Guidelines A, B, C, and E in our January 10 notice) by April 30, 1985, and their analyses (see Guideline D) as soon as practicable thereafter, but not later than a date which may be established by the Safety Panel.

(The Motor Carrier Safety Act of 1984, Pub. L. 98-554, 98 Stat. 2829, October 30, 1984, Title II, section 107)

Issued on: February 14, 1985.

**Kenneth L. Pierson,**

*Director, Bureau of Motor Carrier Safety.*

[FR Doc. 85-4333 Filed 2-21-85; 8:45 am]

BILLING CODE 4910-22-M

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

### 50 CFR Part 20

### Migratory Bird Hunting; Guidelines on Minimum Criteria for Identification of Nontoxic Shot Zones for Waterfowl Hunting

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of draft guidelines; extension of comment period.

**SUMMARY:** Based on comments and inquiries received to date by the U.S. Fish and Wildlife Service on guidelines on minimum criteria for identification of nontoxic shot zones for waterfowl hunting published in the January 16, 1985, **Federal Register** (at 50 FR 2298) the Service believes that additional time for receipt of coments is warranted, and therefore the comment period is extended.

**DATES:** Comments must be submitted by March 22, 1985. When submitting comments on guidelines (as published in 50 FR 2298) please distinguish between the FWS proposal (Table 2) and the recommendations of the representatives from flyway councils (Table 1).

**ADDRESS:** Submit comments to Director (FWS/MBMO), U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240. Telephone 202–254–3207.

**FOR FURTHER INFORMATION CONTACT:** Rollin D. Sparrowe, Chief, Office of Migratory Bird Management, Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240.

Dated: February 20, 1985.

**Robert A. Jantzen,**
*Director, U.S. Fish and Wildlife Service.*

[FR Doc. 85–4423 Filed 2–21–85; 9:21 am]
BILLING CODE 4310-55-M

# Notices

Federal Register
Vol. 50, No. 36
Friday, February 22, 1985

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.

## DEPARTMENT OF AGRICULTURE

### Commodity Credit Corporation

### 1985-Crop Honey Price Support Program

**AGENCY:** Commodity Credit Corporation, USDA.

**ACTION:** Notice of proposed determinations.

**SUMMARY:** The purpose of this notice is to propose a level of loans and purchases for the 1985-crop honey price support program and certain other related determinations. These determinations are to be made in accordance with the Agricultural Act of 1949, as amended. Written comments are invited from interested persons.

**DATE:** Comments must be received on or before March 25, 1985, in order to be assured of consideration.

**ADDRESS:** Mail comments to Dr. Howard C. Williams, Director, Commodity Analysis Division, USDA–ASCS, 3741 South Building, P.O. Box 2415, Washington, D.C. 20013.

**FOR FURTHER INFORMATION CONTACT:** Harry A. Sullivan, Agricultural Economist, Commodity Analysis Division, USDA–ASCS, 3752 South Building, P.O. Box 2415, Washington, D.C. 20013, (202) 447–6758. The Preliminary Regulatory Impact Analysis describing the options considered in developing these proposed determinations and the impact of implementing each option is available from the above-named individual.

**SUPPLEMENTARY INFORMATION:** These proposed determinations have been reviewed under USDA procedures established in accordance with Executive Order 12291 and Departmental Regulation 1512–1 and have been classified "not major."

These determinations will not result in: (1) An annual effect on the economy of $100 million or more; (2) major increases in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The title and number of the federal assistance program to which these proposed determinations apply are: Title—Commodity Loans and Purchases; Number—10–051 as found in the catalog of Federal Domestic Assistance.

It has been determined that the Regulatory Flexibility Act is not applicable to this notice of proposed determinations since the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this notice.

This activity is not subject to provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, Subpart V, published at 48 FR 29115 (June 24, 1983).

The comment period is limited to 30 days in order that there may be adequate time to prepare an analysis of all comments received and publish a Notice of Final Determinations by April 1, 1985—the beginning of the 1985 honey marketing year.

Section 201(b) of the Agricultural Act of 1949, as amended (hereinafter referred to as "the Act"), requires that the Secretary of Agriculture make available through loans, purchases, or other operations, price support to producers of honey at a level which is not in excess of 90 percent nor less than 60 percent of the parity price thereof. With respect to a commodity for which price support is mandatory, section 401(b) of the Act requires that consideration must be given to the following factors in determining a level of price support which is in excess of the minimum level otherwise prescribed by statute: (1) The supply of the commodity in relation to the demand therefor, (2) the price levels at which other commodities are being supported, (3) the availability of funds, (4) the perishability of the commodity, (5) the importance of the commodity to agriculture and the national economy, (6) the ability to dispose of stocks acquired through the price support program, (7) the need for offsetting temporary losses of export markets, and (8) the ability and willingness of producers to keep supplies in line with demand.

Also, in accordance with section 403 of the Act, the loan rate and purchase price for the 1985-crop of honey will be adjusted to reflect floral source, color, class and grade, and other market differentials which are applicable to the marketing of honey.

The projection for honey production in 1985, with a level of support at the minimum statutory level, is 205 million pounds (from 4,450,000 colonies). This is 40 million pounds more than the estimated amount of honey produced in the 1984 crop year and the same level of production achieved in 1983. Imports of honey in 1984 are expected to reach 130 million pounds, 20 million pounds more than the quantity imported in 1983. Imports in 1985 are projected to reach 130 million pounds. Domestic production, imports, and large CCC stocks, are expected to result in total supply of honey in the U.S. for 1985 of 500.4 million pounds.

Domestic disappearance for the 1979 to 1981 crop years averaged 247 million pounds per year. Disappearance levels beginning with the 1981 crop year have been rising due to the added disposition of CCC inventories through non-commercial outlets while commercial disappearance has been declining. As of December 1, 1984, there were approximately 80.9 million pounds of honey in CCC inventory left from the 115 million pounds which were acquired under the price support program from the 1983 crop. The market price for honey has lagged behind the price support increases with the market price declining from 54.4 cents per pound in 1983 to 49.5 cents per pound on a bulk, extracted, wholesale, unprocessed basis in 1984.

The level of price support for the 1984 crop of honey was established at 60 percent of parity or 65.8 cents per pound. Establishing a level of support in excess of 60 percent of parity for the 1985 crop would result in support prices continuing well above projected market prices, thus increasing the amount of CCC acquisitions of honey stocks. It is, therefore, proposed that the level of

support for the 1985 crop of honey be established at 60 percent of parity.

Accordingly, the following proposed determinations with respect to 1985-crop honey are to be made by the Secretary:

**Proposed Determinations**

It is proposed that the loan rate and purchasing price for 1985-crop honey, which is based on 60 percent of parity, will be approximately 65.6 cents per pound. In addition, it is proposed that the 1985-crop honey loan rate and purchase price will be adjusted to reflect floral source, color, class and grade, and other market differentials under which honey is marketed.

Comments on the appropriate level of price support and the appropriate market differentials for 1985-crop honey are requested.

Consideration will be given to any data, views and recommendations that may be received relating to the above items. All comments will be made available for public inspection in room 3741 of USDA's South Building during business hours (8:00 a.m. to 4:30 p.m.).

Signed at Washington, D.C. on February 15, 1985.

**Everett Rank,**

*Executive Vice President, Commodity Credit Corporation.*

[FR Doc. 85-4309 Filed 2-21-85; 8:45 am]

BILLING CODE 3410-05-M

## Forest Service

### Pacific Crest National Scenic Trail Advisory Council, Northern California Subcommittee; Meeting

The Northern California Subcommittee of the Pacific Crest National Scenic Trail Advisory Council will meet on April 5, 1985, at the Oroville Ranger Station, 875 Mitchell Avenue, Oroville. The meeting will begin at 10:00 a.m.

The purpose of the meeting is to discuss and develop recommendations for the Advisory Council and Secretary of Agriculture on broad questions of policy, programs, and procedures affecting the Northern California portion of the Pacific Crest Trail. The Subcommittee will discuss trail location and completion status near Belden, California, water along the Hat Creek Rim, and final rights-of-ways needed to complete the trail in northern California.

The meeting will be open to the public. Persons who wish additional information should contact Dick Benjamin, Recreation Staff Director, Pacific Southwest Region, Forest Service, 630 Sansome Street, San Francisco, California, phone (415) 556-6986.

Dated: January 20, 1985.

**Zane G. Smith, Jr.,**

*Chairman.*

[FR Doc. 85-4244 Filed 2-21-85; 8:45 am]

BILLING CODE 3410-11-M

## Rural Electrification Administration

### Intent To Conduct Public Scoping Meetings and Prepare an Environmental Assessment

**AGENCY:** Rural Electrification Administration, USDA.

**ACTION:** Notice of Intent to Conduct Public Scoping Meetings and Prepare an Environmental Assessment.

**SUMMARY:** The Rural Electrification Administration (REA) intends to conduct scoping meetings and prepare an Environmental Assessment (EA) in connection with possible REA financing assistance to Associated Electric Cooperative, Inc. (AECI), Springfield, Missouri. Due to AECI policy, KAMO Electric Cooperative, Inc. (KAMO), Vinita, Oklahoma, a member of AECI, has been designated as construction agent for AECI. The project which is located within KAMO's service area consists of the construction and operation of a 345 kV transmission line that would extend approximately 225 km (140 mi) from the Arkansas-Missouri line north to the Morgan Substation of AECI. Depending upon the corridor selected, the transmission line may be located in the following counties: Barry, Christian, Dade, Greene, Jasper, Lawrence, McDonald, Newton, Polk and Stone.

**DATES:** REA will conduct public scoping meetings as follows:

March 26, 1985—Republic Mid-School Cafeteria, 518 North Hampton, Republic, Missouri 65738, at 7:30 p.m.

March 27, 1985—Cassville High School Gymnasium, Cassville, Missouri 65625, at 7:30 p.m.

**ADDRESS:** All interested parties are invited to submit written comments to REA prior to, at, or within 30 days after the scoping meetings in order for the comments to be part of the formal record. Comments should be sent to Mr. Alexander E. Sherman, Chief, Distribution and Transmission Engineering Branch, Southwest Area-Electric, U.S. Department of Agriculture, Rural Electrification Administration, Room 0009, South Agriculture Building, Washington, D.C. 20250.

**FOR FURTHER INFORMATION CONTACT:** Mr. Alexander E. Sherman, Southwest Area-Electric, above address, telephone: (202) 382-1915, or FTS 382-1915, or Ms. Robbie Dockery, KAMO Electric Cooperative, Inc., P.O. Box 577, Vinita, Oklahoma 74301, telephone (918) 256-5551.

**SUPPLEMENTARY INFORMATION:** REA, in order to meet its requirements under the National Environmental Policy Act (NEPA) of 1969, the Council on Environmental Quality Regulations (40 CFR Part 1500) and REA Environmental Policies and Procedures (7 CFR Part 1794), intends to conduct public scoping meetings and prepare an Environmental Assessment. This notice is in connection with possible REA financing assistance to AECI for the construction and operation of a 345-kV transmission line to be located in southwestern Missouri.

The proposed project is part of a larger system which will include interconnections between five utilities in Oklahoma, Arkansas and Missouri. This phase will connect with 345-kV transmission lines, the Flint Creek Power Plant in Barton County, Arkansas, owned by Southwestern Electric Power Company (SWEPCO), a proposed 345/161 kV substation near Monett, Missouri, owned by Empire District Electric Company, the 345/161 kV Brookline Substation near Springfield, Missouri, owned by City Utilities of Springfield, to the 345-kV Morgan Substation in Dade County, Missouri, owned by AECI. SWEPCO is responsible for obtaining project related approvals in the state of Arkansas.

Alternatives to be considered by REA include, among other options: (1) No action; (2) wheeling agreements; (3) energy conservation and load management; (4) alternative substation sites; and (5) alternative corridors.

The public scoping meetings, to be conducted by a represntative of REA, will be held to solicit public input and comments including but not limited to, the nature of the proposed project, its possible location, alternatives, and any significant issues and environmental concerns that should be addressed in the EA. Requests for additional information concerning the scoping meetings may be directed to either REA or KAMO at the addresses shown above. Copies of the Macro-Corridor Study are available for public review at the offices of REA, KAMO, and the other project participants.

Any REA financing assistance to AECI will be subject to and contingent upon reaching satisfactory conclusions with respect to the environmental effects of the project, and final action will be taken only after compliance with

environmental procedures required by NEPA have been satisfied.

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

Dated: February 15, 1985.

**Harold V. Hunter,**

*Administrator.*

[FR Doc. 85-4336 Filed 2-21-85; 8:45 am]

BILLING CODE 3410-15-M

## Soil Conservation Service

### Productivity Improvement Review List and Estimated Dates for Beginning Studies

**AGENCY:** Soil Conservation Service (SCS), USDA.

**ACTION:** Notice of intent to conduct productivity improvement reviews under the guidelines set forth in OMB Circular No. A-76.

**SUMMARY:** This notice provides locations and projected dates for starting productivity improvement studies within SCS during 1985.

| Location and type of activity | Projected review start |
|---|---|
| Fifty states and Caribbean Area: | |
| Mail and file | Mar. 1985. |
| Resource inventories | Oct. 1985. |
| District of Columbia, 50 states, and Caribbean Area: | |
| Training | July 1985. |
| Soil surveys | Mar. 1985. |

**FOR FURTHER INFORMATION CONTACT:** W.J. Parker, Director, Productivity Improvement Program, Soil Conservation Service, Department of Agriculture, P.O. Box 2890, Room 6019-S, Washington, D.C. 20013.

**SUPPLEMENTARY INFORMATION:** Reviews will be conducted under the guidelines of OMB Circular No. A-76, Performance of Commercial Activities. Some of the listed activities may be evaluated in subunits or combined with other units for review. This is a notice of intent only and not a request for proposals.

Dated: February 14, 1985.

**Jacqueline G. Sutton,**

*Associate Deputy Chief for Administration.*

[FR Doc. 85-4337 Filed 2-21-85; 8:45 am]

BILLING CODE 3410-16-M

### Dunloup Creek Watershed, WV; Deauthorization of Federal Funding

**AGENCY:** Soil Conservation Service, USDA.

**ACTION:** Deauthorization of Federal funding.

**SUMMARY:** Pursuant to the Watershed Protection and Flood Prevention Act, Pub. L. 83-566, and the Soil Conservation Service Guidelines (7 CFR Part 622); the Soil Conservation Service, U.S. Department of Agriculture, gives notice of the deauthorization of Federal funding for the Dunloup Creek Watershed project, Fayette and Raleigh Counties, West Virginia.

**FOR FURTHER INFORMATION CONTACT:** Rollin N. Swank, State Conservationist, Soil Conservation Service, 75 High Street, Room 301, Morgantown, West Virginia, 26505, telephone: 304-291-4151.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention. State and local review procedures for Federal and federally assisted programs and projects are applicable)

Dated: February 14, 1985.

**Rollin N. Swank,**

*State Conservationist.*

[FR Doc. 85-4396 Filed 2-21-85; 8:45 am]

BILLING CODE 3410-16-M

### Applesway Drive RC&D Measure, Ohio; Finding of No Significant Impact

**AGENCY:** Soil Conservation Service, USDA.

**ACTION:** Notice of Finding of No Significant Impact.

**SUMMARY:** Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Applesway Drive RC&D Measure, Columbiana County, Ohio.

**FOR FURTHER INFORMATION CONTACT:** Harry W. Oneth, State Conservationist, Soil Conservation Service, Federal Building, 200 North High Street, Room 522, Columbus, Ohio 43215, telephone: (614)-469-6962.

**SUPPLEMENTARY INFORMATION:** the environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Harry W. Oneth, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

This measure concerns a plan for flood prevention and drainage improvements in a rural subdivision and on agricultural land near Applesway Drive. Planned works of improvement include a grassed waterway, grade stabilization structure, culverts and open drains.

The Notice of Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Harry W. Oneth.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication.

(Catalog of Federal Domestic Assistance Program No. 10.901, Resource Conservation and Development Program. Office of Management and Budget Circular A-95 regarding state and local clearinghouse review of federal and federally assisted programs and projects is applicable)

February 14, 1985.

**Harry W. Oneth,**

*State Conservationist.*

[FR Doc. 85-4342 Filed 2-21-85; 8:45 am]

BILLING CODE 3410-16-M

## CIVIL RIGHTS COMMISSION

### Georgia Advisory Committee; Amendment

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights that a meeting of the Advisory Committee to the Commission originally scheduled for March 7, 1985, at Atlanta, Georgia (FR Doc. 85-3917 on page 6370, February 15, 1985) has a new convening date and room.

The meeting will convene on March 8, 1985, in the Twelve Oaks Room. The address and time will remain the same.

Dated at Washington, D.C. February 19, 1985.

**Bert Silver,**

*Assistant Staff Director for Regional Programs.*

[FR Doc. 85-4426 Filed 2-21-85; 8:45 am]

BILLING CODE 6335-01-M

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Export Trade Certificate of Review; Global Operations Co.

**AGENCY:** International Trade Administration, Commerce.

**ACTION:** Notice of issuance of an export trade certificate of review.

**SUMMARY:** The Department of Commerce has issued an export trade certificate of review to Global Operations Co. ("Global"). This notice summarizes the conduct for which certification has been granted.

**ADDRESS:** The Department requests public comments on the certificate. Interested parties should submit their written comments, original and five (5) copies, to: Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, Room 5618, Washington DC 20230.

Comments should refer to the certificate as "Export Trade Certificate of Review, application number 84-00035."

**FOR FURTHER INFORMATION CONTACT:** James V. Lacy, Director, Office of Export Trading Company Affairs, International Trade Administration, 202-377-5131. This is not a toll-free number.

**SUPPLEMENTARY INFORMATION:** Title III of the Export Trading Company Act of 1982 ("the Act") (Pub. L. 97-290) authorizes the Secretary of Commerce to issue export trade certificates of review. The regulations implementing the Act are found at 15 CFR part 325 (50 FR 1804, January 11, 1985).

The Office of Export Trading Company Affairs is issuing this notice pursuant to 15 CFR 325.5(b), which requires the Secretary of Commerce to publish in the Federal Register a summary of each certificate issued. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

**Description of Certified Conduct**

*Export Trade*

*Trade Facilitation Services (as they relate to the export of goods and services).* Total intermodal transportation services, non-vessel-operating common carrier services, freight forwarding, contracting or arranging for the provision of freight forwarding, customhouse brokerage in the Export Markets, market and project research, sales promotion, analysis of transportation requirements, financing of cargoes, packing and crating, issuance of marine insurance, warehousing abroad ("Services").

*Export Markets*

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands).

*Export Trade Activities and Methods of Operation*

1. Global may provide Services itself or through any of its Members.

2. Global may enter into nonexclusive and/or exclusive agreements to provide Services for persons engaged in exporting. "Exclusive" means that that person agrees not to purchase Services from anyone except Global.

3. Global may enter into nonexclusive and/or exclusive agreements with individual Export Intermediaries for the provision of Services. "Exclusive" means that (a) Global agrees to deal in Services only through the Export Intermediary; and/or (b) the Export Intermediary agrees not to deal in Services with anyone except Global.

**Members**

William F. Bosque, (d/b/a J. E. Lowden & Company), Ted L. Rausch, Ted L. Rausch Co. (a California corporation), and Poseidon Freight Forwarders, Inc. (a California corporation).

A copy of each certificate is available for inspection and copying in the International Trade Administration's Freedom of Information Records Inspection Facility, Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

Dated: February 19, 1985.

**Richard H. Shay,**

*Acting General Counsel.*

[FR Doc. 85-4448 Filed 2-21-85; 8:45 am]

BILLING CODE 3510-DR-M

## Decision on Application for Duty-Free Entry of Scientific Instrument; the Regents of the University of California

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 am and 5:00 pm in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, D.C.

Docket No. 84-255. Applicant: The Regents of the University of California, Riverside, CA 92521. Instrument: Root Length Scanner. Manufacturer: Commonwealth Aircraft Corporation, Ltd., Australia. Intended use: See notice at 49 FR 35167.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument optically scans and provides a digital readout measurement of sample root lengths for diameters of 0.1 to 5.0 millimeters with a typical accuracy of ±5.0 percent for lengths of 15 to 60 meters. The National Institutes of Health advises in its memorandum dated December 18, 1984 that (1) the capability of the foreign instrument described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

**Frank W. Creel,**

*Acting Director, Statutory Import Programs Staff.*

[FR Doc. 85-4430 Filed 2-21-85; 8:45 am]

BILLING CODE 3510-DS-M

## Applications for Duty-Free Entry of Scientific Instruments; University of Southern California, et al.

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89-651; 80 Stat. 897; 15 CFR Part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with Subsections 301.5(a) (3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 a.m. and 5:00 p.m. in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, D.C.

Docket No. 84–149. Applicant: University of Southern California, School of Medicine, Norris Cancer Hospital & Research Institute (Room 746), Los Angeles, CA 90033. Instrument: 137 Caesium Irradiator System, Model Gamma Cell 40. Manufacturer: Atomic Energy of Canada, Ltd., Canada. Intended use: irradiation of animals and live tissue. Animals will be irradiated in order to inhibit the growth of tumors in cancer research or in order to selectively eliminate all or part of the immune system, more precisely the white blood cells or lymphocytes which are involved in protecting the organism against microbial infections and the growth of tumor cells. The overall aim of these studies is to analyze which part of the immune system is responsible for the elimination of tumors or microbial agents such as viruses, bacteria or parasites. Tissue from animals or humans which is subsequently being used in tissue culture will be irradiated in order to eliminate its ability to proliferate in culture while keeping it alive for a certain period of time. Again, the aim here is to study at this time *in vitro*, i.e., in tissue culture, how the immune system reacts to tumor or other cell types and to elucidate what the specific mechanisms of this reaction may be. The instrument will be used for formal course work involving undergraduate students and informal work involving students and postdoctoral fellows. Application received by Commissioner of Customs: March 22, 1984.

Docket No. 85–065. Applicant: USDA–ARS, Appalachian Fruit Research Station, Route 2, Box 45, Kearneysville, WV 25430. Instrument: Electron Microscope, Model H–600–2 with Accessories. Manufacturer: Nissei Sangyo America, Ltd., Japan. Intended use: Basic research on deciduous fruit trees to determine information on the nature of plant pathogens, host/parasite interactions, and freeze damage to plants. Application received by Commissioner of Customs: January 17, 1985.

Docket No. 85–076. Applicant: The Institute for Cancer Research, 7701 Burholme Avenue, Philadelphia, PA 19111. Instrument: Electron Microscope, Model EM 420T and Accessories. Manufacturer: N.V. Philips, The Netherlands. Intended use: Analysis of nucleic acid structures and subviral particles of duck hepatitis virus as well as for monitoring and checking the purity of various kinds of preparations. In addition, the following investigations will be conducted:

(1) Structure of the RNA/DNA replication intermediates of the minus strand duck hepatitis virus (DHBV) DNA.

(2) Mapping of DHBV m–RNA's by electron microscopy.

(3) Characterization of proteins and enzyme activities in DHBV replicative complexes.

(4) Intracellular location of the sites of assembly of DHBV particles.

(5) Examination of viral assembly in duck hepatocyte cultures.

(6) Exploration of the behavior of virions during adsorption to the host cell.

(7) Periplasmic space studies.

(8) Studies of the chromosome arrangement in gram-negative bacteria.

(9) Characterization of cell surface domains by immuno-electron microscopy.

(10) Studies of susceptibility and response of humans to oncogenic agents. Application received by Commission of Customs: January 4, 1985.

Docket No. 85–078 Applicant: Massachusetts Institute of Technology, Building 18–390, 77 Massachusetts Avenue, Cambridge, MA 02139. Instrument: Automatic Recording Spectropolarimeter System, Model J–500C and Accessories. Manufacturer: Japan Spectroscopic Co., Ltd., Japan. Intended use: Studies of DNA, inorganic complexes, and enzymes containing metals. Experiments will be conducted to obtain circular dichroism spectra of the macromolecules and complexes with the following objectives:

(1) To develop quantitative methods of assessing the structure of DNA and inorganic complexes.

(2) To study subtle changes of the environment of metals in proteins.

(3) To study the mechanism of structure changes when metals bind DNA and enzymes.

(4) To compare predicted and experimental structures of polymers in various environments. Application received by Commissioner of Customs: January 29, 1985.

Docket No. 85–081. Applicant: University of Wyoming, Department of Animal Science, Box 3354, University Station, Laramie, WY 82071. Instrument: Portable Sonic Wool Fineness Tester, Model CSIRO, Model B. Manufacturer: Paton Industries Pty., Ltd., Australia. Intended use: Measurement of wool fiber diameter. Comparisons of wool fiber diameter measures by sonic versus established air-flow and microprojection procedures will be done in a search for a more rapid, yet accurate, method of measuring average fiber diameter of wool samples. Applicant received by Commissioner of Customs: January 29, 1985.

Docket No. 85–082. Applicant: College of William and Mary, Biology Department, Williamsburg, VA 23185. Instrument: Electron Microscope, Model EM 109 with Accessories. Manufacturer: Carl Zeiss, West Germany. Intended use: The instrument will be used in studies of (1) red algal cell division and reproductive differentiation, (2) respiratory and osmoregulatory physiology of invertebrates and (3) osmoregulatory organs and genital papillae of astigmatid mites. The instrument will also be used for teaching electron microscopy techniques. Application received by Commissioner of Customs: February 1, 1985.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free educational and Scientific Materials)

**Frank W. Creel,**

*Acting Director, Statutory Import Programs Staff.*

[FR Doc. 85–4428 Filed 2–21–85; 8:45 am]

BILLING CODE 3510-DS-M

## Decision on Application for Duty-Free Entry of Scientific Instrument; Vanderbilt University

This decision is made pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR Part 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, D.C.

Docket No. 84–86R. Applicant: Vanderbilt University, Nashville, TN 37232. Instrument: Mass Spectrometer/Data System, Model 70/250. Original notice of this resubmitted application was published in the **Federal Register** of March 5, 1984.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument is capable of measuring high mass; 2600 atomic mass units at 6000 volts, and 15 600 at 1000 volts. The National Institutes of Health advises in its memorandum dated December 10, 1984 that (1) the capability of the foreign instrument described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value

to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

**Frank W. Creel,**

*Acting Director, Statutory Import Programs Staff.*

[FR Doc. 85-4429 Filed 2-21-85; 8:45 am]

BILLING CODE 3510-DS-M

## Minority Business Development Agency

### Decision on Petition Submitted by Ex-Felons for Designation as a Minority Group

**AGENCY:** Minority Business Development Agency (MBDA).

**ACTION:** Notice of decision.

**SUMMARY:** MBDA received a petition requesting it to designate ex-felons as a socially or economically disadvantaged group whose members are eligible for MBDA assistance. This notice announces denial of that request.

**FOR FURTHER INFORMATION CONTACT:** Mr. Herbert S. Becker, Assistant Director for Advocacy, Research & Information, Department of Commerce, Minority Business Development Agency, Room 5709, Washington, D.C 20230. Telephone 377-3163.

**SUPPLEMENTARY INFORMATION:** MBDA issued a regulation at 15 CFR Part 1400 for determination of group eligibility for MBDA assistance. (See 49 FR 42697). The purpose of this regulation is to provide procedures through which groups not previously designated can establish their social or economic disadvantage

In accordance with these regulations, a petition was submitted on behalf of all ex-felons, requesting this Agency to designate them as a socially or economically disadvantaged group whose members are eligible for MBDA assistance. Receipt of this petition by MBDA was published in the **Federal Register** and interested persons were invited to submit comments through December 31, 1984. (See FR 46923).

The Agency received fifteen comments on the petition, ten in favor of it and five opposed to it. Those in favor of the petition cited the difficulties which ex-felons have in obtaining employment and the lack of Government assistance available to ex-felons upon their release from prison as justification for granting minority status to the group.

Those opposing the petition relied upon several factors to support their decision. First, they point out that ex-felons voluntarily committed crimes. The criminal record which results from those voluntary acts is what makes it difficult for them to succeed in the business world. They argue that Executive Order 11625 (E.O. 11625) should be interpreted to restrict participation in MBDA programs to people who have done nothing to bring about their social or economic disadvantage. Second, they argue that a criminal should not stand to benefit from his crimes. If this petition were granted, persons not previously eligible to receive MBDA assistance would become eligible to receive a Government benefit solely because they had committed a felony. Finally, the designation would stigmatize those groups already recognized by MBDA.

Having considered the evidence submitted by the petitioners and the comments which the Agency received, the Director of MBDA has decided to deny the petition. His determination follows.

#### Determination

The Minority Business Development Agency issued a regulation at 15 CFR Part 1400 for determination of group eligibility for MBDA assistance. In accordance with these regulations, a petition was submitted on behalf of all ex-felons, requesting this Agency to designate them as a socially or economically disadvantaged group whose members are eligible for MBDA assistance.

This petition is denied for two reasons. First, the regulation requires that social or economic disadvantage be proven by a preponderance of the evidence. Petitioner has not met that burden of proof. Second, even assuming that adequate evidence had been submitted by petitioner, the designation should not be granted because MBDA programs were meant to benefit persons who have done nothing to bring about their social or economic disadvantage. Ex-felons have voluntarily committed crimes and their hardships in business are the direct result of their criminal activity.

The evidence which has been presented to MBDA in support of this petition is insufficient to sustain a designation of social or economic disadvantage. Section 1400.4 of the regulation requires that social or economic disadvantage be established by a preponderance of the evidence. This means that it must be more likely than not that the individual suffers social or economic disadvantage as a result of his membership in the group. Section 1400.4 of the regulation also lists the types of evidence which MBDA will consider in assessing social or economic disadvantage.

The only evidence which MBDA received in favor of this petition was six letters by current inmates stating that they were disadvantaged and one newpaper article on female inmates and a work release program. The statement of six class members, in the absence of any kind of supporting documentation, does not meet petitioner's burden of proof. Accordingly, there is insufficient evidence upon which to base a determination of social or economic disadvantage.

Even if adequate evidence of disadvantage had been presented, MBDA still could not grant minority status to ex-felons. Executive Order 11625 lists six groups whose members are considered socially or economically disadvantaged: Blacks, Puerto-Ricans, Spanish-speaking American, American Indians, Eskimos, and Aleuts. In addition to these six groups, the Department has designated three additional groups eligible to receive MBDA assistance: Chasidic Jews, Asian Pacific Americans, and Asian Indians. All of these groups have one thing in common. Their members are discriminated against in business because of things they cannot control such as their physical appearance, their native language, their native customs, or their family name. What is implicit in the Executive Order, then, is that the purpose of MBDA programs is to help these people overcome obstacles to business participation which they encounter because of characteristics over which they have no control.

Ex-felons, on the other hand, have not established that the hardships which they encounter in the business world are due to similar factors. The members of this group have voluntarily committed serious crimes. They have created their own criminal records. Group members claim that those criminal records stand in the way of their business success. Since they have created those records voluntarily, they cannot claim that the disadvantage which results from their existence is due to factors beyond their control. In keeping with the Executive Order and previous Departmental decisions, I have determined that MBDA should not grant ex-felons minority status.

Accordingly, the petition submitted on behalf of all ex-felons requesting minority designation is denied.

Dated: February 15, 1985.
**James H. Richardson Gonzales,**
*Director.*
[FR Doc. 85-4406 Filed 2-21-85; 8:45 am]
BILLING CODE 3510-21-M

## DEPARTMENT OF DEFENSE

### Department of the Air Force

### Acceptance of Group Application per Pub. L. 95-202 and DODD 1000.20

Under the provisions of section 401 of Pub. L. 95-202 and DODD 1000.20, the DOD Civilian/Military Service Review Board has accepted an application on behalf of the personnel who served aboard Coast and Geodetic Survey Vessels during World War II. Persons with information or documentation pertinent to the determination of whether the service of this group was equivalent to active military service are encouraged to submit such information or documentation within 60 days to the DOD Civilian/Military Service Review Board, Secretary of the Air Force (SAF/MIPC), Washington, DC, 20330-1440. For further information contact Lieutenant Colonel Michael J. Dandar, USAF, 202-692-4743.

**Norita C. Koritko,**
*Air Force Federal Register Liaison Officer.*
[FR Doc. 85-4392 Filed 2-21-85; 8:45 am]
BILLING CODE 3910-01-M

### Air Force Academy Board of Visitors; Meeting

Pursuant to section 9355, Title 10, United States Code, the Air Force Academy Board of Visitors will meet at the Air Force Academy, Colorado Springs, Colorado, March 14-16, 1985. The purpose of the meeting is to consider morale and discipline, the curriculum, instruction, physical equipment, fiscal affairs, academic methods, and other matters relating to the Academy.

A portion of the meeting will be open to the public on March 15, 1985, from 9:15 a.m. to 11:45 a.m. Other portions of this meeting will be closed to the public to discuss matters analogous to those listed in subsections (2), (4), and (6) of section 552b(c), Title 5, United States Code. These closed sessions will include: Attendance at cadet classes and panel discussions with groups of cadets and military staff and faculty officers involving personal information and opinions, the disclosure of which would result in a clearly unwarranted invasion of personal privacy. Closed sessions will also include executive sessions involving discussions of personal information, including fianancial information, and information relating solely to internal personnel rules and practices of the Board of Visitors and the Academy. Meeting sessions will be held in the Superintendent's Conference Room, Harmon Hall, USAF Academy.

In addition to the open meeting session, the public is welcome to attend a press conference scheduled for 11:15 a.m. to 11:45 a.m. on March 16, 1985, in the Falcon Room, USAF Academy Officers' Open Mess.

For further information, contact Major James A. Steele, Headquarters, U.S. Air Force (MPPA), Washington, D.C. 20330, at (202) 697-7116.

**Norita C. Koritko,**
*Air Force Federal Register Liaison Officer.*
[FR Doc. 85-4393 Filed 2-21-85; 8:45 am]
BILLING CODE 3910-01-M

### USAF Scientific Advisory Board; Ad Hoc Committee on the Enhancement of Special Operations Forces; Meeting

February 16, 1985.

The $C^3$ and ECM, Sensors and Navigation subcommittees of the USAF Scientific Advisory Board Ad Hoc Committee on Enhancement of Special Operations Forces will meet 18-19 March at 8:00 a.m. to 5:00 p.m. at Hanscom AFB, MA, location to be determined.

The purpose of the meeting will be to discuss Technology Projects and Systems programs relevant to Special Operations. The meeting concerns matters listed in Section 552b(c) of Title 5, United States Code, specifically, subparagraphs (1) and (4) thereof and is closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 202-697-8404.

**Norita C. Koritko,**
*Air Force Federal Register Liaison Officer*
[FR Doc. 85-4389 Filed 2-21-85; 8:45 am]
BILLING CODE 3910-01-M

### USAF Scientific Advisory Board; Ad Hoc Committee on the Enhancement of Special Operations Forces; Meeting

February 16, 1985.

The Weapons subcommittee of the USAF Scientific Advisory Board Ad Hoc Committee on Enhancement of Special Operations Forces will meet 18-19 March at 8:00 a.m. to 5:00 p.m. at Eglin AFB, FL, Johnson Hall.

The purpose of the meeting will be to discuss Technology Projects and Systems programs relevant to Special Operations. The meeting concerns matters listed in Section 552b(c) of Title 5, United States Code, specifically, subparagraphs (1) and (4) thereof and is closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 202-697-8404.

**Norita C. Koritko,**
*Air Force Federal Register Liaison Officer*
[FR Doc. 85-4391 Filed 2-21-85; 8:45 am]
BILLING CODE 3910-01-M

### USAF Scientific Advisory Board; Meeting

February 13, 1985.

The USAF Scientific Advisory Board's Engineering and Services Advisory Group will meet at the Pentagon, Washington, DC on March 21, 1985.

The purpose of the meeting will be a review of Engineering and Services' worldwide responsibilities and the research and development program to meet Engineering and Services requirements. The meeting will convene from 9:00 a.m. to 5:00 p.m.

The meeting concerns matters listed in Section 552b(c) of Title 5, United States Code, specifically subparagraph (1) thereof, and accordingly, will be closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 202-697-8845.

**Norita C. Koritko,**
*Air Force Federal Register Liaison Officer.*
[FR Doc. 85-4388 Filed 2-21-85; 8:45 am]
BILLING CODE 3910-01-M

### USAF Scientific Advisory Board; Ad Hoc Committee on the Enhancement of Special Operations Forces; Meeting

February 16, 1985.

The ECM, Sensors, and Navigation, and Weapons subcommittees of the USAF Scientific Advisory Board Ad Hoc Committee on Enhancement of Special Operations Forces will meet 20 March at 8:00 a.m. to 5:00 p.m. and 21 March at 8:00 a.m. to 3:00 p.m. at Wright Patterson AFB, OH, location to be determined.

The purpose of the meeting will be to discuss Technology Projects and Systems programs relevant to Special Operations. The meeting concerns matters listed in Section 552b(c) of Title 5, United States Code, specifically, subparagraphs (1) and (4) thereof and is closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 202-697-8404.

Norita C. Koritko,

*Air Force Federal Register Liaison Officer.*

[FR Doc. 85-4390 Filed 2-21-85; 8:45 am]

BILLING CODE 3910-01-M

## Corps of Engineers, Department of the Army

### Intent To Prepare a Draft Environmental Impact Statement (DEIS) for a Department of the Army (DA) Regulatory Permit Action for Work in Conjunction With the Proposed Kuilima Resort Expansion Project, Kahuku, Oahu, HI

**AGENCY:** U.S. Army Corps of Engineers, Honolulu District, Pacific Ocean Division, DOD.

**ACTION:** Notice of intent to prepare a DEIS for regulatory permit action.

**SUMMARY:**

**1. Description of the Proposed Action**

The Kuilima Development Company plans to expand the existing Kuilima Resort Complex. As part of the expansion, the company has applied for a Department of the Army permit requesting authorization to improve Punahoolapa Marsh, to realign an existing drainage channel, to improve two existing drainage channel outlets and to dredge silt from Kawela Bay. These activities require a Department of the Army permit under the authority of section 10, River and Harbor Act of 1899, as amended, and section 404, Clean Water Act, as amended.

The marsh improvements would create a waterbird sanctuary, and require the discharge of fill material into approximately 13.0 acres of wetlands along the fringe of the Punahoolapa Marsh and the construction of a concrete weir water control structure. Excavation in the marsh to create open water bodies and moats are not regulated by the Department of the Army permit. Upon completion, the sanctuary would have 6.2 acres of new marshlands, up to 35 acres of open water and 1.4 acres of man-made islands. A 10-foot wide moat and a 6-foot high chain link fence will encircle the Marsh and prevent predators from entering the sanctuary. Vegetation will be provided to shield the birds from human activities. A walkway and observation facility will allow bird watching activities. The concrete wier will control marsh water levels and prevent seawater infiltration into the marsh.

One drainage channel would be modified to divert a major portion of the Kawela Stream discharge from Kawela Bay to Turtle Bay. Two drainage outlet modifications are proposed. The new drainage outlet together with improvements to another existing drainage outlet require excavation below the mean high water line. The outlet structures would have bottom widths of 75 and 100 feet.

To improve the shoreline and offshore conditions in Kawela Bay, the applicant plans to remove the stream-deposited silt from the bay. The excavated material will be disposed of on the applicant's upland properties.

**2. Description of Reasonable Alternatives**

The alternatives which may be included in the draft environmental impact statement include:

a. No Action.

b. Reduction in the scope of work including one or more of the following:

Limiting the number of actions requested by the permit

Reducing the scope of the project

Eliminating the need for fill in the wetland

Eliminating the need for outlet and channel improvements

Eliminating the need to dredge Kawela Bay.

c. Reasonable and practicable alternatives that can be undertaken by the applicant alone.

d. Reasonable and practicable alternatives that can be instituted by some other government agency and private party.

**3. Scoping Process for the DEIS**

a. The public and affected Federal, State and local agencies, and other interested private organizations and parties are invited to comment on or identify specific concerns which should be addressed in the DEIS. It is estimated that the DEIS will be made available to the public in June 1985. Upon preparation of the DEIS, a public notice shall be issued summarizing the facts of the case and announcing the availability of the DEIS. If a public hearing is requested, it will be held after completion of the DEIS. A public notice announcing the time, date, location and nature of the hearing would be issued at least 30 days prior to the hearing date.

b. The significant issues to be analyzed in the DEIS will include:

(1) Impacts of the fill on water quality in the marsh and secondary effects of other activities in the marsh.

(2) Impacts of the channel and outlet modifications on coastal zone resources including coastal water quality, and on drainage characteristics in the area.

(3) Impacts of authorized actions on flora and fauna, threatened and endangered species, air quality, archaeological and historic resources and recreation.

(4) Relationship of authorized actions to the total project planned by the developer including tertiary and cumulative, aesthetics, socio-economic, infrastructure and land use impacts.

Questions about the proposed action and DEIS can be answered by: Mr. Michael T. Lee, Acting Chief, Operations Branch, Construction-Operations Division, U.S. Army Corps of Engineers, Fort Shafter, Hawaii, 96858-5440, Telephone: (808) 438-9258.

Dated: February 13, 1985.

Michael M. Jenks,

*Colonel, Corps of Engineers, District Engineer.*

[FR Doc. 85-4372 Filed 2-21-85; 8:45 am]

BILLING CODE 3710-NN-M

### Intent to Prepare a Draft Environmental Impact Statement (DEIS) for Proposed Permit Actions Concerning Initial Phase of the Remedial Action Plan Proposed by Olin Corporation for Mitigation of DDT Contamination, Huntsville Spring Branch, Wheeler Reservoir, AL

**AGENCY:** Army Corps of Engineers, Nashville District, DOD.

**ACTION:** Intent to prepare a draft environmental impact statement (DEIS).

**SUMMARY:**

**1. Proposed Action**

Olin Chemical has notified the Nashville District of its intention to apply for Department of the Army Permits (section 10 and 404) covering the first phase of necessary work associated with the Remedial Action Plan to address DDT contamination in Huntsville Spring Branch (HSB) and Indian Creek, Tennessee River, Alabama. The proposed work is the result of several years of study by Federal agencies and their contractors; litigation between the United States of America, the State of Alabama, and four sets of private parties against the Olin Corporation; and a Consent Decree that governs the implementation of the Remedial Plan. The Consent Decree established a review panel composed of members from the United States Environmental Protection Agency (EPA),

Tennessee Valley Authority (TVA), U.S. Fish and Wildlife Service (FWS), Department of the Army (DA), the State of Alabama, and nonvoting members of the Town of Triana, Alabama, and the Olin Corporation. This review panel has approved the Olin proposal to isolate DDT from the environment of the Huntsville Spring Branch (HSB)—Indian Creek (IC) Complex, and the permit review will cover the initial effort of a phased approach designed to meet performance criteria of reducing DDT levels to below 5 parts per million in fillets of three indigenous fish species. Additional remedial actions may be undertaken as necessary to meet the performance criteria.

The central element of Olin's Remedial Action Plan is a diversion of HSB around the heavily-contaminated channel between HBS Miles 5.57 and 4.0. Alignment of the diversion is through an existing side-channel (referred to as the "loop"), 1,500 feet of excavated channel, and an existing embayment. Construction of this diversion would require installation of two dams, approximately 8,300 feet of access roads, and two staging areas totalling 15 acres.

Upon completion of the HSB diversion the contaminated channel between HSB Miles 5.57 and 4.0 would be isolated from HSB flow by constructing two dams across the channel at HSB miles 4.2 and 4.0. Construction of these dams would require 4,000 feet of access roads and a 5-acre staging area. A diversion ditch would be excavated north of the isolated HSB channel segment to route surface runoff to a point below the dam at HSB Mile 4.0. The impounded channel between the dams at HSB Miles 4.2 and 4.0 would act as a settling basin for water discharged from the channel upstream of HBS Mile 4.2.

Filling of the bypassed, contaminated channel with clean off-site material would proceed upstream from the dam at HSB Mile 4.2 and downstream from the dam at HSB Mile 5.57 simultaneously. Once this section is complete, the channel between dams at HSB Miles 4.0 and 4.2 would be covered. The covered channel would be graded to conform to existing topography and revegetated. Staging areas would be returned to their approximate original grade and revegetated upon completion of the channel covering. Access roads would remain in place and would be maintained as necessary.

**2. Alternatives**

Alternatives which have been identified at this time are (1) no action (denial of the permits), (2) issuance of permits with normal conditions and (3) issuance of permits with special conditions requiring a variety of environmental mitigation or enhancement measures.

**3. Scoping Process**

a. *Input.* The public is invited to aid in determining the issues to be covered in the DEIS by submitting written comments within 20 days of this notice. Additionally, input from concerned Federal, State, and local agencies and from organizations or individuals known to have interest in the work is being solicited by letter. The Tennessee Valley Authority, Environmental Protection Agency, and U.S. Fish and Wildlife Service have been requested to participate in the process as cooperating agencies. The DEIS will also provide NEPA documentation for TVA's 26A Permit action and FWS's Refuge Use Permit action.

b. *Issues.* The following is as preliminary list of significant issues which have been identified for analysis in the DEIS.

(1) Appropriate environmental conditions which could be included in the requested permits.

(2) Effects on wildlife and wildlife habitat.

(3) Effects on Redstone Arsenal operations.

(4) Effects on water quality (including turbidity, water supply, toxic materials, and recreation impacts).

(5) Effects on cultural resources.

(6) Socioeconomic impacts.

(7) Effects on aquatic organisms and habitat.

(8) Effects on endangered species.

c. *Other Environmental Review and consultation.* (1) Public notices soliciting comments concerning the permit actions will be distributed as part of the public interest review.

(2) The work must be evaluated in light of the Environmental Protection Agency's 404(b) Guidelines (40 CFR Part 230).

(3) Pursuant to the National Historic Preservation Act, the State Historic Preservation Officer will be consulted concerning the permit actions.

(4) The action will be coordinated with the U.S. Fish and Wildlife Service to determine whether consultation under the Endangered Species Act is required.

**4. Scoping Meeting**

No scoping meeting will be conducted. Scoping input will be entirely solicited by letter, newspaper notices and this Notice of Intent.

**5. Estimated Completion**

It is estimated that the DEIS will be made available to the public in July 1985.

*Questions*: The Nashville District point-of-contact for questions or scoping input concerning the DEIS is: Mr. Ray Hedrick, Planning Branch, U.S. Army Engineer District, Nashville, P.O. Box 1070, Nashville, Tennessee 37202.

Dated: February 13, 1985.

**William T. Kirkpatrick,**

*Colonel, Corps of Engineers, District Engineer.*

[FR Doc. 85-4395 Filed 2-21-85; 8:45 am]

BILLING CODE 3710-GF-M

## DEPARTMENT OF EDUCATION

### National Center for Research in Vocational Education Advisory Committee; Meeting

**SUMMARY:** This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the National Center for Research in Vocational Education Advisory Committee. This notice also describes the functions of the Committee. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend.

**DATE:** March 18, 1985.

**ADDRESS:** The National Center for Research in Vocational Education, Ohio State University, 1960 Kenny Road, Columbus, Ohio 43210.

**FOR FURTHER INFORMATION CONTACT:** Dr. Howard F. Hjelm, Director, Office of Vocational and Adult Education, Division of Innovation and Development, 7th and D Streets, SW., Rm. 5044, ROB 3, Washington, D.C., 20202-3572, (202) 245-2278.

**SUPPLEMENTARY INFORMATION:** The National Center for Research in Vocational Education Advisory Committee is established under Section 404 of the Carl D. Perkins Vocational Education Act of 1984 (Pub. L. 98-524). The Committee is established to advise the Secretary and the National Center's Director with respect to policy issues in the administration of the National Center and in the selection and conduct of major research and demonstration projects and activities of the National Center. Meetings held at the request of the Secretary are conducted in accordance with the Federal Advisory Committee Act (FACA).

The meeting of the Committee is governed by FACA and is open to the

public on March 18, 1985 from 1:00 p.m. to 4:30 p.m. The proposed agenda includes:

1:00–2:30

A. Dialogue on the Implications of the New Vocational Education Legislation for the National Center for Research in Vocational Education.

1. Functions of the National Center for Research in Vocational Education.

2. Composition and Role of the National Center for Research in Vocational Education Advisory Committee.

2:30–3:15

B. Secretary's Vocational and Adult Education Discretionary Programs

3:15–4:00

C. Mid-Contract Review for the National Center for Research in Vocational Education.

4:00–4:30

D. Year IV Grant for the National Center for Research in Vocational Education.

This meeting will be held in conjunction with a regular meeting of the Committee to advise the Center Director.

Records are kept of all Committee proceedings and are available for public inspection in the Program Improvement Systems Branch, 7th & D Streets SW., Room 5018, ROB 3, Washington, D.C. 20202–3575; telephone: (202) 245–2617.

Dated: February 14, 1985.

**Robert M. Worthington,**

*Assistant Secretary for Vocational and Adult Education.*

[FR Doc. 85–4325 Filed 2–21–85; 8:45 am]

BILLING CODE 4000-01-M

## DEPARTMENT OF ENERGY

### Decision of the Secretary of Energy—California-Oregon Transmission Project; Correction

**AGENCY:** Department of Energy.

**ACTION:** Publication of attachment, Memorandum of Decision, to a notice which was published on February 20, 1985 (50 FR 7102).

**SUMMARY:** In the referenced **Federal Register** notice, and announcement of a decision by the Secretary of Energy on the terms and conditions for development of a third 500-kV AC line to the Pacific Northwest-Southwest Intertie, was published. The attached Memorandum of Decision document was inadvertently not published with the notice.

Issued in Washington, D.C., February 20, 1985.

**Ronald K. Greenbalgh,**

*Assistant Administrator for Washington Liaison, Western Area Power Administration*

### Decision of the Secretary of Energy California-Oregon Transmission Project

Pursuant to the authority of Title III of the Energy and Water Development Appropriations Act for Fiscal Year 1985 (Pub .L. 98–360), and after a full and complete review and consideration of the comments, recommendations and record of public hearing, held January 25, 1985, regarding a proposed memorandum of Understanding (MOU) for the financing, construction and operation of a new alternating current 500-kV transmission line from the Pacific Northwest to California, known as the California-Oregon Transmission Project, I have determined, on behalf of the U.S. Department of Energy, that the MOU should be and is hereby approved, subject to the modifications and conditions set forth in the attached Memorandum of Decision.

February 7, 1985.

Donald Paul Hodel.

### Memorandum of Decision for the California-Oregon Transmission Project

*Introduction and Summary*

Title III of the Energy and Water Development Appropriations Act for Fiscal Year 1985 (Pub. L. 98–360) authorized the Secretary of Energy to "construct or participate in the construction of such additional facilities as he deems necessary to allow mutually beneficial power sales between the Pacific Northwest and California." The Conference Report to this legislation required the Secretary to submit a conceptual plan for construction of a new 500 kV AC line to Congress within 120 days.

Pursuant to this authority, the Western Area Power Administration (Western) published on August 6, 1984 (49 FR 31335) a request for statements of interest in the development of such an intertie line between the Pacific Northwest and California. On December 24, 1984 the Secretary transmitted to Congress a conceptual plan for development of the California-Oregon Transmission Project (the Project), including a proposed implementation plan in the form of a Memorandum of Understanding (MOU) developed by California investor and publicly-owned utilities. By public notice of January 3, 1985 (50 FR 420), all interested parties were provided with an opportunity to comment on the proposed MOU. A public hearing on the proposed MOU was held on January 25, 1985 in Sacramento, California.

Based upon a full and complete review of the transcript of the public hearing and the written comments, the Secretary has determined that the MOU represents an appropriate plan for development of the Project, subject to the following modifications and conditions:

1. Ownership of the upgraded segment of the Project shall be retained by the United States as part of the federal Central Valley Project (CVP).

2. Users of the 6.25% of Project transfer capability reserved to Western for the Department of Energy (DOE) laboratories and the federal wildlife refuges shall pay the CVP reasonable transmission fees to be established by Western. Project transfer capability not used by the DOE laboratories and the federal wildlife refuges shall be available to other federal agencies. Acceptable firm transmission service arrangements under reasonable rates, terms, and conditions shall be provided by Project Participants to those laboratories, refuges and agencies.

3. The opportunity to participate in 3.125 percent of the transfer capability of the Project shall be made available for allocation by Western among the non-federal public entities who responded to both the August 6, 1984 and the January 3, 1985 **Federal Register** notices, excluding those entities who are MOU Participants or signatories or are represented by such Participants. Such entities shall, upon acceptance of an allocation, receive equal status with other Participants, including all rights, privileges and responsibilities set forth in the MOU.

*Comments*

In response to the January 3, 1985 notice, DOE received more than 50 written comments, and thirty people testified at the Janaury 25 public hearing. Commenters included Members of Congress, state officials, Participants in the MOU, irrigation districts, public utilities, federal agencies, Pacific Northwest entities and others.

A number of commenters enthusiastically endorsed the Project and the MOU, saying that the Project would provide low cost power to millions of consumers. They explained that utilities serving more than 98% of California's electrical customers are represented under the MOU. Further, several commenters stated that, since the MOU is structured so that no federal funds are required for the Project, the MOU should be adopted.

On the other hand, several of the irrigation districts and public utility districts complained that they had been unfairly excluded from the negotiations that resulted in the proposed MOU. Other commenters proposed specific amendments to the MOU to liberalize access to non-participants. One party complained that no provision had been made for new or emerging utilities, while others sought various levels of participation in the Project.

The Pacific Northwest entities raised a number of concerns, including the effect of the MOU upon access, rates and terms of displacement sales. The federal entities questioned the sufficiency of compensation to the federal government, including whether the federal entities are entitled to a greater share of the newly available energy. In addition to other specific recommendations, the federal entities complained that they too were denied sufficient access to the process by which the MOU was developed.

*Discussion*

*Compensation for federal contribution.* The Conference Report accompnaying H.R. 5653, which became Pub. L. 98-360, enjoined the Secretary to derive "fair compensation" for the contributed federal facilities. The report states:

> To recompense the Federal taxpayer for the value of the contributed Federal facilities the Secretary shall obtain fair compensation from the non-Federal participants. Such compensation may be in the form of transmission capacity on the new 500 kV AC line, monetary payment, or other benefit which the Secretary may determine a fair equivalent." H.R. Report No. 98-866, p. 57.

Although the money for all activities related to development of the Project will come from non-federal sources, the United States will make an important contribution in the form of the use of its existing right-of-way and towers for the 200-mile segment of the line from Redding to Tracy. This segment constitutes about two-thirds of the total distance of the line.

A comparison of the CVP transfer capability presently available with that available to the CVP after the upgrade is completed shows that CVP operations will not be impaired. That is, while the two existing 230 vK circuits have a potential transfer capability of up to 600 mW, the actual load they carry has never exceeded 325 mW. Under the proposed MOU, Western is guaranteed a transfer capability of 300 mW in the upgrade of the existing 230 kV circuits (Section 5.4.1), plus priority rights on the capability above 1900 mW up to an additional 300 mW (Section 5.4.2). The ongoing studies indicate that such additional capability above 1900 mW is technically feasible. Thus the CVP's transmission capability will equal or exceed that presently utilized.

In addition, the United States will receive 6.25 percent of the Project transfer capability, or 100 mW of the anticipated total transfer capability of 1600 mW. This is a substantial benefit. The proposed MOU provides that this capacity will be used to serve the needs of the DOE laboratories and the federal wildlife refuges (Section 5.1.4). The Conference Report, however, indicated the possibility of other federal entities participating in the Project, although priority was to be given to federal laboratories and wildlife refuges. Report, p. 57. Therefore, the Secretary has determined that the MOU should be modified to provide for use of this capacity by other federal agencies to the extent that it is not needed by the DOE laboratories and federal wildlife refuges. Required transmission services for such federal loads shall be made available, consistent with the intent of Congress. Furthermore, since the 100 mW represents compensation for the use of a right-of-way and facilities that were acquired and constructed many years ago and which have been paid for over the years by all beneficiaries of the CVP, the entities which use this capacity should pay Western a reasonable transmission fee to be credited to the CVP.

The Conference Report also provides that "in no event shall the Secretary reserve more than 50 percent of the total uprated transfer capability of any modified and upgraded Federal facilities, or more than 12.5 percent of the transfer capability of the non-federal segment of the line." Report, p. 57. Some commenters have taken the position that this statement represents a directive that the MOU should provide for federal transfer capability in these amounts. It is clear that Congres intended that the indicated percentages are maximums only. The report recognizes that further evaluation by the Secretary would be necessary to arrive at the appropriate percentages. Therefore the MOU, as modified, conforms with Congress' intent.

In addition to the reservation of capacity, the United States will receive real benefits in the form of increased system stability and reliability from Western's use of the new substation facility at Redding.

The MOU contemplates that, in addition to the use of the Federal right-of-way and existing towers, ownership of the right-of-way and the upgraded facility will be transferred by the United States to the Participants. New statutory authority would be necessary to effect this transfer. Moreover, studies have questioned the adequacy of the compensation to the United States if such ownership is transferred. Therefore, the Secretary has determined that it would be prudent to retain the ownership of these facilities in the United States.

For the reasons stated above, the MOU, as modified, satisfies the requirement of fair compensation to the federal government.

*Participation by additional public utilities.*—Several commenters complained that they were not included in the negotiations that resulted in the MOU. The MOU, however, is not the final word on participation in the Project. To the contrary, the **Federal Register** notices of August 6, 1984 and January 3, 1985 and the public hearing held January 25 were for the express purpose of ensuring that all interested parties were aware of and had the opportunity to comment on the development of the Project.

Through the comment and hearing process a number of publicly-owned utilities and irrigation districts have demonstrated that they possess the need, capability and seriousness of commercial purpose to participate in the Project, in accordance with the intent of Congress. Accordingly, taking into account respective peak demands, existing and proposed Intertie capacities, and other practical and equitable considerations, the Secretary has determined that a modification to the MOU is appropriate. An opportunity to participate in 3.125 percent of the transfer capability of the Project shall therefore be allocated by Western among the non-federal public entities who responded to the August 6 and January 3 notices, excluding those entities who are MOU Participants or signatories or are represented by Participants. This 3.125 percent capability, which is 50 mW of the anticipated Project transfer capability level of 1600 mW, will be made available from a pro-rata reduction in the shares of the present Participants int he MOU other than Western. Western will conduct a proceeding to determine the allocation of this amount. Each allottee will be expected to make an up-front contribution for its share of the cost of the Project.

*Comments of Pacific Northwest entities.*—A number of commenters expressed concern that the MOU may be a possible vehicle for influencing the access or rate policies of Pacific Northwest entities with respect to the

use of intertie lines or transactions over those lines. These concerns were summarized in a letter of Jnuary 31, 1985 from Senator Mark O. Hatfield to the Secretary, to which he responded by letter of February 4, 1985. Copies of these letters are attached. The Secretary assured Senator Hatfield that each region, the Pacific Northwest and the Pacific Southwest, should determine the sales, purchase and access policies that are in their own best interest. The MOU therefore does not affect in any manner the policies, actions or proceedings of the Pacific Northwest entities.

*Other issues.*—The Secretary has noted that the proposed MOU commits Participants to support additional legislation and report language regarding the Project (Section 11.2). The Secretary cannot obligate DOE or Western to support legislation without prior internal government approval, which has not occurred. The Secretary therefore has approved the MOU upon the additional condition that this provision is not binding on either DOE or Western.

In addition, since Congress meant for the Project to proceed as promptly as possible, the Secretary intends to notify Congress within 60 days of publication of this decision in the **Federal Register** whether he is in receipt of an MOU consistent with the conditions and modifications set forth above.

*Conclusion*

The MOU, as amended, reflects the culmination of a complex process aimed at assuring the benefits of a new transmission facility to as many ratepayers as possible. Consistent with that intent and with the authority and flexibility provided by Congress, the Secretary has determined that the MOU, as modified and conditioned herein, is in the public interest and should be approved.

February 4, 1985.

Honorable Mark O. Hatfield,
*United States Senate, Washington, D.C. 20510*

Dear Mark: Thank you for your kind letter of February 1, 1985, regarding the Memorandum of Understanding (MOU) on the third 500 kV AC line, which Congress authorized in Title III of the Energy and Water Development Appropriation Act for Fiscal Year 1985. I agree that it provides a landmark opportunity for interregional cooperation and that significant mutual benefits can accrue to both the Pacific Southwest (PSW) and the Pacific Northwest (PNW).

Your interpretation of the MOU is the same as ours. The Department of Energy's understanding in reviewing and forwarding the draft MOU to Congress was that each region, the PSW and the PNW respectively, must decide the sales or purchases that is in their own best interest. Further, the MOU should not be read as impinging upon the Bonneville Power Administration (BPA) authorities and policies respecting rates and intertie access.

With respect to extraregional access, the BPA's near term Intertie Access Policy provides access to Canadian utilities when capacity is not otherwise subscribed by PNW utilities. I understand that BPA has offered and continues to discuss the possibility of greater access if agreement by extraregional utilities can be reached on improved coordination between the Canadian and PNW power systems. This policy and continuing effort is consistent with the MOU, but not otherwise affected by it.

The Department is also aware that the proper level and design of BPA rates for sales of non-firm power to PSW utilities are currently the subject of a proceeding at the Federal Energy Regulatory Commission. It is not our intent that the MOU should affect or be affected by the outcome of that proceeding.

I trust that this clarifies the Department's understanding with regard to the MOU and the issues you raised.

Sincerely,

Donald Paul Hodel.

January 31, 1985.

The Honorable Donald Paul Hodel,
*Secretary of Energy,*
*Department of Energy,*
*Washington, D.C. 20959*

Dear Don: On December 24, 1985, you forwarded to Congress a draft Memorandum of Understanding (MOU) negotiated by major California utilities that intend to participate in the construction of the third AC Pacific Northwest-Pacific Southwest Intertie line.

I want to congratulate you and the Department of Energy on your efforts in facilitating this agreement which represents a tremendous opportunity for both regions. Significant mutual benefits from increase of intertie capacity will be forthcoming, and all participants may look forward to sharing in these benefits. However, it is important to emphasize that Pacific Southwest utilities are not forced to purchase and Pacific Northwest utilities are not forced to sell resources against their interest. While regional interdependence is facilitated, regional independence is also assured.

On this latter point, I have had numerous inquiries seeking assurance that the MOU and related discussions are to be interpreted in a manner consistent with BPA's existing authorities and policies respecting rates and access to the Intertie, including Canadian access. This would appear to be the intent of the MOU. As you are aware, many members of Congress are on record as supporting the adoption and implementation of BPA's near-term Intertie Access Policy. I would appreciate the Department's further assurance that my interpretation of the MOU is correct and that it in no way is to be interpreted as impinging on these authorities and policies.

Thank you for your prompt attention to this matter.

Sincerely,

Mark O. Hatfield,
*Chairman.*

[FR Doc. 85-4612 Filed 2-21-85; 12:54 pm]

BILLING CODE 6450-01-M

## National Petroleum Council; Refinery Capability Task Group; Meeting

Notice is hereby given that the Refinery Capability Task Group will meet in March 1985. The National Petroleum Council was established to provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and natural gas or the oil and natural gas industries. The Refinery Capability Task Group will address previous Council refining studies and evaluate future refinery operations and their impact on petroleum markets. Its analysis and findings will be based on information and data to be gathered by the various task groups.

The Refinery Capability Task Group will hold its forth meeting on Tuesday, March 5, 1985, starting at 9:00 a.m., in the Austin Room of the Houston Airport Marriott Hotel, 18700 Kennedy Boulevard, Houston, Texas.

The tentative agenda for the Refinery Capability Task Group meeting follows:

1. Opening remarks by Chairman and Government Cochairman.

2. Review the work of the Task Group.

3. Discuss any other matters pertinent to the overall assignment from the Secretary of Energy.

The meeting is open to the public. The Chairman of the Refinery Capability Task Group is empowered to conduct the meeting in a fashion that will, in his judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Refinery Capability Task Group will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements should inform Mrs. Carolyn Klym, Office of Oil, Gas, Shale and Coal Liquids, Fossile Energy, 301/353-2709, prior to the meeting and reasonable provisions will be made for their appearance on the agenda.

Summary minutes of the meeting will be available for public review at the Freedom of Information Public Reading Room, Room 1E-190, DOE Forrestal Building, 1000 Independence Avenue SW., Washington, D.C., between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, D.C. on February 14, 1985.

William A. Vaughan,

*Assistant Secretary, Fossil Energy.*

[FR Doc. 85-4451 Filed 2-21-85; 8:45 am]

BILLING CODE 6540-01-M

## Economic Regulatory Administration

### Application by Northern States Power Company To Amend the Presidential Permit Issued in Docket No. PP-63

**AGENCY:** Economic Regulatory Administration, DOE.

**ACTION:** Notice of an application filed by Northern States Power Company (NSP) for an amendment of the Presidential permit issued by the Economic Regulatory Administration (ERA) in 1979.

**SUMMARY:** NSP has petitioned ERA to amend and modify the Presidential permit issued in Docket No. PP-63 to authorize changes in import provisions agreed to between NSP and the Manitoba Hydro Electric Board (MHEB) and the Manitoba Energy Authority (MEA).

**FOR FURTHER INFORMATION CONTACT:**

Anthony J. Como, Coal and Electricity Division, Office of Fuels Programs, Economic Regulatory Administration, Department of Energy, Forrestal Building, Room GA-033, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 252-5935

Lise Courtney M. Howe, International Trade and Emergency Preparedness, Office of General Counsel, Department of Energy, Forrestal Building, Room 6A-167, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 252-2900.

**SUPPLEMENTARY INFORMATION:** On January 31, 1985, NSP petitioned ERA to amend and modify its order in Docket No. PP-63 authorizing NSP to construct, connect, operate and maintain electric transmission facilities at the international border between the United States and Canada. New import provisions agreed to between NSP and the MHEB and the MEA call for a firm capacity purchase by NSP of 500 megawatts at a 75% year-round capacity factor. The price of this capacity and energy is essentially 80% of the cost of NSP's next generating unit, and the energy that will be produced from it. Additionally, Manitoba has guaranteed an average annual delivery of 1.5 million megawatt hours of surplus to NSP during this contract period. The existing contract provides for a 500 megawatt purchase by NSP from Manitoba during the summer season and a 300 megawatt delivery by NSP to Manitoba during the winter.

The facilities to be used under the new contract are the same as those used under the existing contract and order.

Any person desiring to be heard or to protest this application to amend the Presidential permit in Docket No. PP-63 should file a petition to intervene or protest with the Economic Regulatory Administration, Room GA-033, Forrestal Building, Washington, D.C. 20585, in accordance with §§ 385.211 or 385.214 of the Rules of Practice and Procedure (18 CFR 385.211, 385.214).

Any such petitions and protests should be filed on or before March 15, 1985. Protests will be considered by ERA in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application will, upon request, be made available for public inspection and copying at the Department of Energy's Freedom of Information Reading Room, Room 1E-190, Forrestal Building, Washington, D.C., from 9:00 a.m. to 4:00 p.m., Monday through Friday.

Issued in Washington, D.C. on February 14, 1985.

James W. Workman,

*Director, Office of Fuels Programs, Economic Regulatory Administration.*

[FR Doc. 85-4450 Filed 2-21-85; 8:45 am]

BILLING CODE 6450-01-M

## Federal Energy Regulatory Commission

**[Docket No. RP84-79-004]**

### Gas Gathering Corp.; Petition for Waiver of Regulations

February 15, 1985.

Take notice that on February 8, 1985, Gas Gathering Corporation (GGC) tendered for filing a Petition For Waiver Of Regulations establishing fees for pipeline rate matters set by Commission Order No. 361. In the petition, GGC requests a refund of the filing fee paid in Docket No. RP84-79-003. GGC contends that the $2,000 filing fee should not apply to the new tariff sheet filed along with its section 4(e) motion to put a suspended rate into effect.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such petitions or protests should be filed on or before February 25, 1985. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any persons wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

*Secretary.*

[FR Doc. 85-4409 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

**[Docket Nos. ER85-273-000, et al.]**

### Holyoke Water Power Co., et al.; Electric Rate and Corporate Regulation Filings

February 15, 1985.

Take notice that the following filings have been made with the Commission:

#### 1. Holyoke Water Power Company

[Docket No. ER85-273-000]

Take notice that on February 4, 1985, Holyoke Water Power Company submitted for filling a Notice of Termination, on behalf of itself and Holyoke Power and Electric Company, for CL&P's Rate Schedule FPC No. 41, HELCO's Rate Schedule FPC No. 36, WMECO's Rate Schedule FPC No. 53, HWP Rate Schedule FPC No. 23 and HP&E Schedule No. 14.

*Comment date:* March 1, 1985, in accordance with Standard Paragraph E at the end of this notice.

#### 2. Duquesne Light Company

[Docket No. ER85-264-000]

Take notice that Duquesne Light Company (DLC) on January 30, 1985, tendered for filing proposed changes in its FERC Municipal Electric Resale Service Tariff for Pitcairn, Pennsylvania. DLC requested that the proposed rate scheduled change become effective on April 1, 1985. DLC indicates that the proposed change would increase revenues from jurisdictional sales by $159,110.75 based on the twelve-month period ending March 1, 1985. DLC indicates that it has experienced increased costs for service to the Borough.

DLC states that copies of the filing were mailed to the Pennsylvania Public Utility Commission and to the Secretary of the Borough of Pitcairn on Janaury 29, 1985.

*Comment date:* March 1, 1985, in accordance with Standard Paragraph E at the end of this notice.

**3. Detroit Edison**

[Docket No. ER85-248-000]

Take notice that on January 18, 1985, Detroit Edison submitted for filing a Letter of Understanding of Amendment No. 6 to the operating agreement dated March 1, 1966. This agreement between Consumers Power Company, The Detroit Edison Company, and the Toledo Edison Company is designated as Detroit Edison Rate Schedule FERC No. 11.

The letter will reduce the amount of the Specific Capacity Power by the Specific Capacity Energy—Thermal portion for an indefinite period commencing on January 1, 1985. This temporary reduction in power does not alter in any way the rates and terms of Amendment No. 6 to the Operating Agreement dated March 1, 1966.

*Comment date:* March 4, 1985, in accordance with Standard Paragraph E at the end of this notice.

**4. Otter Tail Power Company**

[Docket No. ER84-38-003]

Take notice that on Janaury 29, 1984, Otter Tail Power Company (Otter Tail) submitted for filing a compliance report pursuant to the Commission's letter dated July 3, 1984.

The Compliance Report indicates that the transmission loss value should be further reduced by one and one half percent (1.5%) and the transformer loss value of 1.5% will supersede the 2% transformer loss value included as part of the current tariffs. Otter Tail also submitted revised rate schedules.

*Comment date:* March 4, 1985, in accordance with Standard Paragraph H at the end of this notice.

Standard Paragraphs:

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

H. Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, on or before the comment date. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 85-4420 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

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**[Docket No. TA85-1-53-004]**

## K N Energy, Inc.; Notice of Filing

February 15, 1985.

Take notice that on January 17, 1985, K N Energy, Inc. (K N) tendered for filing Alternate Twentieth Revised Sheet No. 4 to its FERC Gas Tariff, Third Revised Volume No. 1 to be effective December 1, 1984. According to § 381.103(b)(2)(iii) of the Commission's regulations (18 CFR 381.103(b)(2)(iii)), the date of filing is the date on which the Commission receives the appropriate filing fee, which in the instant case was not until February 5, 1985.

K N states that this filing reflects the elimination of accrued but unpaid purchase gas costs from Account No. 191 and is submitted pursuant to the Commission's orders dated November 23, 1984 and December 31, 1984. K N further states that since the proposed tariff sheet became effective December 1, 1984 under the Commission's November 23, 1984 order, K N billed its customers for their December, 1984 consumption at the rates shown on this sheet, and therefore, no refunds were necessary for this period.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such petitions or protests should be filed on or before February 22, 1985. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary*

[FR Doc. 85-4410 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

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**[Docket No. TC85-7-000]**

## Montana-Dakota Utilities Co.; Tariff Filing

February 15, 1985.

Take notice that on February 1, 1985, Montana-Dakota Utilities Co. (MDU), 400 North Fourth Street, Bismarck, North Dakota 58501, filed the following revised tariff sheets in Docket No. TC85-7-000, pursuant to the Commission's Order Approving Settlement Amendment issued February 19, 1982, in Docket No. RP76-91-000 and pursuant to Part 154 and Part 281, Subpart C of the Commission's Regulations:

Third Revised Sheet No. 51
Second Revised Sheet No. 51A
Eighth Revised Sheet No. 101
Ninth Revised Sheet No. 103
Eighth Revised Sheet No. 105
Seventh Revised Sheet No. 108
Sixth Revised Sheet No. 109
Seventh Revised Sheet No. 110.

MDU proposes that these sheets be effective July 1, 1985. MDU states that the priority entitlement volume changes on the tariff sheet reflect updated reclassification of natural gas for essential agricultural uses which meet the alternative fuels determination, established pursuant to Order No. 55, *et seq.* MDU avers that it has submitted copies of this filing to all customers and persons listed on the official service list in Docket No. RP76-91-000. Also, MDU indicates that curtailment has been lifted on its system and no volume limitations would be imposed on industrial customers during the 1985-86 supply year. In addition, MDU indicates that one customer name change is incorporated in the field tariff sheets.

Any person desiring to be heard or to make any protest with reference to said tariff sheet filings should on or before February 25, 1985, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211).

All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 85-4411 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

**[Docket Nos. TA84-2-37-009]**

## Northwest Pipeline Corp.; Proposed Change in FERC Gas Tariff

February 15, 1985.

Take notice that on February 7, 1985 Northwest Pipeline Corporation ("Northwest") submitted for filing, to be a part of its FERC Gas Tariff, First Revised Volume No. 1, the following tariff sheets in compliance with Ordering Paragraph C of the Federal Energy Regulatory Commission's ("Commission's") order dated January 14, 1985 at the above referenced docket.

First Amended Second Revised Sheet No. 124
First Amended Third Revised Sheet No. 124
First Amended Third Revised Sheet No. 127
First Amended First Revised Sheet No. 127-A.

Northwest states the purpose of the filing is to eliminate the mid-period surcharge adjustment mechanism and adjust Northwest's tariff to clearly provide that all gas supplier cash refunds will be credited to Account No. 191.

Northwest requests an effective date of April 1, 1984 corresponding to the effective date allowed in the Commission's January 14, 1985 order for First Amended Second Revised Sheet No. 124, First Amended Third Revised Sheet No. 127, and First Amended First Revised Sheet No. 127-A. An effective date of November 1, 1984 is requested for First Amended Third Revised Sheet No. 124 corresponding to the effective date allowed in the Commission's October 31, 1984 order at Docket No. TA85-1-37.

A copy of this filing has been served on Northwest's jurisdictional customers and interested state commissions.

Any persons desiring to be heard or protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests should be filed on or before February 22, 1985. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 85-4412 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

**[Docket Nos. RP73-36-013, et al.]**

## Panhandle Eastern Pipe Line Co., et al.; Filing of Pipeline Refund Reports and Refund Plans

February 15, 1985.

Take notice that the pipelines listed in the Appendix hereto have submitted to the Commission for filing proposed refund reports or refund plans. The date of filing, docket number, and type of filing are also shown on the Appendix.

Any person wishing to do so may submit comments in writing concerning the subject refund reports and plans. All such comments should be filed with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, on or before February 25, 1985. Copies of the respective filings are on file with the Commission and available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

### Appendix

| Filing date | Company | Docket No. | Type filing |
|---|---|---|---|
| 12/21/84 | Panhandle Eastern Pipe Line Co. | RP73-36-013 | Report. |
| 1/29/85 | Algonquin Gas Transmission Co. | RP72-110-038 | Report. |
| 1/31/85 | ANR Pipeline Co. | RP82-60-020 | Compliance filing. |
| 2/5/85 | Consolidated Gas Supply Corp. | RP72-157-072 | Report. |

[FR Doc. 85-4413 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

**[Docket Nos. OF-85-187-000, et al.]**

## County of Olmsted, et al.; Small Power Production and Cogeneration Facilities; Qualifying Status; Certificate Applications, etc.

February 15, 1985.

Comment date: Thirty days from publication in the **Federal Register**, in accordance with Standard Paragraph E at the end of this notice.

Take notice that the following filings have been made with the Commission:

### 1. County of Olmsted

[Docket No. QF85-187-000]

On January 14, 1985, the County of Olmsted, 1421 SE. 3rd Avenue, Rochester, Minnesota (Applicant) submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The small power production facility will be located in Rochester, Minnesota within the County of Olmsted. The facility will be comprised of an existing heating plant containing three gas/oil fired boilers connected in parallel with a new municipal solid waste combustion plant containing two steam generators. Steam from either plant can be used to drive steam-turbine generators and to provide thermal energy for process use. Anticipated operation of the existing heating plant will be only for peaking and emergency service after completion of the new plant. The primary energy source for the combined facility will therefore be biomass in the form of municipal solid waste. The electric power production capacity of the facility will be approximately 3500 kW. Construction of the new plant is scheduled to begin on or about September 1, 1985. There are no other biomass-fueled small power production facilities owned by the applicant located within one mile of the site. No electric utility, electric utility holding company, or any combination thereof has any ownership interest in the facility.

### 2. Western Energy Engineers, Inc. (Klondike I)

[Docket No. QF85-213-000]

On January 28, 1985, Paul R. Gerst, Managing Director, Western Energy Engineers, Inc. (Applicant) of Box 474 Newport Beach, California 92662 submitted for filing an application for certification of a facility known as Klondike I as a qualifying cogeneration facility pursuant to § 292.207 of the

Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The proposed topping-cycle Klondike I cogeneration facility is located at Foussat and Industrial Streets in Oceanside, California. The facility will contain a combustion turbine-generator, a two pressure level heat recovery boiler (HRB) and an extraction steam turbine-generator. The extracted steam together with low pressure steam from the HRB will be supplied to the host laundry and to absorption refrigeration equipment which provide refrigeration at the host athletic facility. The net electric power production of the facility will be 12,040 kW. The primary energy source will be natural gas. The facility is scheduled to start commercial operation in winter of 1986.

**3. Sweetwater Power Corporation (San Bernardino)**

[Docket No. QF85-218-000]

On January 31, 1985, Sweetwater Power Corporation (Applicant), of 4573 Candleberry Avenue, Seal Beach, California 90740 submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The facility is located in the city of Colton, in San Bernardino County, California. The primary energy source is biomass, in the form of wood waste. The electric power production capacity is 3.5 megawatts. Natural gas will be used for combustion chamber startup (preheating) and occasional flame stabilization, and the facility may use up to 15% low sulfur coal for the same purpose; but these fuels will amount to no more than 15% of the total annual fuel consumption.

**4. Sweetwater Power Corporation (San Joaquin)**

[Docket No. QF85-219-000]

On January 31, 1985, Sweetwater Power Corporation (Applicant), of 4573 Candleberry Avenue, Seal Beach, California 90740 submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The facility is located in the city of Manteca, in San Joaquin County, California. The primary energy source is biomass, in the form of wood waste. The electric power production capacity is 3.5 megawatts. Natural gas will be used for combustion chamber startup (preheating) and occasional flame stabilization, and the facility may use up to 15% low sulfur coal for the same purpose; but these fuels will amount to no more than 15% of the total annual fuel consumption.

**5. County of Olmsted**

[Docket No. QF85-187-001]

On January 14, 1985, the County of Olmsted, (Applicant) of 1421 SE. 3rd Avenue, Rochester, Minnesota 55902 submitted for filing an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The topping-cycle cogeneration facility will be located in Rochester, Minnesota within the County of Olmsted. The facility will be comprised of an existing heating plant containing three gas/oil fired boilers connected in parallel with a new municipal solid waste combustion plant containing two steam generators. Steam from either plant can be used to drive steam-turbine generators and to provide thermal energy for process use. Anticipated operation of the existing heating plant will be only for peaking and emergency service after completion of the new plant. The primary energy source for the combined facility will therefore be biomass in the form of municipal solid waste. The electric power production capacity of the facility will be approximately 3500 kW. Construction of the new plant is scheduled to begin on or about September 1, 1985. No electric utility, electric utility holding company, or any combination thereof has any ownership interest in the facility.

**6. Sweetwater Power Corporation (Tulare County)**

[Docket No. QF85-217-000]

On January 31, 1985, Sweetwater Power Corporation (Applicant), of 4573 Candleberry Avenue, Seal Beach, California 90740 submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The facility is located in the city of Goshen, in Tulare County, California. The primary energy source is biomass, in the form of wood waste. The electric power production capacity is 3.5 megawatts. Natural gas will be used for combustion chamber startup (preheating) and occasional flame stabilization, and the facility may use up to 15% low sulfur coal for the same purpose; but these fuels will amount to no more than 15% of the total annual fuel consumption.

**7. Richmond Sanitary Service**

[Docket No. QF85-215-000]

On January 29, 1985, Richmond Sanitary Service, (Applicant) of 205 41st Street, Richmond, California 94805, submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The small power production facility, to be located at the West Contra Costa Landfill, will have up to 3 megawatts of output capacity and will be fueled by methane gas recovered from the West Contra Costa Landfill which is located at the foot of Parr Boulevard in Richmond, California.

**8. Leeming/Pacquin Division, Pfizer, Inc.**

[Docket No. QF85-205-000]

On January 24, 1985, the Leeming/Pacquin Division of Pfizer, Inc., 100 Jefferson Road, Parsippany, New Jersey 07054 (Applicant) submitted for filing an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The proposed topping-cycle cogeneration facility will be located in Parsippany, New Jersey. The facility will consist of a 9-cylinder reciprocating engine generator set which will exhaust through a waste heat recovery boiler to produce hot water and steam for process and heating uses. The primary energy source will be natural gas with diesel fuel usable as an alternative if and as required. The electric power production capacity will be 648 kW on natural gas operation, and 683 MW on diesel fuel operation. Construction is scheduled to begin in March 1985 and operation is expected to commence in October 1985.

**9. Bio-Energy Services Corp.**

[Docket No. QF85-223-000]

On February 4, 1985, Bio-Energy Services Corp., (Applicant) of 221 Canal Street, Ellenville, New York 12428, submitted for filing an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's regulations. No determination has been

made that the submittal constitutes a complete filing.

The topping-cycle cogeneration facility will be installed at the Riverside General Hospital in Secaucus, New Jersey. It will consist of a natural gas fueled reciprocating engine driving an induction generator and producing approximately 168 kW of electric power. The engine's waste heat will be used to supply energy to both the domestic and hydronic hot water systems. The installation of the facility will begin in early March, 1985.

**10. Atlantic Power Development Corp.**

[Docket No. QF85-216-000]

On January 30, 1985, Atlantic Power Development Corp. (Applicant), of 401 C Street, NE., Washington, D.C., 20002 submitted for filing an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's regulations. No determination has been made that the submittal constitutes a complete filing.

The 5.0 megawatt hydroelectric facility (P. 3228) is located in Armstrong County, Pennsylvania near the Mahoning Creek Dam.

Any person desiring to be heard or objecting to the granting of qualifying status should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests must be filed within 30 days after the date of publication of this notice and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

A separate application is required for a hydroelectric project license, preliminary permit or exemption from licensing. Comments on such applications are requested by separate public notice. Qualifying status serves only to establish eligibility for benefits provided by PURPA, as implemented by the Commission's regulations, 18 CFR Part 292. It does not relieve a facility of any other requirements of local, State or Federal law, including those regarding siting, construction, operation, licensing and pollution abatement.

Standard Paragraphs:

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 85-4408 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

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**[Docket Nos. ID-2153-000, et al.]**

## Harrie R. Nims; Interlocking Directorate Applications

February 15, 1985.

Take notice that the following filings have been made with the Commission:

**1. Harrie R. Nims**

[Docket No. ID-2153-000]

Take notice that on February 4, 1985, Harrie R. Nims (applicant) filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

Vice President—The Connecticut Light and Power Company

Vice President—Western Massachusetts Electric Company

Vice President—Holyoke Water Power Company

Vice President—Holyoke Power and Electric Company.

Comment date: March 4, 1985, in accordance with Standard Paragraph E at the end of this notice.

**2. John N. Nordstrom**

[Docket No. ID-2155-000]

Take notice that on February 7, 1985, John N. Nordstrom (applicant) filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

Director—Puget Sound Power & Light Company

Director—Seafirst Corporation

Director—Seattle—First National Bank.

Comment date: March 4, 1985, in accordance with Standard Paragraph E at the end of this notice.

**3. Anthony G. Schuster**

[Docket No. ID-2156-000]

Take notice that on February 7, 1985, Anthony G. Schuster (applicant) filed an application pursuant to Section 305(b) of the Federal Power Act to hold the following positions:

Vice President—Power Supply, Northern States Power Company—Minnesota

Vice President—Power Supply, Northern States Power Company—Wisconsin.

Comment date: March 4, 1985, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs:

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NW., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for pubic inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 85-4407 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

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## Tenneco Oil Co. et al.; Quarterly Status Conferences

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|---|---|
| Tenneco Oil Company, Houston Oil & Minerals Corporation, Tenneco Exploration, Ltd., Tenneco Exploration II, Ltd., Tinco, Ltd., and Tenneco West, Inc., | Docket Nos. CI83-269-000 through CI83-269-023. |
| Transcontinental Gas Pipe Line Corporation. | Docket Nos. RP83-11-000 through RP83-11-028, RP83-30-000. |
| Producer-Suppliers of Transcontinental Gas Pipe Line Corporation. | Docket No. CP83-279-002. |
| Producer-Suppliers of Transco Gas Supply Company. | Docket No. CP83-340-003. |
| Producer-Suppliers of Transco Gas Supply Company and Transcontinental Gas Pipe Line Corporation. | Docket Nos. CP83-428-001 through CP83-428-014. |
| Columbia Gas Transmission Corporation and Columbia Gulf Transmission Company. | Docket Nos. CP83-452-000 through CP83-452-015. |

| | |
|---|---|
| Tennessee Gas Pipe Line Company, a Division of Tenneco Inc. | Docket Nos. CP83-502-000 through CP83-502-004, CP83-502-008, CP83-502-013. |
| PanMark Gas Company | Docket Nos. CP83-333-000 through CP83-333-016. |
| Trunkline Gas Company | Docket No. CP83-342-000. |
| Panhandle Eastern Pipe Line Company. | Docket No. CP83-343-000. |
| Trunkline Gas Company and PanMark Gas Company. | Docket No. CP83-354-000. |
| Panhandle Eastern Pipe Line Corporation and PanMark Gas Company. | Docket No. CP83-355-000. |
| Texas Eastern Transmission Corporation and Producer-Suppliers of Texas Eastern Transmission Corporation. | Docket Nos. CP84-244-000, CP83-244-001. |
| Cities Service Oil and Gas Corporation, Cities Offshore Production Company and Oxy Petroleum, Inc. | Docket Nos. CI84-332-000 through CI84-332-003. |
| TXP Operating Company | Docket No. CI84-374-000. |
| Amoco Production Company. | Docket No. CI84-485-000. |
| El Paso Natural Gas Company. | Docket No. CP84-539-000. |

February 19, 1985.

Listed below are quarterly status conferences to be held pursuant to Commission order of September 26, 1984, to evaluate whether the implementation of the special marketing program in each proceeding is achieving the Commission's purposes. The conferences shall be held at the offices of the Commission at 825 North Capitol Street, N.E., Washington, D.C. All interested persons and Staff are invited to attend.

1. Amoco, 2:00 p.m., Tuesday, March 12, 1985.

2. PanMark, 10:00 a.m., Tuesday, March 19, 1985.

3. Tenneflex, 2:00 p.m., Tuesday, March 19, 1985.

4. Columbia, 2:00 p.m., Wednesday, March 20, 1985.

5. Transmart, 2:00 p.m., Thursday, March 21, 1985.

6. COGS, 10:00 a.m., Friday, March 22, 1985.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 85-4421 Filed 2-21-85; 8:45 am]

BILLING CODE 6717-01-M

## Office of Hearing and Appeals

### Cases Filed; Week of January 18 Through January 25, 1985

During the Week of January 18 through January 25, 1985, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR Part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20585.

**George B. Breznay,**

*Director, Office of Hearings and Appeals.*

February 12, 1985.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of Jan. 18 through Jan. 25, 1985]

| Date | Name and location of applicant | Case No. | Type of submission |
|---|---|---|---|
| Jan. 24, 1985 | Atlantic Richfield Co., Los Angeles, CA | HRD-0266 | Motion for Discovery. If granted: Discovery would be granted to Atlantic Richfield Co. in connection with the Statement of Objections submitted in response to the Proposed Remedial Order (Case No. HRO-0219) issued to Atlantic Richfield Co. |
| Jan. 24, 1985 | Transcontinental Energy Corp., Shreveport, LA | HEE-0114 | Exception to the Reporting Requirements. If granted: Transcontinental Energy Corp. would no longer be required to file Form EIA-23 "Annual Survey of Domestic Oil and Gas Reserves." |

REFUND APPLICATIONS RECEIVED

[Week of January 18 through January 25, 1985]

| Date | Name of refund proceeding and name of refund applicant | Case No. assigned |
|---|---|---|
| Jan. 11, 1985 | Wisconsin Industrial Fuel/Asphalt & Petroleum, Inc. | RF75-1 |
| Jan. 16, 1985 | The Hertz Corp./J.B.H. Co. | RF76-1 |
| Do | Hendel's Inc., Donatello Frozen Foods, Inc. | RF79-3 |
| Jan. 17, 1985 | Van Gas, Inc./Edward J. Kelly. | RF68-4 |
| Jan. 18, 1985 | J.A.L. Oil Co./Zac's Service Center. | RF71-3 |
| Do | Aztex Energy/Homer Hughes. | RF73-2 |
| Jan. 22, 1985 | Reinhard Distributors/Cle Flum Wash. | RF72-2 |
| Do | Aztex Energy/Grover Wilson. | RF73-3 |
| Do | Aztex Energy/Freddie's Citgo. | RF73-4 |
| Do | Aztex Energy/Whaley's Chevron. | RF73-5 |
| Do | Aztex Energy/Moroney Oil Co. | RF73-6 |
| Do | Aztex Energy/Howard McCuiston. | RF73-7 |

REFUND APPLICATIONS RECEIVED—Continued

[Week of January 18 through January 25, 1985]

| Date | Name of refund proceeding and name of refund applicant | Case No. assigned |
|---|---|---|
| Do | Aztex Energy/Ken Nipper | RF73-8 |
| Do | Consolidated Gas Supply/Pargas. | RF77-1 |
| Do | Hendel's Inc./Blanchard's Chevron Service. | RF79-2 |
| Jan. 23, 1985 | Aztex Energy/Blue Dot Oil Corp. | RF73-9 |
| Do | Conoco/Martin Oil Marketing, Inc. | RF34-32 |
| Do | Richards Oil Co./Owens-Illinois. | RF70-15 |
| Do | Richards Oil/Joslyn Mfg. & Supply Co. | RF70-16 |
| Do | Richards Oil/Donaldsons | RF70-17 |
| Do | Brown Oil Co./John W. Hulet. | RF39-3 |
| Do | Waller Petroleum Co./SMO, Inc. | RF78-1 |
| Do | Hendel's Inc./Connecticut College. | RF79-1 |
| Do | Waller Pet. Co./Maryland State Penitentiary. | RF78-2 |

REFUND APPLICATIONS RECEIVED—Continued

[Week of January 18 through January 25, 1985]

| Date | Name of refund proceeding and name of refund applicant | Case No. assigned |
|---|---|---|
| Jan. 24, 1985 | Waller Pet Co.-Space Pet & Chemical Co | RF78-3 |

NOTICES OF OBJECTION RECEIVED

[Week of Jan. 18 through Jan. 25, 1985]

| Date | Name and location of applicant | Case No. Assigned |
|---|---|---|
| Jan. 23, 1985 | Riner Oil Co., Lebannon, IN. | HEE-0110 |

[FR Doc. 85-4444 Filed 2-21-85; 8:45 am]

BILLING CODE 6450-01-M

## Cases Filed; Week of January 25 Through February 1, 1985

During the Week of January 25 through February 1, 1985, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR Part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20585.

Dated: February 12, 1985.

**George B. Breznay,**

*Director, Office of Hearings and Appeals.*

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of Jan. 25 through Feb. 1, 1985]

| Date | Name and location of applicant | Case No. | Type of submission |
|---|---|---|---|
| Jan. 30, 1985 | Economic Regulatory Administration, Los Angeles, CA | HRZ-0231 | Interlocutory Order. If granted: The Dec. 14, 1984, Supplemental Brief submitted by Getty Oil Co. (Case Nos. HEX-0091 and HRR-0074) would be striken from the record. |
| Jan. 31, 1985 | Barrett & Hanna, Washington, DC | HFA-0271 | Appeal of an Information Request Denial. If granted: The Jan. 6, 1985, Freedom of Information Request Denial issued by the Dallas Field Operations Office would be rescinded, and Barrett & Hanna would receive access to copies of all documents in the possession of the Economic Regulatory Administration which set forth volumes of refined products sold by Gary Energy Corp. |
| Do | Wakeland Oil Co., Owosso, MI | HEE-0115 | Exception to the Reporting Requirements. If granted: Wakeland Oil Co. would not be required to file Form EIA-782B, "Reseller/Retailers' Monthly Petroleum Product Sales Report." |
| Feb. 1, 1985 | Department of Interior, Washington, DC | HEE-0116 | Exception from the Certification Rules. If granted: The Department of Interior would receive an exception from certain certification requirements applicable to first sellers of crude oil as set forth in 10 CFR Part 212, with respect to its sales of onshore crude oil to Western Refining Co. |
| Do | Standard Oil Co. (Indiana) Washington, DC | HEF-0562 | Implementation of Special Refund Procedures. In 1980, Amoco and the DOE settled most allegations that Amoco had violated the DOE price and allocation regulations during the period March 1973 through December 1979. Under the 1980 settlement Amoco agreed to refund $29 million directly to customers, and pay $71 million to the DOE. The 1980 settlement has been the subject of an ongoing DOE refund proceeding, Case No. BFF-0007. At the same time in 1980, DOE and Amoco executed a side agreement to exclude from the 1980 settlement matters relating to pending litigation involving the counting of injection wells for purposes of qualifying for the stripper well exemption in the DOE price regulations. The 1980 side agreement provided that if the courts determined that injeciton wells could not be counted for the stripper well exemption, any amounts determined to be pricing violations would be treated as a reduction in Amoco's "banks then available," or to the extent that the amount of violations exceeded available banks, the parties would engage in further settlement negotiations. After final judicial resolution of the injection well issue in DOE's favor, further negotiations took place. On Feb. 1, 1985, Amoco paid $308.5 million to the DOE to satisfy its obligations under the 1980 side agreement. The ERA has now filed a petition to implement a Subpart V proceeding to distribute the $308.5 million. |

REFUND APPLICATIONS RECEIVED

[Week of Jan. 25 to Feb. 1, 1985]

| Date | Name of refund proceeding and name of refund applicant | Case No. assigned |
|---|---|---|
| Jan. 25, 1985 | Reinhard Distributors/ Jem Locke. | RF72-3 |
| Do | Hendel's Inc./ Woodlawn Filling Station, Inc. | RF79-4 |
| Do | Richards Oil Co./ Flour City Architectural Metals. | RF70-18 |
| Do | Waller Pet. C./Bulk Sales Corp. | RF78-4 |
| Jan. 28, 1985 | Richards Oil Co./Ford Motor Co. | RF70-19 |
| Do | Hendel's Inc./Andy's Service Center & Sons. | RF79-5 |
| Jan. 25, 1985 | Amoco/Tredethorn & Associates. | RF21-12373 |
| Do | do | RF21-12374 |
| Do | Amoco/Will Oil Co. | RF21-12375 |
| Do | do | RF21-12376 |
| Do | Amoco/Klaers Oil Co. | RF21-12377 |
| Jan. 28, 1985 | Van Gas, Inc./L.A. Ruse. | RF68-6 |
| Do | Van Gas, Inc./Janice M. O'Brien. | RF68-5 |

REFUND APPLICATIONS RECEIVED—Continued

[Week of Jan. 25 to Feb. 1, 1985]

| Date | Name of refund proceeding and name of refund applicant | Case No. assigned |
|---|---|---|
| Jan. 29, 1985 | Richard Oil/Stevens County Court House. | RF70-20 |
| Jan. 30, 1985 | Richards/Sears, Roebuck & Co. | RF70-21 |
| Jan. 31, 1985 | Amtel/Grable Oil Co., Inc. | RF46-28 |
| Jan. 28, 1985 to Feb. 1, 1985. | Gulf Refund Applications. | RF40-1647 through RF40-1668. |

[FR Doc. 85-4445 Filed 2-21-85; 8:45 am]

BILLING CODE 6450-01-M

## Issuanace of Proposed Decisions and Orders; Period of December 24, 1984, Through January 11, 1985

During the period of December 24, 1984 through January 11, 1985, the proposed decisions and orders summarized below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to applications for exception.

Under the procedural regulations that apply to exception proceedings (10 CFR Part 205, Subpart D), any person who will be aggrieved by the issuance of a proposed decision and order in final form may file a written notice of objection within ten days of service. For purpose of the procedural regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date an aggrieved person receives actual notice, whichever occurs first.

The procedural regulations provide that an aggrieved party who fails to file a Notice of Objection within the time period specified in the regulations will be deemed to consent to the issuance of the proposed decision and order in final form. An aggrieved party who wishes to contest a determination made in a

proposed decision and order must also file a detailed statement of objections within 30 days of the date of service of the proposed decision and order. In the statement of objections, the aggrieved party must specify each issue of fact or law that it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these proposed decisions and orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room 1E-234, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays.

February 14, 1985.

**George B. Breznay,**

*Director, Office of Hearings and Appeals.*

*Abajo Petroleum, Inc., Monticello, Utah, HEE-0108, reporting requirements*

On November 23, 1984, Abajo Petroleum, Inc. (Abajo) filed an Application for Exception from the requirement to file Form EIA-782B, entitled "Reseller/Retailers' Monthly Petroleum Product Sales Report." The exception request, if granted, would permit Abajo to forego the monthly reporting requirement. On January 10, 1985, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

*L.B. Carter Heating, Caribou, Maine, HEE-0107, reporting requirements*

On November 14, 1984, L.B. Carter Heating (Carter) filed an Application for Exception from the requirement to file Form EIA-782B, entitled "Reseller/Retailers' Monthly Petroleum Product Sales Report." The exception request, if granted, would permit Carter to forego the monthly reporting requirement. On January 10, 1985, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

*Zoubek Oil Company, Norfolk, Nebraska, HEE-0106, reporting requirements*

On November 6, 1984, Zoubek Oil Company (Zoubek) filed an Application for Exception from the requirement to file Form EIA-782B, entitled "Reseller/Retailers' Monthly Petroleum Product Sales Report." The exception request, if granted, would permit Zoubek to forego the monthly reporting requirement. On January 11, 1985, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

[FR Doc. 85-4441 Filed 2-21-85; 8:45 am]

BILLING CODE 6450-01-M

## Issuance of Proposed Decision and Order; Week of January 14 Through January 18, 1985

During the week of January 14 through January 18, 1985, the proposed decision and order summarized below was issued by the Office of Hearings and Appeals of the Department of Energy with regard to an application for exception.

Under the procedural regulations that apply to exception proceedings (10 CFR Part 205, Subpart D), any person who will be aggrieved by the issuance of a proposed decision and order in final form may file a written notice of objection within ten days of service. For purposes of the procedural regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date an aggrieved person receives actual notice, whichever occurs first.

The procedural regulations provide that an aggrieved party who fails to file a Notice of Objection within the time period specified in the regulations will be deemed to consent to the issuance of the proposed decision and order in final form. An aggrieved party who wishes to contest a determination made in a proposed decision and order must also file a detailed statement of objections within 30 days of the date of service of the proposed decision and order. In the statement of objections, the aggrieved party must specify each issue of fact or law that it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of this proposed decision and order are available in the Public Docket Room of the Office of Hearings and Appeals, Room 1E-234, Forrestal Building, 1000 Independence Avenue, SW, Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except Federal holidays.

**George B. Breznay,**

*Director, Office of Hearings and Appeals.*

February 14, 1985.

*Riner Oil Company, Lebanon, Indiana, HRO-0110, reporting requirements*

Riner Oil Company filed an Application for Exception from the provisions of the EIA reporting requirements. The exception request, if granted, would relieve Riner of its obligation to submit Form EIA-782B, entitled "Reseller/Retailers' Monthly Petroleum Product Sales Report." On January 14, 1985, the Department of Energy issued a Proposed Decision and Order which determined that the Exception request be denied.

[FR Doc. 85-4442 Filed 2-21-85; 8:45 am]

BILLING CODE 6450-01-M

## Issuance of Proposed Decision and Order; Week of January 22 Through January 25, 1985

During the week of January 22 through January 25, 1985, the proposed decision and order summarized below was issued by the Office of Hearings and Appeals of the Department of Energy with regard to an application for exception.

Under the procedural regulations that apply to exception proceedings (10 CFR Part 205, Subpart D), any person who will be aggrieved by the issuance of a proposed decision and order in final form may file a written notice of objection within ten days of service. For purposes of the procedural regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date an aggrieved person receives actual notice, whichever occurs first.

The procedural regulations provide that an aggrieved party who fails to file a Notice of Objection within the time period specified in the regulations will be deemed to consent to the issuance of the proposed decision and order in final form. An aggrieved party who wishes to contest a determination made in a proposed decision and order must also file a detailed statement of objections within 30 days of the date of service of the proposed decision and order. In the statement of objections, the aggrieved party must specify each issue of fact or law that it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of this proposed decision and order are available in the Public Docket Room of the Office of Hearings and Appeals, Room 1E-234, Forrestal Building, 1000 Independence Avenue, SW, Washington, D.C. 20585, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., except federal holidays.

**George B. Breznay,**

*Director, Office of Hearings and Appeals.*

February 12, 1985.

*Ball Tire & Gas, Inc., Alpena, Michigan, HEE-0109*

Ball Tire & Gas, Inc. filed an Application for Exception which, if granted, would relieve the firm of the requirement to file Form EIA-782B, entitled "Reseller/Retailers' Monthly Petroleum Product Sales Report." On January 25, 1985, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

[FR Doc. 85-4443 Filed 2-21-85; 8:45 am]

BILLING CODE 6450-01-M

## Western Area Power Administration

### Record of Decision To Construct the Rifle-San Juan 345-kV Transmission Line Project in Colorado and New Mexico

**AGENCY:** Western Area Power Administration, DOE.

**ACTION:** Record of decision for the Rifle-San Juan 345-kV Transmission Line Project, Colorado and New Mexico.

**SUMMARY:** The U.S. Department of Energy (DOE), Western Area Power Administration (Western) has decided to fund its participation in the construction of about 283 miles of single-circuit 345-kV transmission line and associated facilities between the Colorado-Ute Electric Association, Inc. (Colorado-Ute), Rifle Substation near Rifle, Colorado, and the San Juan Generating Station near Farmington, New Mexico. The Rural Electrification Administration (REA), the lead agency in the preparation of the Rifle to San Juan 345-kV transmission line and associated facilities environmental impact statement (EIS), issued a drafts EIS (USDA–REA–WAE–EIS (ADM) 81–4–D) in July 1981; a supplemental draft EIS (USDA–REA–WAE–EIS (ADM) 83–1–D) in July 1983; a final EIS (USDA–REA–WAE–EIS (ADM) 83–1–D) in March 1984; and a record of decision (ROD) on August 14, 1984. Western has been involved in the REA environmental process for the project as a cooperating agency, and has independently evaluated the alternatives presented in the REA EIS. The environmentally preferred corridor identified in the final EIS has been selected for the construction of a single-circuit 345-kV transmission line from Rifle, Colorado, to San Juan, New Mexico.

DOE has adopted the REA's EIS for the project and the mitigation measures identified in section 2.3 of the final EIS. After issuing the final EIS, REA requested Western to assume the lead agency role for project compliance with section 106 of the National Historic Preservation Act. Western will ensure the provisions of section 106 are met before financing its participation.

**FOR FURTHER INFORMATION CONTACT:** Mr. Mark N. Silverman, Area Manager, Western Area Power Administration, P.O. Box 11606, Salt Lake City, UT 84147, (801) 524–6372.

**SUPPLEMENTARY INFORMATION:** Three participants—Colorado-Ute, Western, and Public Service Company of Colorado (PSC)—will design, construct, operate, and maintain approximately 283 miles of single-circuit 345-kV transmission line from Colorado-Ute's Rifle Substation in Garfield County, Colorado, to the San Juan Generation Station in San Juan County, New Mexico. Associated facilities include expansion of existing substations at Grand Junction, Montrose, and Durango; construction of a new substation (Long Hollow) near Durango, Colorado; addition of transmission line termination facilities at Colorado-Ute's Rifle Substation and at the San Juan Generating Station Switchyard; and the construction of approximately 7 miles of 115-kV transmission line on double-circuit towers from the proposed Long Hollow Substation to the existing Durango Substation.

The cost, maintenance, and capacity of the proposed line would be shared among the three participants. For the line section between Rifle and Grand Junction, the line would be shared as follows: Colorado-Ute, 37.5 percent; Western, 37.5 percent; and PSC, 25 percent. For the line section between Grand Junction and the San Juan Generating Station, the line would be shared as follows: Colorado-Ute, 50 percent; and Western, 50 percent. Western is not participating in the 7 miles of 115-kV transmission line from proposed Long Hollow Substation to the Durango Substation.

In 1979, Colorado-Ute proposed to construct and operate a 345-kV transmission line project from Rifle, Colorado, to the San Juan Generating Station near Farmington, New Mexico. REA contracted other governmental agencies and interest organizations to obtain their opinion and guidance in fields in which they may have special knowledge or authority, and the public was formally requested to provide input at scheduled public meetings held in Rifle, Grand Junction, Delta, Montrose, Norwood, Dove Creek, Cortez, and Durango, Colorado, and Farmington, New Mexico. Western, the Bureau of Land Management (BLM), and the Forest Service (FS) became cooperating agencies.

A draft EIS was issued in July 1981, evaluating a double-circuit 345-kV transmission line and associated facilities from Rifle to the San Juan Generating Station. The double-circuit project, as described in the draft EIS, was jointly proposed by Colorado-Ute and Western. The preferred route extended from Rifle to the North Fork Valley, to Delta, to Montrose, to Norwood, to Lost Canyon, to Durango, and then to the San Juan Generating Station and Western's Shiprock Substation. Alternatives to the proposed project and alternative routes were also identified and evaluated.

In August 1981, REA held three public hearings to obtain comments on the draft EIS. These hearings were held in Montrose and Durango, Colorado, and Farmington, New Mexico. Written comments were also received from Federal, State, and local agencies and interested individuals. In the meantime, the Colorado Public Utilities Commission (PUC) denied Colorado-Ute a Certificate of Public Convenience and Necessity (certificate) for the proposed project. Consequently, REA decided not to issue a final EIS on the proposed project.

In issuing its denial of a certificate, the PUC suggested that Colorado-Ute and Western revise their plan and include PSC as a participant. Colorado-Ute then developed a coordinated transmission system plan with Western and PSC.

Project modifications in the coordinated proposal resulted from PUC staff recommendations and input from Federal, State, and local agencies, and the public. The modified proposal, consisting of a single-circuit 345-kV transmission line and associated facilities, from Rifle, Colorado, to the San Juan Generating Station.

After studying the modified project proposal, REA, Western, BLM, and FS, determined that the modifications constituted a substantial change from the originally proposed project. As a result, under the Council on Environmental Quality (CEQ) Regulations, 40 CFR Parts 1500–1508, the lead and cooperating agencies decided that a supplemental draft EIS should be prepared. The purpose of the supplemental draft EIS was to evaluate the revised project, alternative corridors and other reasonable options, and allow adequate opportunity for public review of and comment on the revised project. Western participated in the development of the supplemental draft EIS.

The PUC issued a certificate for the revised project. The public has had an opportunity to comment on the revised project at hearings before the PUC and at several meetings held in Garfield, Mesa, Delta, and Montezuma Counties of Colorado. The public was also invited to submit additional comments to REA during public information meetings hosted by Colorado-Ute in Rifle, DeBeque Palisade, Durango, and Montrose, Colorado, in March 1983, and in the Federal Register issued by REA on March 18, 1983. The public had further opportunity to comment on the revised project and the supplemental draft EIS at public comment hearings held in Grand Junction, Montrose,

Durango, and Cortez, Colorado, from July 25 through July 28, 1983. Western cooperated in the meetings and hearings in regard to its participation in the project. A final EIS was issued in March 1984.

**Description of Alternatives**

DOE cooperated in the development and adopted the alternatives presented in the REA EIS. The alternatives include:

1. Energy conservation.
2. Purchase of required power.
3. Noncentralized generation facilities.
4. Upgrading/rebuilding existing transmission facilities.
5. Installation of series compensation.
6. Transmission system alternatives proposed by others.
7. Construction of a 500-kV or 765-kV transmission line.
8. Construction of a 400-kV direct-current transmission line.
9. Construction of an underground transmission line.
10. Rifle-Grand Junction, single-circuit 345=kV; Grand Junction-Shiprock, single-circuit 230-kV transmission line.
11. Rifle-Grand Junction, single-circuit 345=kV; Grand junction-Shiprock, double-circuit 345-kV transmission line.
12. Rifle-Shiprock, single-circuit 230-kV transmission line.
13. Rifle-Shiprock, two single-circuit 115-kV transmission lines.
14. Rifle-Grand Junction, double-circuit 345-kV; Grand Junction-San Jaun single-circuit; 345=kV transmission line.
15. Rifle-San Juan, double-circuit 345-kV transmission line (original project).
16. Rifle-San Juan, single-circuit 345-kV transmission line (proposed project).
17. Alternative routes and substation sites.
18. Alternative tower designs.

These alternatives are described in detail in the supplemental draft EIS. Western has selected the proposed action, i.e., construction of a single-circuit 345-kV transmission line from Rifle, Colorado, to the San Juan Generating Station, New Mexico. This alternative is the environmentally preferred corridor for the construction of the project.

**Basis of Decision**

Western considered power demands, reliability needs, cost, environmental impacts, system studies, existing access, and future planning needs in its decision. Insufficient transmission capacity in southwestern Colorado would result from the no action alternative. This alternative, while not impacting the environment, would not resolve the power supply and reliability problems associated with the existing Rifle-Curecanti 230-kV transmission line. Maintaining the present system would not satisfy Western's existing and projected long-range energy requirements. The no action alternative would necessitate Western to construct their own separate facilities.

The Rifle to Grand Junction single-circuit 345-kV; Grand Junction to Shiprock single-circuit 230-kV transmission line alternative would use somewhat smaller towers and narrower ROW between Grand Junction and Shiprock but does not meet the energy requirements of Western. This alternative would improve reliability of service to southwestern Colorado, but is not as effective as the proposed alternative, Rifle to San Juan single-circuit 345-kV transmission line.

A variation of the preceding alternative is the Rifle to Grand Junction single-circuit 345–kV; Grand Junction to Shiprock double-circuit 230–kV transmission line alternative. This alternative satisfies the requirements for all participants, but would require larger structures, greater costs, and greater transmission line losses than a single-circuit 345–kV line. Larger structures would create more visual impacts and soil disturbance impacts from excavations of structure footings.

The Rifle to Shiprock single-circuit 230–kV transmission line alternative would be constructed by Colorado-Ute. Western and PSC would have to construct their own facilities. Disadvantages of this plan include greater line losses and reduced interconnection capability at Shiprock.

The two Rifle-Shiprock single-circuit 115–kV transmission lines alternative would be constructed by Colorado-Ute. Colorado-Ute would be the sole owner of the 115–kV circuits. Western would have to construct their own facilities to maintain their transmission reliability. As previously noted, this alternative would increase costs and cause higher transmission losses and reduced interconnection capability without benefit of the transmission capacity of the proposed alternative.

The Rifle to Grand Junction double-circuit 345–kV; Grand Junction to San Juan 345–kV transmission line is similar to the proposed alternative. It places into service additional capacity before it is required. This is based on current load projections. This alternative increases costs to all participants and uses larger towers in the northern section with increased environmental impacts.

The original proposal was Rifle to San Juan double-circuit 345–kV transmission line. This plan was denied by PUC on February 5, 1982. It was evaluated as an alternative, but was not a viable plan because of the decrease in growth rate in southwestern Colorado, high cost of construction, and the denial by the PUC.

The evaluation of the alternatives in the supplemental draft EIS indcates no identifiable financial advantage from the alternative transmission plans. Independent construction would result in greater environmental impact than the jointly proposed 345–kV plan. The construction of the proposed alternative, Rifle to San Juan single-circuit 345–kV transmission line is in the best interests of the public, designated participants, and the environmental concerns.

Mitigation and Environmental Monitoring: Construction and operation of the proposed transmission line and associated facilities will result in unavoidable impacts to the environment. To minimize these impacts, mitigation measures have been developed and are identified in Section 2.3 of the final EIS. DOE adopted these mitigation measures. Western will ensure that mitigation measures in the final EIS are implemented as they related to Western's participation.

Western will inspect the cosntruction areas of the proposed project to ensure compliance with the final EIS. During operation, the transmission line segment owned and operated by Western will be inspected by air every 2 months and once a year on the ground.

**Other Requirements**

The proposed project will cross five large rivers and several smaller streams, many of which have an intermittent flow. From map examinaiton and aerial overflights no wetland areas were recorded that could not be easily spanned. Wetlands will be avoided during the location of the centerline, towers, access roads, and substation facilities. Sediment control structures will be used near wetlands and fill material resulting from construction will not be placed in wetlands.

During the design phase of the project, floodplains will be spanned if practicable. However, if it is not possible to completely span a floodplain, structures would be placed where the severity of flooding is lease, constructed to withstand a 100-year flood, and in accordance with State and local floodplain requirements. The provisions of DOE's "Compliance with Floodplain/Wetlands Environmental Review Requirements" (10 CFR 1022) would be met prior to any construction if a floodplain cannot be spanned.

The Fish and Wildlife Service (FWS) has been consulted on the presence of endangered species in the project area. The FWS identified species that may be present in the area and a biological assessment was prepared. Based on the results of the assessment, it was

determined that the project will not jeopardize the continued existence of any threatened or endangered species or adversely modify their critical habitats. The FWS has concurred with the results of the biological assessment. The mitigation applicable to endangered species as described in the final EIS will be implemented.

Known historic and archeological resources listed or eligible for listing on the National Register for Historic Places have been avoided during the corridor delineation process. A cultural resource survey will be completed for the transmission line right-of-way, access roads, and new expanded substations. Cultural resource sites discovered will be evaluated in accordance with the Advisory Council on Historic Preservation Regulations, 36 CFR 800. No construction will be initiated until the procedures prescribed in these regulations have been carried out. If any sites are unearthed during construction, work will be stopped until an appropriate assessment can be made in consultation with the appropriate State Historic Preservation Officer.

Copies of this ROD will be sent to the Colorado and New Mexico State Clearinghouses, appropriate Federal, State, and local agencies, and to other agencies, organizations, and individuals commenting on the supplemental draft EIS or final EIS.

Issued at Golden, Colorado, October 30, 1984.

**Robert L. McPhail,**

*Administrator.*

[FR Doc. 85-4452 Filed 2-21-85; 8:45 am]

BILLING CODE 6450-01-M

## ENVIRONMENTAL PROTECTION AGENCY

[A-9-FRL-2782-7]

### Approval of Modification of Prevention of Significant Air Quality Deterioration (PSD) Permit to Beacon Oil Company (EPA Project Number SJ 78-70)

**AGENCY:** Environmental Protection Agency (EPA), Region 9.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that on November 26, 1984 the Environmental Protection Agency issued a modified PSD permit (which was originally issued on September 19, 1978 under EPA's federal regulations 40 CFR 52.21) to the applicant named above. The PSD permit grants approval to construct refinery equipment at their existing refinery in Hanford, California. The permit is subject to certain conditions, including an allowable emission rate as follows: $NO_x$ at 0.181 lbs/MMBTU while firing gas and 0.57 lbs/MMBTU while firing oil; $SO_2$ at 0.8% sulfur in fuel oil and 30 ppm $H_2S$ in refinery gas.

**FOR FURTHER INFORMATION CONTACT:** Copies of the permit modification are available for public inspection upon request; address request to: Cris Tiongson (P-8-2), U.S. Environmental Protection Agency, Region 9, 215 Fremont Street, San Francisco, CA 94105, 415-454-8201.

**DATE:** The PSD permit modification is reviewable under section 307(b)(1) of the Clean Air Act only in the Ninth Circuit Court of Appeals. A petition for review must be filed within 60 days of the date of this notice.

Dated: February 11, 1985.

**David P. Howekamp,**

*Director, Air Management Division, Region 9.*

[FR Doc. 85-4358 Filed 2-21-85; 8:45 am]

BILLING CODE 6560-50-M

[A-9-FRL-2782-6]

### Approval of Modification of Prevention of Significant Air Quality Deterioration (PSD) Permit to Witco Chemical Corporation (EPA Project Number SJ 83-07)

**AGENCY:** Environmental Protection Agency (EPA), Region 9.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that on December 19, 1984 the Environmental Protection Agency issued a modified PSD permit (which was originally issued on November 2, 1983 under EPA's federal regulations 40 CFR 52.21) for the applicant named above. The PSD permit grants approval to construct a cogeneration system at the Witco refinery in Oildale, Kern County, California. The permit was modified to add a second duct burner, which necessitates the addition of a third stack.

**FOR FURTHER INFORMATION CONTACT:** Copies of the permit modification are available for public inspection upon request; address request to: Cris Tiongson (P-8-2), U.S. Environmental Protection Agency, Region 9, 215 Fremont Street, San Francisco, CA 94105, 415-454-8021.

**DATE:** The PSD permit modification is reviewable under Section 307(b)(1) of the Clean Air Act only in the Ninth Circuit Court of Appeals. A petition for review must be filed within 60 days of the date of this notice.

Dated: February 11, 1985.

**David P. Howekamp,**

*Director, Air Management Division, Region 9.*

[FR Doc. 85-4359 Filed 2-21-85; 8:45 am]

BILLING CODE 6560-50-M

[ER-FRL-2784-2]

### Environmental Impact Statements; Availability

**Responsible Agency**

Office of Federal Activities, General Information (202) 382-5073 or (202) 382-5075. Availability of Environmental Impact Statements filed February 11, 1985 through February 15, 1985 Pursuant to 40 CFR 1506.9.

EIS No. 850059, DSuppl, FHW, IA, Relocated IA-58 and US 218 (formerly 518) Improvement, Relocated US 20 in Cedar Falls to IA-3 in Waverly, Black Hawk and Bremer Counties, Due: April 10, 1985, Contact: H. A. Willard (515) 233-1664

EIS No. 850060, Final, COE, VA, Roanoke River Upper Basin Flood Damage Reduction, Roanoke, Botetourt, Floyd, and Montgomery Counties, Due: March 25, 1985, Contact: Richard Jackson (919) 343-4745

EIS No. 850061, Draft, AFS, ID, Nezperce National Forest Land and Resource Management Plan, Idaho County, Due: June 1, 1985, Contact: Tom Kovalicky (208) 983-1950

EIS No. 850062, Final, FHW, AL, Lakeshore Drive Extension, Green Springs Highway to Oxmoor Road, Jefferson County, Due: March 25, 1985, Contact: Joe Wilkerson (205) 832-7372

EIS No. 850063, Final, OSM, WA, John Henry No. 1 Mine Operation, Permit, King County, Due: March 25, 1985, Contact: Charles Albrecht (303) 844-5656

EIS No. 850064, DRevised, AFS, MT, Lolo National Forest, Land and Resource Management Plan, Due: June 1, 1985, Contact: Orville Daniels (406) 329-3804

EIS No. 850065, Draft, UMT, CA, San Diego East Urban Corridor Transportation Improvement, San Diego County, Due: April 8, 1985, Contact: Robert Hom (415) 974-7543

EIS No. 850066, FSuppl, COE, VA, Virginia Beach, Beach Erosion Control and Hurricane Protection, Virginia Beach, Due: March 25, 1985, Contact: Richard Muller (804) 441-3767.

**Amended Notices**

EIS No. 830568, Draft, OSM, WY, Red Rim Coal Development Leasing, Fremont, Sweetwater, and Carbon

Counties. Due: 2-7-85. Published FR 4-20-84—The review period has officially closed. All reviewing parties were notified by a letter and a notice was published by OSM in the December 19, 1984 **Federal Register** (49 FR 49388).

EIS No. 840482, DSuppl, AFS, MT, Flathead National Forest, Land and Resource Management Plan, Due: March 15, 1985, Published FR 11-16-84—Review extended

EIS No. 840488, Draft, OSM, NM, La Plata Mine Operation, Approval/Permit, San Juan Basin, San Juan County, Due: March 6, 1985, Published FR 11-2-84—Review extended

EIS No. 840493, DSuppl, AFS, MT, Lewis and Clark National Forest, Land and Resource Management Plan, Wilderness Designation, Due: March 15, 1985, Published FR 11-16-84—Review extended

EIS No. 850047, Draft USN, NV, Fallon Naval Air Station, Master Land Withdrawal, Application for Withdrawal of Federally Owned Land from Public Land Laws, Due: April 9, 1985, Published FR 2-8-85—Review extended

EIS No. 850054, FSuppl, FHW, VA, I-664 Bridge-Tunnel Complex Construction, crossing Hampton Roads, connecting Hampton and Newport News to Suffolk, Due: March 18, 1985, Published FR 2-15-85—Incorrect status.

Dated: February 19, 1985.

**Allan Hirsch,**

*Director, Office of Federal Activities.*

[FR Doc. 85-4438 Filed 2-21-85; 8:45 am]

BILLING CODE 6560-50-M

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[ER-FRL-2784-3]

## Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared February 4, 1985 through February 8, 1985 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)[c] of the National Environmental Policy Act, as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 382-5075/76. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in **Federal Register** dated October 19, 1984 (49 FR 41108).

### Draft EISs

ERP No. D-AFS-D65010-00, Rating EC2, George Washington Nat'l Forest, Land and Resource Mgmt. Plan, VA and WV. Summary: EPA expressed concern over potential water quality impacts and noted deficiencies in the analysis of geological profiles in the management plan.

ERP No. D-AFS-J65133-00, Rating EC2, Wasatch-Cache Nat'l Forest Land and Resource Mgmt. Plan, UT and WY. Summary: EPA believes that the proposed forest plan alternative (Alt. 8), with corrective measures, provides an environmentally acceptable management program. EPA expressed concerns regarding the management of such activities as timber harvesting, road construction, grazing, and recreational development in relation to water quality, soils, and riparian/wetland areas. To meet these concerns, EPA has requested additional impact analysis and further development of management direction for individual and cumulative impact assessment, best management practices, watershed planning, monitoring, project-specific NEPA Compliance, and inter-governmental/public coordination.

ERP No. D-COE-F90005-WI, Rating EC2, Green Bay Harbor Confined Disposal Facility, Construction, Operation, and Maintenance, WI. Summary: Elevated levels of polychlorinated biphenyls (PCBs), and polychlorinated dibenzofurans (PCDFs) are present in both the sediments to be dredged from the Fox River and Green Bay as well as the sediments and soils within the confined disposal facility. Fish and wildlife in the Fox River and Green Bay system have been contaminated with these toxic pollutants. There is some leakage of waters through the dikes of the existing facility, bypassing the sand filters. It has also been documented that the area around the facility supports a diverse fishery. Therefore, there is a strong potential for bioaccumulation in aquatic life of contaminants that might leak from the disposal facility. In view of the above, EPA recommends a more comprehensive, systematic evaluation of the routes and rates of exposure of fish, wildlife, and humans to these contaminants. EPA recommends that recently developed risk assessment guidelines be utilized.

ERP No. D-FHW-L50002-WA, Rating EC2, Palix R. Bridge Replacement, US 101, WA. Summary: Because the proposed alternative is the least environmentally desirable alternative, EPA requested a more thorough analysis of potential impacts to water quality, wetlands, aquatic organisms and wildlife.

ERP No. D-OSM-J01057-WY, Rating EO2, Red Rim Area Coal Development, Leasing, WY. Summary: EPA has concerns for reclamation and reestablishment of critical winter range habitat for pronghorn antelope, if this proposed federal coal lease is granted. EPA has requested that the FEIS provide a detailed discussion of reclamation and revegetation activities under similar geographic conditions.

### Final EISs

ERP No. F-AFS-H65001-00, Nebraska Nat'l Forest Land and Resource Mgmt. Plan, NB and SD. Summary: EPA's concerns on the DEIS received an adequate response and the agency agrees with the selecton of Alternative F as a reasonable choice to balance the economic needs of the area with the need to protect the public land.

ERP No. F-BLM-L65089-ID, Monument Resource Area Mgmt. Plan, ID. Summry: EPA made no formal comments. Review of the FEIS was completed and the project found to be satisfactory.

ERP No. F-FAA-E51040-FL, Palm Beach Int'l Airport, Fan Out Departure Procedures Elimination, Approval, FL. Summary: Although the FAA selected alternative is a compromise between fan-out and elimination of fan-out, from a noise perspective, EPA believes the environmentally preferable alternative is Alt. 5 (expanded fan-out).

ERP No. F-IBR-K05021-00, Hoover Dam Powerplant Modification, Construction, NV and AZ. Summary: EPA stated that the FEIS did not address the concerns it had raised on the DEIS, and that a number of FEIS conclusions regarding water quality impacts were not adequately substantiated. EPA also requested to participate in future planning efforts for the upgrade project.

ERP No. F-ICC-A53050-00, Nationwide Coal Rate Guidelines Ex Parte No. 347 (Sub. No. 1). Summary: EPA's review of the FEIS was completed and the analysis found to be satisfactory.

ERP No. F-SCS-D36094-PA, Jacobs Creek Watershed and Flood Protection Plan, PA. Summary: EPA's major concerns at the DEIS review stage were resolved in the FEIS.

Dated: February 19, 1985.

**Allan Hirsch,**

*Director, Office of Federal Activities.*

[FR Doc. 85-4439 Filed 2-21-85; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-59184; TSH-FRL 2783-1]

## Certain Chemicals; Test Marketing Exemption Application

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA may upon application exempt any person from the premanufacturing notification requirements of section 5(a) or (b) of the Toxic Substances Control Act (TSCA) to permit the person to manufacture or process a chemical for test marketing purposes under section 5(h)(1) of TSCA. Requirements for test marketing exemption (TME) applications, which must either be approved or denied within 45 days of receipt, are discussed in EPA's final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). This notice, issued under section 5(h)(6) of TSCA, announces receipt of three applications for exemption, provides a summary, and requests comments on the appropriateness of granting each of the exemptions.

**DATE:** Written comments by March 11, 1985.

**ADDRESS:** Written comments, identified by the document control number "[OPTS-59184]" and the specific TME number should be sent to: Document Control Officer (TS-793), Chemical Information Branch, Information Management Division, Office of Toxic Substances, Environmental Protection Agency, Rm. E-4201, 401 M Street, SW, Washington, DC 20460 (202-382-3532).

**FOR FURTHER INFORMATION CONTACT:** Wendy Cleland-Hamnett, Premanufacture Notice Management Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-611, 401 M Street, SW, Washington, DC 20460, (202-382-3725).

**SUPPLEMENTARY INFORMATION:** A nonsubstantive change in the prefixes is being initiated for information published under sections 5(d)(2) and 5(h)(6) of the Toxic Substances Control Act (TSCA). The notices will contain essentially the same information but the prefixes to the specific number assignment will appear in an abbreviated form. Prefixes under the modified format will use the letters "T" (TMEA), "P" (PMN) and "Y" (POLYMER EXEMPTION). The following notice contains information estracted from the non-confidential version of the submission provided by the manufacturer on the TME received by EPA. The complete non-confidential document is available in the Public Reading Room E-107 at the above address.

**T 85-21**

*Close of Review Period.* March 24, 1985.

*Manufacturer.* Confidential.

*Chemical.* (G) Modified polyether.

*Use/Production.* (G) Binder constituent for an industrial coating having an open, non-dipsersive use. Prod. range: 8,000 kg/6 months.

*Toxicity Data.* No data submitted.

*Exposure.* Manufacture: dermal, a total of 8 workers, up to 2 hrs/da, up to 24 da/yr.

*Environmental Release/Disposal.* 3 to 4 kg/batch released to land. Disposal by incineration and landfill.

**T 85-22**

*Close of Review Period.* March 29, 1985.

*Manufacturer.* Confidential.

*Chemical.* (S) Brominated unsaturated polyester resin.

*Use/Production.* (G) Building materials. Prod. range: Confidential.

*Toxicity Data.* No data submitted.

*Exposure.* Manufacture: Dermal and inhalation, a total of 6 workers, up to 4 hrs/da, up to 50 da/yr.

*Environmental Release/Disposal.* No release.

**T 85-23**

*Close of Review Period.* March 20, 1985.

*Manufacturer.* Confidential.

*Chemical.* (G) Unsaturated polyester resin.

*Use/Production.* (S) Intermediate polymer. Prod. range: Confidential.

*Toxicity Data.* No data submitted.

*Exposure.* Manufacture: dermal and inhalation, a total of 5 workers, up to 4 hrs/da, up to 13 da/yr.

*Environmental Release/Disposal.* 1,300 kg/batch released to air. Disposal by incineration.

Dated: February 19, 1985.

**Linda A. Travers,**

*Acting Director, Information Management Division.*

[FR Doc. 85-4356 Filed 2-21-85; 8:45 am]

BILLING CODE 6560-50-M

## FEDERAL COMMUNICATIONS COMMISSION

### Satellite Relay, Inc.; Order Designating Applications for Hearing

In the Matter of the Applications of Satellite Relay, Inc. for Authority to Construct and Operate a Point-to-Point Microwave Common Carrier Radio Station, and for Authority to Transfer Control from Jon W. Knudson to Ralph E. Evans, III (Common Carrier Docket No. 85-35, File No. 2546 CF-MP-83, File No. 171 CF-TC (1)-83).

Adopted February 5, 1985.

Released February 8, 1985.

By the Common Carrier Bureau.

1. The Bureau has before it an application for modification of a construction permit filed by Satellite Relay, Inc. (SRI), along with an application for consent *nunc pro tunc* to transfer control of SRI. Petitions to deny the application to modify have been filed by Centel Videopath, Inc. (Videopath) and by Midwestern Relay Company (MRC). In addition, Videopath has petitioned to deny the transfer application. For the reasons stated below, we conclude that the petitions raise substantial and material questions of fact, and therefore designate these applications for hearing.

**Background**

2. On February 2, 1982 SRI filed an application for authority to construct and operate facilities for a new station in the Point-to-Point Microwave Radio service, to provide an eight-channel microwave link from a transmitter located in Evanston, Illinois to a receive location in downtown Chicago.[1] The application consisted of an executed standard FCC Form 435 accompanied by a Licensee Qualification Report (FCC Form 430). SRI's proposed service would permit its customer, Satellite Television Inc. (Sat-Tel) to have programming transmitted from Sat-Tel's earth station in Evanston to the River Plaza Apartment Building in Chicago (SRI's proposed receive location). SRI's application was executed by Jon W. Knudson, as president; the application also listed Knudson as sole shareholder in SRI.[2] The radio facilities were to be leased from Sat-Tel,[3] and Sat-Tel's president, Earl J. Niemoth, was listed as the chief engineer in charge of the station.[4] Niemoth was also the sole incorporator of SRI.[5]

3. By letter dated April 13, 1982 the Bureau requested additional information about SRI's application. Among other items, the Bureau requested "an explanation of the apparent affiliation between the proposed common carrier (Satellite Relay, Inc.) and the customer/programmer."

4. In a response filed on April 27, 1982 SRI stated, *inter alia*, that "[n]o affiliation of any kind exists between SRI and Satellite Television, Inc. ("Sat-

[1] The application was listed as acceptable for filing by Public Notice dated February 24, 1982.

[2] Form 430, Question 6c.

[3] Form 435, Exhibit Q. This exhibit is required as a disclosure of *all* agreements which affect ownership or control of the proposed facilities. Other than the lease arrangement, no other disclosures were made by SRI in its initial application.

[4] Form 435, Exhibit N; *see also id.* Exhibit M-1.

[5] *See* Form 430, Exhibit II, at Art. Two.

Tel") other than that of carrier to customer." While acknowledging that Sat-Tel would lease the equipment to SRI, and noting that Niemoth was the sole incorporator of SRI, the response stated that the two companies "shared no common officers, directors or stockholders," and that "Mr. Niemoth . . . has no relationship to SRI other than as the president of the initial subscriber to its microwave service." The response was verified by attached affidavit of Knudson.

5. Based upon the record as described, on May 20, 1982 the Bureau granted a construction permit for the microwave facilities requested. The permits were for a construction period of 18 months, to expire on December 1, 1983.

6. On June 7, 1983, approximately 12 months after grant of the initial construction permit, SRI filed an application to modify its permit and to add four additional receive locations.[6] This application was executed by Ralph E. Evans III as president of SRI. The application proposed a new maintenance agreement,[7] and listed Telstar Chicago, Inc. as the entity from which SRI would now lease its radio equipment.

7. Petitions to deny this application were filed by Videopath and MRC. The gist of the two petitions [8] can be summarized as follows: (a) To serve multiple receive locations from one transmitter location in an area where intense radio transmissions make frequencies scarce (such as Chicago), SRI should have had to show why alternative, less potentially interfering means of delivery would not be feasible; (b) SRI is not a bona fide common carrier eligible to hold authorizations under Section 21.700, in that it is "merely an accommodation agent for its proposed customer." [9]

8. In an opposition filed on August 22, 1983 SRI challenged these arguments. The opposition did disclose, however, that 100% of the stock of SRI had been transferred from Knudson to Evans on August 5, 1983, a date after the filing of the petitions to deny. Such a transfer, without prior Commission approval, would appear to violate Section 310 of the Communications Act, 47 U.S.C. 310.[10]

9. On October 11, 1983 SRI filed an application for consent to transfer of control, *nunc pro tunc*. In this application SRI admitted that an unauthorized transfer has occurred, but that the violations was "technical" in that the facilities were not built and were not in operation, and that "prompt disclosure of the transfer was made by the transferee and corrective actions were taken." [11]

10. The transfer application also revealed that, at the time of SRI's original application in February of 1982, Sat-Tel had an assignable option to purchase 100% of the stock of SRI.

11. A petition to deny the transfer application was filed by Videopath. The petition was founded on two issues: (a) That SRI is not a bona fide common carrier (reiterating and expanding on its previous argument); and (b) that SRI had misrepresented material facts to the Commission regarding its applications. A timely opposition was filed by SRI.[12]

## Issues

12. The pleadings in the various stages of this proceeding raise essentially three issues: (a) Must SRI demonstrate that alternatives other than the addition of four new receive locations are available to permit it to serve its customer; (b) is Sat-Tel (which on February 5, 1983 became Telstar of Chicago, Inc.) or any of its affiliates the real party in interest behind the SRI application; and (c) did SRI intentionally misrepresent material facts, or exhibit a lack of candor, in its applications of the Commission.

13. With regard to the first issue, we conclude that the service proposed to be offered over the frequencies applied for is a permissible service, and therefore the need showing in this instance is adequate. While petitioners may be correct that some other service (such as multipoint distribution service) or some other configuration (such as new satellite receive stations) may be a more suitable alternative, this does not place upon the applicant a burden of refuting these alternatives. Where feasible the Commission prefers to rely on the marketplace, rather than Commission edict, to insure that frequencies are put to the most economically efficient use. So long as the proposed use is consistent with Part 21 of the Commission's Rules and any other applicable regulations, we will not require that SRI prove it to be the "best" use. As such, the petitions will be denied to the extent that they seek such a justification from SRI.[13]

14. With regard to the question of the real party in interest, the Bureau finds that a substantial and material question of fact exists. Petitioners have submitted sufficient evidence to put into issue the relationship between SRI and Sat-Tel/Telstar of Chicago. As noted, it appears that SRI's only customer will build, own and lease to SRI all the proposed facilities. That customer apparently founded SRI, assigned SRI's stock to Knudson, and retained an assignable option (later exercised by the parent corporation of Telstar of Chicago). Finally, several of the addresses provided as those of SRI have been that of its customer. For these reasons, we are designating the issue of the affiliation between SRI and Telstar of Chicago, to explore more fully the question of the real party in interest, as well as to determine whether SRI is not a *bona fide* common carrier because it is merely an accommodation agent for its customer.[14]

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[6] The application (File no. 2546 CF-MP-83) included a different proposed transmitter and one change in polarization. This application was listed as acceptable for filing by Public Notice date June 29, 1983.

[7] The equipment would now be maintained by Tennaplex Services, Inc., of Evanston. *See* Amended Application, Exhibit N.

[8] Other procedural defects were cited by the petitioners, including a failure to make the specific 50% non-affiliation showing required by a common carrier point-to-point microwave applicant proposing to serve cable systems (MRC Petition at 3-4), as well as a failure to execute and co-ordinate the application properly (Videopath Petition at 9-12).

[9] Videopath Petition at 2.

[10] Section 310(d) states, in relevant part:

> No construction permit or station license, or any rights thereunder, shall be transferred, assigned, or disposed of in any manner, voluntarily or involuntarily, directly or indirectly, or by transfer of control of any corporation holding such permit or license, to any person except application to the Commission and upon finding by the Commission that the public interest, convenience, and necessity will be served thereby.

[11] Application for Consent to Transfer, Exhibit IV, at 6.

[12] One final action of SRI was contested. On October 27, 1983 SRI requested special temporary authority pursuant to 47 CFR 21.25, to operate its initial links. Videopath opposed this request, opposition to the transfer application. Because we find that there are substantially on the same grounds as in its substantial and material questions of fact regarding the underlying application, we conclude that a grant of the STA would be inappropriate at this time, and are therefore dismissing it without prejudice.

[13] We also decline to accept MRC's suggestion that SRI is in fact subject to the 50% non-affiliation rule because it is serving a cable television system. *See* 47 CFR 21.700. The Commission's Rules defining "cable television system" specifically exclude any system "that serves or will serve only subscribers in one or more multiple unit dwellings under common ownership, or management." 47 CFR 76.5(a)(2).

[14] As the Commission noted in its decision in Community Antenna Television Systems (CARS):

> While we may be belaboring the obvious, we wish to stress the importance to the public interest of not having common carrier frequencies taken up by persons serving principally their own businesses. These frequencies are allocated for use by common carriers in rendering services to the public. In order to permit the common carriers to serve the diverse needs of the public adequately and dependable, they are permitted to engage in special operating practices and to construct facilities of extraordinary complexity which are not ordinarily required by private users. It is important that the development of common

Continued

15. We also find that SRI's candor in dealing with the Commission raises questions of fact regarding its qualifications to become a licensee. Despite a specific request from the Bureau for "an explanation of the apparent affiliation" between SRI and Sat-Tel, SRI failed to disclose that Sat-Tel (through its sole owners) held an assignable option to purchase 100% of its stock.[15] In addition, SRI admits that an unauthorized transfer of 100% of its stock occurred; while SRI subsequently did file to rectify this situation, SRI's action occurred only after petitions to deny its modification application revealed the transfer. The issue of SRI's candor in its dealings with the Commission therefore presents an additional substantial and material question of fact.

**Ordering Clause**

16. Accordingly, it is ordered that the petitions of MRC and Videopath are granted to the extent consistent with the foregoing opinion, and denied in all other respects.

17. It is further ordered that the application of SRI to modify its construction permits, and the application of SRI for consent to transfer corporate ownership, are designated for hearing in accordance with section 309(e) of the Communications Act, as amended, 47 U.S.C. 309(e), upon the following issues:

(1) To determine the relationship between SRI and Telstar of Chicago, including their respective principals as well as any parent, subsidiary, or otherwise related companies;

(2) To determine the facts and circumstances surrounding the conception, initiation, preparation, filing and prosecution of all applications of SRI in the instant proceeding;

(3) To determine, in light of the evidence adduced above,

(a) Whether Telstar of Chicago, or any of its affiliates or principals, are real parties in interest in SRI's applications in the instant proceeding;

(b) Whether SRI or its principals have exhibited a lack of candor or intentionally misrepresented material facts to the Commission; and

(c) Whether a grant of the captioned applications would serve the public interest, convenience and necessity.

18. It is further ordered that if SRI files and application for license and a request for service tests prior to the issuance of an initial decision in the case, the application for license and the request for service tests shall be designated for inclusion in this hearing by further order of the Chief, Common Carrier Bureau. The Administrative Law Judge before whom this matter is being heard will enlarge the issues in an appropriate manner on such further designation. No service shall be instituted prior to express approval by the Commission.

19. It is further ordered that SRI shall have the responsibility to adduce evidence of the issues set forth above, and that the burden of proof on the issues set forth above shall be placed on SRI.[16]

20. It is further ordered that Videopath, MRC, SRI, and the Chief, Common Carrier Bureau are made parties to this proceeding.

21. It is further ordered that the hearing shall be held at a time an place and before and Administrative Law Judge to be specified in a subsequent order.

22. It is further ordered that all designated parties shall file written notices of appearance, pursuant to § 1.221 of the Rules, 47 CFR 1.221, within 20 days of the release date of this Order.

23. It is further ordered that other parties desiring to participate in the hearing, including parties with applications mutually exclusive with the instant applicant and that wish to participate in this proceeding, shall file a petition to intervene, pursuant to § 1.221 of the Rules, within 30 days of the publication of this Order in the **Federal Register.**

24. It is further ordered that the application of SRI for special temporary authority is hereby denied without prejudice.

25. It is further ordered that the Secretary shall cause a copy of this Order to be published in the **Federal Register.**

Common Carrier Bureau.

**Albert Halprin,**

*Chief.*

[FR Doc. 85-4305 Filed 2-21-85; 8:45 am]

BILLING CODE 6712-01-M

carriers serving the public should not be blocked or inhibited by the presence in the common carrier bands of persons serving principally their own businesses, who have other frequencies allocated for such activities. It requires little foresight regarding trends toward frequency congestion to anticipate that the development of common carrier routes will soon be thwarted or affected adversely if persons serving primarily their own interests are allowed to freely occupy substantial amounts of the spectrum space available in the common carrier bands.

1 F.C.C. 2d 897, 901-2 (1965). Indeed, our conclusion that SRI does not have to demonstrate that its use of this spectrum is the optimal use is premised upon our conclusion that SRI's use is a permitted use; if it is not, then the frequency congestion which MRC and Videopath describe may in fact be unjustifiably aggravated.

[15] SRI claims that this option was "immaterial to any issue raised by SRI's application," citing cases to show that the *acquisition* of such an option would not be considered a transfer of control under 47 CFR 21.39. This is irrelevant to SRI's responsibility to provide such information upon reasonable request by the Commission, and to any misrepresentation or lack of candor for failing to do so. The Commission must depend upon the accuracy of the information provided by applicants; in this sense, the materiality of the matter misrepresented my be even less important than the fact that a misrepresentation occurred: FCC v. WOKO, 325 U.S. 223 (1945); Granberry Communications Co., 68 F.C.C.2d 966, 968 (1978).

[16] Where an applicant, against whom charges of misconduct have been raised, has within its peculiar knowledge the facts regarding the alleged misconduct, the applicant will have the burdens of production and proof on such issues. *See generally* Granbury Communications Co., 68 F.C.C.2d 966, 969 (1978); Miami Broadcasting Corp., 11 F.C.C.2d 920, 923 (Rev. Bd. 1968).

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**[Report No. DS-372]**

## Advisory Committee on Reduced Orbital Spacing; Meeting

February 14, 1985.

A meeting of the FCC Advisory Committee on Reduced Orbital Spacings will take place on March 7, 1985 as indicated below. The purpose of this advisory committee is to obtain expert technical and operational advice on how to better implement 2° spacing in the 4/6 GHz and 12/14 GHz bands.

Date: 7 March 1985.
Time: 1:00 p.m.
Place: Room 856. Federal Communications Commission, 1919 M Street NW., Washington, D.C.
Agenda: 1. Adoption of agenda.
2. Adoption of minutes from last meeting.
3. Report from Working Group Chairmen.
4. Discussion of time table for final report.
5. Other business.

This meeting is open to the public. For more information contact Roger Herbstritt at the FCC on (202) 634-1624.

**William J. Tricarico,**

*Secretary, Federal Communications Commission.*

[FR Doc. 85-4306 Filed 2-21-85; 8:45 am]

BILLING CODE 6712-01-M

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**[Report No. 1498]**

## Petitions for Reconsideration of Actions in Rulemaking Proceedings

February 14, 1985.

The following listings of petitions for reconsideration filed in Commission rulemaking proceedings is published pursuant to 47 CFR 1.429(e). Oppositions to such petitions for reconsideration must be filed within 15 days after publication of this Public Notice in the **Federal Register.** Replies to an

opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: MRTS and WTS Market Structure. Amendment of Part 67 of the Commission's Rules and Establishment of a Joint Board. (CC Docket No. 78–72 & CC Docket No. 80–286)

Filed by:

Bruce J. Weston & Maureen R Grady, Associate Consumers' Counsel for The Office of the Consumers' Counsel, State of Ohio on 2–7–85.

John L. Bartlett, Robert J. Butler & Renee R. Matalon, Attorneys for Aeronautical Radio, Inc., on 2–7–85.

The Idaho Public Utilities Commission on 2–7–85.

Subject: Amendment of the Commission's Rules to Allow the Selection from Among Certain Applications Using Random Selection or Lotteries Instead of Comparative Hearings. (Gen Docket No. 81–768)

Filed by:

Andrew Jay Schwartzman & Robert M. Gurss, Attorneys for Youth News on 1–22–85.

Charlotte B. Rutherford & Wilhelmina Reuben Cooke, Attorneys for The National Latino Media Coalition, et al on 1–22–85.

Subject: Modification of Policy on Ownership and Operation of U.S. Earth Stations that Operate with the INTELSAT Global Communications Satellite System (CC Docket No. 82–540)

Filed by: Phillip L. Spector, Attorney for Equatorial Communication Services on 1–25–85.

Subject: Investigation of Access and Divestiture-Related Tariffs. (CC Docket No. 83–1145, Phase I and Phase II, Part I)

Filed by:

Arthur H. Simms & Peter G. Wolfe for The Western Union Telegraph Company on 1–28–85.

J. Manning Lee & Jeffrey H. Matsuura, Attorneys for Satellite Business Systems on 1–28–85.

Robert L. Barada, Maya A. Mathews & Stanley J. More, Attorneys for Pacific Bell & Nevada Bell on 1–28–85.

Michael Yourshaw & Robert J. Butler, Attorneys for SATellite Data Broadcast NETworks, Inc., on 1–28–85.

Subject: Amendment of § 97.121 of the Amateur Rules to make clear when the call sign of another amateur station can be transmitted.

Filed by: David B. Popkin on 2–5–85.

**William J. Tricarico,**

*Secretary, Federal Communications Commission.*

[FR Doc. 85–4304 Filed 2–21–85; 8:45 am]

BILLING CODE 6712–01–M

## FEDERAL EMERGENCY MANAGEMENT AGENCY

### Review Schedule Under OMB Circular No. A–76 for FEMA In-House Commercial Activities

**AGENCY:** Federal Emergency Management Agency.

**ACTION:** Notice.

In accordance with OMB Circular No. A–76, Revised, Performance of Commercial Activities, dated August 4, 1983, and the Supplement to the Circular, this notice announces the Federal Emergency Management Agency's (FEMA) intention to conduct in fiscal year 1985 cost comparisons of the following functions. The studies are scheduled to begin in February 1985 and be completed by September 30, 1985.

1. Mail and File Operations, Washington, D.C.

2. Arts and Graphics, Washington, D.C.

**FOR FURTHER INFORMATION CONTACT:** Pierre Goiran, Office of Program Analysis and Evaluation, Federal Emergency Management Agency, Washington, D.C. 20472, telephone 202–646–2677.

Dated: February 14, 1985.

**Fred A. Newton, III,**

*Director, Program Analysis and Evaluation.*

[FR Doc. 85–4311 Filed 2–21–85; 8:45 am]

BILLING CODE 6718–01–M

## FEDERAL RESERVE SYSTEM

### First NH Banks, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. 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 is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. 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.

Unless otherwise noted, comments regarding each of these applications must be received not later than March 15, 1985.

A. **Federal Reserve Bank of Boston** (Richard E. Randall, Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02106:

1. *First NH Banks, Inc.*, Manchester, New Hampshire; to acquire 100 percent of the voting shares of The National Bank of Lebanon, Lebanon, New Hampshire.

B. **Federal Reserve Bank of Cleveland** (Lee S. Adams, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *Metamora Bancorp, Inc.*, Metamora, Ohio; to become a bank holding company by acquiring 100 percent of the voting shares of The Metamora State Bank, Metamora, Ohio.

C. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *American Bancorp, Inc.*, Suring, Wisconsin; to become a bank holding company by successor by merger to The Suring State Bank, Suring, Wisconsin and The First National Bank of Oconto, Oconto, Wisconsin, to be known as American Bank of Wisconsin, Oconto, Wisconsin; to acquire 94.13 percent of the voting shares of The First National Financial Corporation, Marinette, Wisconsin, thereby indirectly acquiring The First National Bank of Marinette, Wisconsin.

D. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Interamerican Credit Holding, N.V.*, Oranjestad, Aruba, Netherlands Antilles; to become a bank holding company by acquiring 51 percent of the voting shares of Creditbank Shares, Inc., Coral Gables, Florida.

E. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *The Bank of New Mexico Holding Company*, Albuquerque, New Mexico; to acquire at least 80 percent of the voting

shares of The Bank of Northern New Mexico; Las Vegas, New Mexico.

F. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Parker County Bancshares, Inc.*, Weatherford, Texas; to become a bank holding company by acquiring 99.85 percent of the voting shares of Weatherford Bancshares, Inc., Weatherford, Texas, thereby indirectly acquiring The First National Bank of Weatherford, Weatherford, Texas.

Board of Governors of the Federal Reserve System, February 15, 1985.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 85-4312 Filed 2-21-85; 8:45 am]

BILLING CODE 6210-01-M

## First Railroad & Banking Company of Georgia; Application To Engage de Novo in Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(3) of the Board's Regulation Y (12 CFR 225.23(a)(3)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)), to engage *de novo* through a national bank subsidiary in deposit-taking, including the taking of demand deposits, and other activities specified below. The proposed subsidiary will not engage in commercial lending transactions as defined in Regulation Y. The Board has determined by order that such activities are closely related to banking. *U.S. Trust Company* (70 Federal Reserve Bulletin 371 (1984)).

The application is available or immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing 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 request for a hearing on this question must be accompanied by 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 the proposal.

Comments regarding the application must be received at the Federal Reserve Bank or the offices of the Board of Governors not later than March 15, 1985.

A. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street NW., Atlanta, Georgia 30303:

1. *First Railroad & Banking Company of Georgia*, Augusta, Georgia; to engage through a national bank subsidiary, Capital National Bank of South Carolina, Aiken, South Carolina, in certain consumer banking activities consisting of making direct and indirect loans at fixed and variable rates to consumers, issuing and operating credit and debit card services, and offering various types of high yield and limited access deposit accounts.

Board of Governors of the Federal Reserve System, February 15, 1985.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 85-4314 Filed 2-21-85; 8:45 am]

BILLING CODE 6210-01-M

## Henry County Bancshares, Inc.; Application To engage de novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence,or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing 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 interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by 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 the proposal.

Unless othwerwise noted, comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 13, 1985.

A. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Henry County Bancshares, Inc.*, Stockbridge, Georgia; to endage *de novo* through its subsidiary, First Metro Mortgage Co., Stockbridge, Georgia, in the origination and selling of mortgage loans. This activity will be conducted from an office located in Stockbridge, Georgia.

Board of Governors of the Federal Reserve System, February 15, 1985.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 85-4313 Filed 2-21-85; 8:45 am]

BILLING CODE 6210-01-M

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## 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 February 15, 1985.

### Office of the Secretary

Subject: Request for Advance or Reimbursement—Extension (0990-0059).

Respondents: State/local governments, businesses or other for-profit, non-profit institutions.

Subject: Update Study of Consumer Complaint Handling by Government, Business and Voluntary Groups—New.

Respondents: State/local governments, businesses, non-profit institutions.

Subject: Federal Cash Transaction Report—Extension (0990–0078).

Respondents: State/local governments, businesses or other for-profit, non-profit institutions.

OMB Desk Officer: Robert J. Fishman.

**Health Care Financing Administration**

Subject: Payments to Health Maintenance Organizations and Competitive Medical Plans HCFA–R–29—New.

Respondents: Health Maintenance Organizations and Competitive Medical Plans.

Subject: Licensure Forms for the Clinical Laboratory Improvement Act HCFA–200, 201, 202, 203, 206 and 209 Extension—(0938–0151).

Respondents: Clinical Labs.

Subject: Electronic Media Claim/Hard Copy Study HCFA–471—New.

Respondents: Providers/carriers.

Subject: Regional Office Medicaid Quality Control Federal Rereview Process HCFA–9010—Extension (0938–0210).

Respondents: Medicaid State Agencies.

Subject: Questions on Other Insurance Available to Medicare Beneficiary HCFA–9009 HCFA–L–365—Reinstatement (0938–0214).

Respondents: Intermediaries/carriers.

Subject: Inpatient Admission and Billing/Christian Science Sanatorian HCFA–1486—Extension (0938–0015).

Respondents: Hospital/SNFs.

Subject: Installment Agreement on Beneficiary Refund of Overpayment HCFA–9005—Reinstatement (0938–0211).

Respondents: Beneficiaries.

OMB Desk Officer: Fay S. Iudicello.

**Social Security Administration**

Subject: Vocational Rehabilitation "301" Program Development SSA–4290—Revision (0960–0282).

Respondents: States.

OMB Desk Officer: Robert Fishman.

**Public Health Service**

*National Institutes of Health*

Subject: Format Instructions for Research Centers in Minority Institutions—New.

Respondents: Non-profit institutions.

**Alcohol, Drug Abuse and Mental Health Administration**

Subject: Confidentiality of Alcohol and Drug Abuse Patient Records—Reinstatement (0930–0092).

Respondents: Federal agencies; non-profit institutions; businesses.

OMB Desk Officer: Fay S. Iudicello.

**Food and Drug Administration**

Subject: New Drug and Antibiotic Regulations Revision (0910–0001).

Respondents: Drug Manufacturers.

OMB Desk Officer: Bruce Artim.

Copies of the above information collection clearance packages can be obtained by calling the HHS Reports Clearance Officer on 202–245–6511.

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, D.C. 20503. ATTN: (name of OMB Desk Officer).

Dated: February 15, 1985.

**Wallace O. Keene,**

*Acting Deputy Assistant Secretary for Management Analysis and Systems.*

[FR Doc. 85–4335 Filed 2–21–85; 8:45 am]

BILLING CODE 4150–04–M

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## Centers for Disease Control

## Occupational Safety and Health; Request for Comments and Secondary Data on the Use and Health Effects of 1,3-Dichloropropene

*Correction*

In FR Doc. 85–2784 beginning on page 4913, in the issue of Monday, February 4, 1985, make the following correction:

On page 4914, in the first column, in the second paragraph under "**SUPPLEMENTARY INFORMATION**", in the fifth line, "dibromochloropane" should read "dibromochloropropane".

BILLING CODE 1505–01–M

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## Food and Drug Administration

**[Docket No. 85F–0024]**

## EMS–CHEMIE AG; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that EMS-CHEMIE AG has filed a petition proposing that the food additive regulations be amended to provide for the safe use of nylon 6/12, which may contain nylon 6/66/12 and *N, N'*-distearoylethylenediamine, as a component of laminated films for high temperature food contact.

**FOR FURTHER INFORMATION CONTACT:** George H. Pauli, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 3B3743) has been filed by EMS–CHEMIE AG, CH–7013 Domat/Ems, Switzerland, proposing that the food additive regulations be amended to provide for the safe use of nylon 6/12, which may contain nylon 6/66/12 and *N, N'*-distearoylethylenediamine, as a component of laminated films which contact food at high temperature.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: February 15, 1985.

**Richard J. Ronk,**

*Acting Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 85–4307 Filed 2–21–85; 8:45 am]

BILLING CODE 4160–01–M

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**[Docket No. 85F–0035]**

## Witco Chemical Corp.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Witco Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of the reaction products of 1,6–hexanediol with azelaic acid, and/or polybasic and monobasic acids identified in 21 CFR 175.300(b)(3)(vii) (*a*) and (*b*), and/or tetrahydrophthalic acid as components of adhesives for use in articles intended for use in contact with food.

**FOR FURTHER INFORMATION CONTACT:** Vir Anand, Center for Food Safety and Applied Nutrition HFF–334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5B3844) has been filed by Witco Chemical Corp., 3230 Brookfield

St., Houston, TX 77045, proposing that § 175.105 *Adhesives* (21 CFR 175.105) be amended to provide for the safe use of the reaction products of 1,6-hexanediol with azelaic acid, and/or polybasic and monobasic acids identified in 21 CFR 175.300(b)(3)(vii) (*a*) and (*b*), and/or tetrahydrophthalic acid as components of adhesives for use in articles intended for use in contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 ER 71742).

Dated: February 14, 1985.

**Richard J. Ronk,**

*Acting Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 85-4308 Filed 2-21-85; 8:45 am]

BILLING CODE 4160-01-M

## Health Resources and Services Administration

### Application Announcement for Advanced Nurse Training Grants, Nurse Practitioner Training Grants, and Nursing Special Project Grants

The Bureau of Health Professions, Health Resources and Services Administration announces that applications for the following nursing programs will be accepted in 1985:

(1) Advanced Nurse Training Grants.
(2) Nurse Practitioner Training Grants.
(3) Nursing Special Project Grants.

#### Advanced Nurse Training Grants

Section 821, Public Health Service Act, and 42 CFR Part 57, Subpart Z, authorize assistance to meet the costs of projects to (a) plan, develop and operate, (b) significantly expand, or (c) maintain existing programs for advanced training of professional nurses to teach in the various fields of nurse training, to serve in administrative or supervisory capacities, or to serve in other professional nursing specialties (including service as nurse clinicians).

Eligible Applicants: Public and nonprofit private collegiate schools of nursing.

This program is listed at 13.299 in the Catalog of Federal Domestic Assistance.

#### Nurse Practitioner Training Grants

Section 822(a)(1), Public Health Service Act, and 42 CFR Part 57, Subpart Y, authorize assistance to plan, develop and operate, significantly expand or maintain existing programs for the training of nurse practitioners.

Eligible Applicants: Public or nonprofit private schools of nursing, medicine, and public health, public or nonprofit private hospitals and other public or nonprofit entities.

This program is listed at 13.298 in the Catalog of Federal Domestic Assistance.

#### Nursing Special Project Grants

Section 820(a), Public Health Service Act, and 42 CFR Part 57, Subpart T, authorize assistance in meeting the costs of special projects to carry out one or more of the following designated purposes:

(1) To increase nursing education opportunities for individuals from disadvantaged backgrounds as determined in accordance with criteria prescribed by the Secretary of Health and Human Services by:

(i) Identifying, recruiting, and selecting such individuals,

(ii) Facilitating the entry of such individuals into schools of nursing,

(iii) Providing counseling or other services designed to assist such individuals to complete successfully their nursing education,

(iv) Providing, for a period prior to the entry of such individuals into the regular course of education at a school of nursing, preliminary education designed to assist them to complete successfully such regular course of education,

(v) Paying such stipends as the Secretary may determine for such individuals for any period of nursing education; and

(vi) Publicizing, especially to licensed vocational or practical nurses, existing sources of financial aid available to persons enrolled in schools of nursing or who are undertaking training necessary to qualify them to enroll in such schools;

(2) To provide continuing education for nurses;

(3) To provide appropriate retraining opportunities for nurses who (after periods of professional inactivity) desire again actively to engage in the nursing profession;

(4) To help to increase the supply or improve the distribution by geographic area or by specialty group of adequately trained nursing personnel (including nursing personnel who are bilingual) needed to meet the health needs of the Nation, including the need to increase the availability of personal health services and the need to promote preventive health care; or

(5) To provide training and education to upgrade the skills of licensed vocational or practical nurses, nursing assistants, and other paraprofessional nursing personnel.

Eligible Applicants: Public or nonprofit private schools of nursing or other public or nonprofit private entities.

This program is listed at 13.359 in the Catalog of Federal Domestic Assistance.

#### Application Deadlines

Three review cycles are held annually for Advanced Nurse Training Grants, Nurse Practitioner Training Grants, and Nursing Special Project Grants. The application deadline dates are March 1, July 1 and November 1. Applications shall be considered as meeting the deadline if they are either:

(1) *Received* on or before the deadline date, or

(2) *Postmarked* on or before the deadline date, and received in time for review.

A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks shall not be acceptable as proof of timely mailing.

#### Amounts Available

The following amounts are expected to be available for Fiscal Year 1985 competing awards:

| | Million |
|---|---|
| Advanced nurse training grants | $6.8 |
| Nurse practitioner training grants | 4.7 |
| Nursing special projects grants | 3.3 |

For specific guidelines and information regarding these programs contact: Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 5C-26, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-5786.

Questions regarding grants policy should be directed to: Grants Management Officer, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8C-22, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-6915.

These programs are not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs or 42 CFR Part 100.

Dated: February 15, 1985.

**Robert Graham,**

*Administrator, Assistant Surgeon General.*

[FR Doc. 85-4303 Filed 2-21-85; 8:45 am]

BILLING CODE 4160-16-M

## Office of Human Development Services

### Native American Programs; Amendment to Program Announcement

**AGENCY:** Office of Human Development Services, HHS.

**ACTION:** Subject: Amendment to Program Announcement 13612–851, published in the Federal Register on August 1, 1984 (49 FR 30880–30882).

**SUMMARY:** The Administration for Native Americans (ANA) is amending ANA Program Announcement 13612–851 to include an emphasis on housing initiatives to enlarge and improve the housing stock available to Native Americans. Those applicants who were funded on the October 10, 1984 and those who are selected on the February 28, 1984 closing dates of 13612–851, may submit an additional application for one or more housing objectives or projects. The deadline for these supplemental applications is May 10. Applicants for the June 30, 1985 closing date may include housing initiatives in their social and economic development strategies (SEDS).

**FOR FURTHER INFORMATION CONTACT:** Applicants may contact Dorothy S. Johnson, ANA, Office of Human Development Services, DHHS, 330 Independence Avenue, SW., Washington, D.C. 20201, (202) 245–7730.

**SUPPLEMENTARY INFORMATION:** The Administration for Native Americans is authorized under the Native American Programs Act of 1974, Pub. L. 93–644, as amended, 42 U.S.C. 2991 *et seq.* Regulations covering this program are published in the Code of Federal Regulations in 45 CFR Part 1336. Program Announcement 13612–851 announced that financial assistance is available for Indian tribes and Native American organizations under a competitive grant application process. It established closing dates for the receipt of applications as follows: October 10, 1984; February 28, 1985; and June 30, 1985. The purpose of this program announcement is to announce the availability of assistance to promote self-sufficiency for Native Americans through support of local social and economic development projects. We are amending the announcement to emphasize our commitment to improving the quality and quantity of housing units available to Native Americans.

The amendments to Program Announcement 13612–851 are as follows: Under "Program Priority and Expected Outcomes," the following additional examples of results expected from ANA supported housing projects are to be added:

**Governance—ANA Goal 1**

- Zoning ordinances or land use codes.
- Contracts for management of housing programs.
- Conversion of Federally-owned housing units to tribally-owned units.
- Development of legislation to form tribal home finance authorities and Indian lands enterprise zones.
- Codes and standards to regulate the construction industry on the reservation.

**Economic Development—ANA Goal 2**

- Attraction of a manufacturer of homes, modules or components to a near reservation or on reservation site to produce employment, to reduce transporation costs of finished products, and to develop a manufactured house specifically designed for use on an Indian reservation.
- Development, expansion, or both of tribal home mortgage financial institutions by, but not limited to: forming a tribal trust or correspondent mortgage company; expanding a tribal credit program; or joint venturing with an existing correspondent mortgage company, bank, organization, business enterprise, or another tribal government.
- Development mechanisms or provisions to organize, coordinate, or package existing housing related activities, such as construction loans, bonding, surety, insurance, etc.

**Social Development—ANA Goal 3**

- Licenses obtained by Native American urban organizations to provide housing or other related services for State and local governments.
- Initiation of an "Urban Homesteading" program for off-reservation families.
- Development of alternate housing concepts, designs, or both that address socially distressed children and adults, such as "safe" homes, youth-elderly facilities promoting "foster-grandparenting," and "independent living" for near-adults.
- Tenant-landlord courts.
- Eligible Applicants: No Change from Program Announcement 13612–851. Those applicants who were funded on the October 10, 1984 and those who are selected on the February 28, 1984 closing dates may submit an additional application for one or more housing objectives or projects. The deadline for these supplemental applications is May 10. Applicants for the June 30, 1985 closing dates may include housing initiatives in their social and economic development strategies.

Dated: February 15, 1985.

**William Lynn Engles,**

*Commissioner, Administration for Native Americans.*

Approved: February 19, 1985.

**Dorcas R. Hardy,**

*Assistant Secretary for Human Development Services.*

[FR Doc. 85–4440 Filed 2–21–85; 8:45 am]

BILLING CODE 4130–01–M

## Public Health Service

### Annual Reports of Federal Advisory Committees; Availability

Notice is hereby given that, pursuant to section 13 of Pub. L. 92–463, the Annual Reports for the following Office of the Assistant Secretary for Health Federal Advisory Committees have been filed with the Library of Congress:

Health Services Research and Developmental Grants Review Committee

Health Care Technology Study Section

Copies are available to the public for inspection at the Library of Congress, Special Forms Reading Room, Main Building, or weekdays between 9 am and 4:30 pm at the Department of Health and Human Services, Department Library, North Building, Room 1436, 330 Independence Avenue, Southwest, Washington, D.C. 20201, telephone (202) 245–6791. Copies may be obtained from Mr. Ralph L. Sloat, National Center for Health Services Research and Health Care Technology Assessment, Room 152, Park Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–3091.

**John E. Marshall,**

*Director, National Center for Health Services Research and Health Care Technology Assessment.*

[FR Doc. 85–4437 Filed 2–21–85; 8:45 am]

BILLING CODE 4160–17–M

## DEPARTMENT OF THE INTERIOR

## Office of the Secretary

### Privacy Act of 1974; Revision of Notices of Systems of Records

Pursuant to the provisions of the Privacy Act of 1974, as amended (5 U.S.C. 552a), notice is hereby given that the Department of the Interior proposes to revise five notices describing systems of records maintained by the Bureau of Reclamation. Except as noted below, all changes being published are editorial in

nature, and reflect organization changes and other minor administrative revisions which have occurred since the previous publication of the material in the **Federal Register.**

The five Bureau of Reclamation systems of records notices listed below are being combined into one composite notice because of the similarity of the nature and purposes of the records. The composite notice, published in its entirety below, is titled "Individual Records of Issue—Interior, Reclamation—11", and replaces the following notices:

| System number | System name | Federal Register publication |
|---|---|---|
| LBR-8 | Driver's License—Interior, Reclamation—8. | 4/11/77, 42 FR 19096 |
| LBR-10 | Identification Cards—Interior, Reclamation—10. | 4/11/77, 42 FR 19097 |
| LBR-11 | Individual Record of Issues—Interior, Reclamation—11. | 4/11/77, 42 FR 19097 |
| LBR-23 | Parking—Interior, Reclamation—23. | 4/11/77, 42 FR 19101 |
| LBR-30 | Safe Driving Records—Interior, Reclamation—30. | 4/11/77, 42 FR 19104 |

One new compatible routine use is being added to the composite notice published below which provides for routine disclosures to other Federal agencies for the purpose of collecting a debt owed the Federal government. All other routine uses in the composite notice were contained in the individual notices being replaced.

5 U.S.C. 552a(e)(11) requires that the public be provided a 30-day period in which to comment. Therefore, written comments on these proposed changes can be addressed to the Department Privacy Act Officer, Office of the Secretary (PIR), U.S. Department of the Interior, Washington, D.C. 20240. Comments received on or before March 25, 1985, will be considered. The notice published below shall be effective as proposed without further notice at the end of the comment period, unless comments are received which would require a contrary determination.

Dated: February 12, 1985.

**James P. Jadlos,**

*Acting Director, Office of Information Resources Management.*

**INTERIOR/WBR-11**

**SYSTEM NAME:**

Individual Records of Issue—Interior, Reclamation—11.

**SYSTEM LOCATION:**

Bureau of Reclamation Headquarters Office, Engineering and Research Center, Regional Offices: Pacific Northwest, Mid-Pacific, Lower Colorado, Upper Colorado, Southwest, Upper Missouri, Lower Missouri. See appendix for addresses.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Reclamation and contract employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Registers and records of Reclamation and contract employees having assigned Government parking spaces; I.D. cards, and passes; keys issued; drivers' licenses and driving records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

40 U.S.C. 471, 486, 491, and 44 U.S.C. 3101.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

The primary uses of these records include: assignment and control of Government parking spaces, keys issues, and official identification cards and passes; recording I.D. numbers, drivers license numbers and expiration dates; facilitating collection of I.D. cards, passes, parking permits, drivers' licenses, and keys when employees terminated employment; recommending safe driving awards, administration of the Bureau's driver license program; and for reporting purposes. Disclosures outside the Department of the Interior may be made: (1) To the Department of Justice when related to litigation or anticipated litigation; (2) of information indicating a violation or potential violation of a statute, regulation, rule, order, or license to appropriate Federal, State, local, or foreign agencies responsible for investigating or prosecuting the violation or for enforcing or implementing the statute, rule, regulation, order, or license; (3) from the record of an individual in response to an inquiry from a congressional office made at the request of that individual; (4) to the National Safety Council for issuance of safe driving awards; (5) where relevant or necessary to the hiring or retention of an employee, or the issuance of a security clearance, license, contract, grant, or other benefit, information may be disclosed: (a) To a Federal agency that has requested the information, or (b) to a Federal, State, or local agency to enable the Department of the Interior to obtain information from such agency; and (6) to a Federal agency for the purpose of collecting a debt owed the Federal Government through administrative or salary offset.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual and computer.

**RETRIEVABILITY:**

By employee name or number.

**SAFEGUARDS:**

In accordance with requirements of 43 CFR 2.51 for computer and manual records.

**RETENTION AND DISPOSAL:**

In accordance with approved retention and disposal schedules.

**SYSTEM MANAGER(S) AND ADDRESS:**

Issuing Officers. Bureau of Reclamation Headquarters Offices, Engineering and Research Center, Regional Offices: Pacific Northwest, Mid-Pacific, Lower Colorado, Upper Colorado, Southwest, Upper Missouri, Lower Missouri. See appendix for addresses.

**NOTIFICATION PROCEDURE:**

Written inquiries regarding the existence of a record(s) should be sent to the System Manager at the appropriate address listed in the appendix. See 43 CFR 2.60.

**RECORD ACCESS PROCEDURE:**

Same as Notification above. See 43 CFR 2.63.

**CONTESTING RECORD PROCEDURE:**

Written petitions for amendment should be sent to the System Manager at the appropriate address listed in the appendix. See 43 CFR 2.71.

**RECORD SOURCE CATEGORIES:**

Individuals on whom records are maintained, responsible Reclamation employees, and applicable Reclamation and State Department of Motor Vehicle records.

[FR Doc. 85–4385 Filed 2–21–85; 8:45 am]

BILLING CODE 4310-09-M

## Bureau of Land Management

### Worland District, Washakie Resource Area, Portions of Big Horn, Washakie, and Hot Springs Counties, WY; Call for Coal Resource Information

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Call for coal resource information for the Washakie Resource Area, Worland District, Wyoming.

**SUMMARY:** The Worland District is preparing a Resource Management Plan (RMP) to guide future management actions on the public lands within the Washakie Resource Area. The Washakie Resource Area consists of the portions of Hot Springs and Washakie Counties east of the Big Horn River and the portion of Big Horn County east of the Big Horn River and south of Shell Creek. Lands in the Wind River Indian Reservation and the Big Horn National Forest which may fall within the area described above are excluded from the planning area. The Notice of Intent To Prepare a Resource Management Plan was published on February 3, 1983.

This notice is the call for coal resource information required by 43 CFR 3420–2. As a result of this notice, any serious indications of interest, information on coal resource development potential and additional information on surface resource values related to the twenty coal unsuitability criteria described in 43 CFR 3461.1 will be used to identify areas of interest for possible leasing of Federal coal in the Washakie Resource Area between 1986 and 1996. In addition, any such information submitted will help to ensure that the RMP and subsequent EIS cover the fullest possible range of resource considerations.

The BLM has limited coal resource data for the planning area and will be unable to conduct further inventories. Parties interested in Federal coal leasing and development will be expected to provide coal resource data for their areas of interest. The planning schedule for this RMP/EIS requires that areas of interest, coal resource data and other related resource data must be submitted to the address below by March 29, 1985.

The Washakie Resource Area is not within a designated coal production region. Federal coal leasing in areas outside of coal regions may be considered apart from the competitive leasing process set out in 43 CFR 3420.3 through 3420.5–2. Coal leasing in the Washakie Resource Area will be done on a case-by-case basis called "Leasing on Application," under the appropriate provisions of 43 CFR and 3425 and 43 CFR 3420.1–4 through 3420.1–8. (Note that the sale and issuance of Federal coal leases under these provisions is still done through a competitive bidding process.)

Identification at this time of definite interests in leasing during the 1986 to 1996 period, substantiated with adequate coal and other resource data, will allow these interests to be addressed in the RMP. Thus, unnecessary work, delays, or near term revisions of the plan may be avoided if coal lease applications are submitted.

**ADDRESS:** Indications of interest and information on coal resource development should be submitted by March 29, 1985 to: Washakie Resource Area Manager, Bureau of Land Management, P.O. Box 119; Worland, Wyoming 82401.

**FOR FURTHER INFORMATION CONTACT:** For further information, contact Roger Inman, Area Manager, at the address above or telephone (307) 347–9871.

**Chester E. Conrad,**

*District Manager.*

[FR Doc. 85–4328 Filed 2–21–85; 8:45 am]

BILLING CODE 4310–22–M

## Application for Issuance of Disclaimer of Interest to Lands in Oregon

Notice is hereby given that the United States of America, pursuant to the provisions of the Federal Land Policy and Management Act of 1976 (FLPMA), Section 315, 43 U.S.C. 1745 (1976), does hereby give notice of its intention to disclaim all interest in the following described property:

**Willamette Meridian, Oregon, Lane County**

T. 23 S., R. 3 W.,
Sec. 3, NW¼NW¼.
Containing 39.84 acres.

After review of the official records, it has been determined by the Bureau of Land Management that all of the above-described land was erroneously conveyed to the United States on July 30, 1936, by Lane County.

Any person wishing to submit a protest, claim or comments on the above disclaimer should do so in writing before the expiration of 90 days from the date of publication of this notice. If no protest is received, the disclaimer will become effective on or about June 1, 1985, and title will pass to Lane County. Information concerning this land and the proposed disclaimer may be obtained from the Bureau of Land Management, Oregon State Office, P.O. Box 2965, Portland, Oregon 97208.

Dated: February 15, 1985.

**Harld A. Berends,**

*Chief, Branch of Lands and Minerals Operations.*

[FR Doc. 85–4398 Filed 2–21–85; 8:45 am]

BILLING CODE 4310–33–M

## Proposed Notice to Lessees and Operators of Federal Geothermal Leases

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Proposed Notice to Lessees and Operators of Federal Geothermal Leases.

**SUMMARY:** The California State Office, Bureau of Land Management proposes a Notice to Lessee (NTL) on drilling deep temperature gradient holes in California. This NTL proposes guidelines to geothermal lessees/operators for drilling temperature gradient holes deeper than 500 feet (152 meters). The NTL presents requirements for permit application, drilling, and reporting the completion of operations.

**ADDRESS:** Copies of the proposed NTL may be obtained between the hours of 7:30 a.m. and 4:00 p.m. PST, at: California State Office, Bureau of Land Management, 2800 Cottage Way, Rm. E-2727, Sacramento, CA 95825, (916) 484–4515.

**DATE:** Comments must be received at the above address no later than April 15, 1985.

**FOR FURTHER INFORMATION CONTACT:** Douglas Koza, Division of Mineral Resources, (916) 484–4515.

Dated: February 15, 1985.

**Robert M. Anderson,**

*Deputy State Director, Mineral Resources.*

[FR Doc. 85–4399 Filed 2–21–85; 8:45 am]

BILLING CODE 4310–40–M

## Public Meeting on Proposed Transfer of Jurisdiction, Alaska

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** This notice is to inform the public that a meeting will be held to gather comments and suggestions in connection with the proposed transfer of administrative jurisdiction over the Gilmore Creek Tracking Station from the National Aeronautics and Space Administration to the National Oceanic and Atmospheric Administration. The public is welcome to attend the meeting.

**DATE:** The meeting will be held on March 26, 1985, from 6:30 p.m. to 8:30 p.m.

**ADDRESS:** The meeting will be held at the Noel Wien Memorial Library auditorium, 1215 Cowles Street, Fairbanks, Alaska 99701.

**FOR FURTHER INFORMATION CONTACT:** Michael Green, Yukon Resource Area Manager, Bureau of Land Management, Fairbanks District Office, P.O. Box 1150, Fairbanks, Alaska 99707, Tel: (907) 356–5368.

**SUPPLEMENTARY INFORMATION:** On August 14, 1984, the National Oceanic

and Atmospheric Administration filed an application to transfer jurisdiction of the Gilmore Creek Tracking Station from the National Aeronautics and Space Administration. The facility is located 13 miles northeast of Fairbanks on approximately 8,500 acres of public lands. These lands are presently withdrawn and are proposed to remain withdrawn from settlement, sale, location or entry under the general public land laws, including the mining laws, but not from leasing under the mineral leasing laws.

The purpose of the withdrawal is for continued use of the Spaceflight Tracking and Data Network Station in support of weather satellites and other programs. The natural terrain features of the withdrawn lands contribute to a "quiet" radio environment, relatively free of man-made sources of radio frequency interference which cause degradation of data received from satellites. The lands have been used for this purpose since 1965.

A Notice of Proposed Transfer of Jurisdiction was published in the November 9, 1984 issue of the **Federal Register** as FR Doc. 84-29547 on page 44815. Written comments, suggestions or objections in connection with the proposed transfer were sought for a period of 90 days from the date of publication.

Notice is hereby given that a public meeting will be held in connection with the proposed transfer at the time and place stated above. The public will have the opportunity to express any comments during the meeting. Written comments will continue to be accepted through April 15, 1985, at the Fairbanks District Office. All commments will become part of the permanent record pertaining to the proposed transfer.

The application is being processed in accordance with the regulations set forth in 43 CFR Part 2300.

**Donald E. Runberg,**

*Acting District Manager.*

[FR Doc. 85-4424 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-JA-M

## Shoshone District Advisory Council and Grazing Advisory Board; Joint Meeting

**AGENCY:** Bureau of Land Management (BLM), Interior.

**ACTION:** Notice of Meeting.

**SUMMARY:** This notice sets forth the schedule and proposed agenda for a joint meeting of the Shoshone District Advisory Council and Grazing Advisory Board.

**DATE:** Wednesday, March 20, 1985 at 1:30 p.m.

**ADDRESS:** BLM District Office, 400 West F Street, Shoshone, Idaho 83352.

**FOR FURTHER INFORMATION CONTACT:** Jon Idso, ADM for Resources, Shoshone District Office, P.O. Box 2B, Shoshone, Idaho 83352. Telephone (208) 886-2206 or FTS 554-6576.

**SUPPLEMENTARY INFORMATION:** The proposed agenda for the meeting includes the following items:

Monument RMP Update
Grazing Fee Study
BLM/Forest Service Interchange

The Shoshone District Advisory Council is established under Section 309 of the Federal Land Policy and Management Act of 1976 (Pub. L. 94-579; 43 U.S.C. 1701 et seq.) as amended. The Shoshone District Grazing Advisory Board is established under section 403 of the Federal Land Policy and Management Act, as amended. Operation and administration of the Council and Board will be in accord with the Federal Advisory Committee Act of 1972 (Pub. L. 92-463; 5 U.S.C. Appendix 1) and Department of Interior regulations, including 43 CFR Part 1784.

The meeting will be open to the public. Anyone may present an oral statement between 2:00 and 3:00 p.m. or may file a written statement regarding matters on the agenda. Oral statements will be limited to ten minutes. Anyone wishing to make an oral statement should notify the Shoshone District Manager by March 19, 1985. Records of the meeting will be available in the Shoshone District Office for public insection or copying within 30 days after the meeting.

**Charles J. Haszier,**

*District Manager.*

[FR Doc. 85-4329 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-GG-M

## Casper District Office, Wyoming; Casper District Grazing Advisory Board, Meeting

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** District Grazing Advisory Board Meeting.

**SUMMARY:** The Casper District Grazing Advisory Board will meet at 10:00 a.m. on March 26, 1985. The agenda will include election of a chairman, discussion of range improvement projects, the Forest Service/BLM Interchange, cooperative management agreements, and brief reports on the status of land use planning in the Buffalo and Platte River Resource areas.

**DATE:** March 26, 1985; 10:00 a.m.

**ADDRESS:** To request summary minutes or time on the agenda, contact: Bureau of Land Management, Casper District Office, 951 North Poplar, Casper, WY 82601.

**SUPPLEMENTARY INFORMATION:** This meeting is held in accordance with Pub. L. 92-463 and 94-579. The meeting is open to the public. Time will be available for public statements to the Board. Interested persons may testify or submit written statements for Board consideration. Anyone wishing to make an oral statement should notify the district manager by March 26, 1985. Depending on the number of persons wishing to make statements, a per person time limit may be imposed by the district manager.

Summary minutes of the Board meeting will be maintained in the district office and be available for public inspection within 30 days following the meeting.

**FOR FURTHER INFORMATION CONTACT:** Runore Wycoff, (307) 261-5557.

Dated: February 13, 1985.

**James W. Monroe,**

*District Manager.*

[FR Doc. 85-4371 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-84-M

## Prineville District Grazing Advisory Board and Prineville District Advisory Council; Meeting

Notice is hereby given in accordance with Pub. L. 92-463 of a meeting of the Prineville District Grazing Advisory Board and Advisory Council to be held March 19, 1985.

The meeting will take place at 10:00 a.m. in the conference room of the Bureau of Land Management office located at 185 East 4th Street, P.O. Box 550, Prineville, OR 97754.

The agenda will center on the following information items:

1. BLM/USFS Interchange Program.
2. Grazing Fee Study.
3. Stewardship Program.

The meeting is open to the public. Anyone wishing to attend and/or make written or oral statements to the board is requested to contact the District Manager at the above address prior to March 12, 1985.

Summary minutes of the meeting will be available for review and

reproduction within 30 days following the meeting.

James L. Hancock,
*Associate District Manager.*
February 12, 1985.

[FR Doc. 85-4326 Filed 2-21-85; 8:45 am]
BILLING CODE 4310-33-M

## Shoshone District Grazing Advisory Board; Meeting

**AGENCY:** Bureau of Land Management (BLM), Interior.

**ACTION:** Notice of Meeting.

**SUMMARY:** This notice sets forth the schedule and proposed agenda for a meeting of the Shoshone District Grazing Advisory Board.

**DATE:** Thursday, March 21, 1985 at 9:30 a.m.

**ADDRESS:** BLM District Office, 400 West F Street, Shoshone, Idaho 83352.

**FOR FURTHER INFORMATION CONTACT:** Jon Idso, ADM for Resources, Shoshone District Office, P.O. Box 2B, Shoshone, Idaho 83352. Telephone (208) 886-2206 or FTS 554-6576.

**SUPPLEMENTARY INFORMATION:** The proposed agenda for the meeting includes the following items:

Election of Officers
Disbursement of Advisory Board Funds
Financial Report
Update on Weed Control Program

The Shoshone District Grazing Advisory Board is established under section 403 of the Federal Land Policy and Management Act of 1976 (Pub. L. 94-579; 43 U.S.C. 1701 et seq.) as amended. Operation and administration of the Board will be in accord with the Federal Advisory Committee Act of 1972 (Pub. L. 92-463; 5 U.S.C. Appendix 1) and Department of Interior regulations, including 43 CFR Part 1784.

The meeting will be open to the public. Anyone may present an oral statement between 1:00 and 2:00 p.m. or may file a written statement regarding matters on the agenda. Oral statements will be limited to ten minutes. Anyone wishing to make an oral statement should notify the Shoshone District Manager by March 20, 1985. Records of the meeting will be available in the Shoshone District Office for public inspection or copying within 30 days after the meeting.

Charles J. Haszier,
*District Manager.*

[FR Doc. 85-4330 Filed 2-21-85; 8:45 am]
BILLING CODE 4310-GG-M

[C-38371-A]

## Colorado; Notice of Realty Action—Sale of Public Land in Gunnison County

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Realty Action C-38371-A. Sale of public land in Gunnison County, Colorado.

**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 appraised fair market value of $24,000.

New Mexico Principal Meridian, Colorado
T. 48 N. R. 4 W
Sec. 6, lot 18 and SE¼SW¼.
Containing 80.00 acres.

The lands described are hereby segregated from appropriation under the public land laws, including the mining laws, pending disposition of this action.

This sale is consistent with the Bureau's Land Use Plan for the area. Further, the lands are difficult and uneconomic to manage by this or any other Federal agency.

### Bidding

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 of the United States. Bids may be made by a principal (the one desiring to purchase the land) or his duly qualified agent. Each bid must be for all the land in a specified parcel.

### Method of Bidding

Bidding will be sealed bid only. To be considered, bids must be received in the Montrose District Office, on or before 10:00 a.m. the day of the sale. Bids accompanied by a certified check, postal money order, bank draft, or cashier's check made payable to the "Department of the Interior—Bureau of Land Management" for not less than one-fifth (20%) of the amount of the bid, must be in a separate sealed envelope within the transmittal envelope. The sealed envelope must be marked in the lower left-hand corner "Sealed Bid, Public Land Sale, C-38371-A, sale to be May 15, 1985." All sealed bids will be opened at 1:00 p.m. on the day of the sale. If two or more envelopes are received containing valid bids of the same amount for the same parcel, the successful bid shall be determined by drawing. The successful high bidder will be required to submit the remainder of the bid price in cash, by certified check, bank draft, money order, or any combination of these within 180 days after the determination of the highest bid.

### Sale Continuation

If the parcel does not sell at the May 15, 1985, sale the parcel will be offered the second Wednesday of every month beginning on June 12, 1985, and continuing until the parcel is sold or withdrawn.

### Mineral Estate Disposition

This parcel has been determined to be without mineral value. Accordingly, the successful high bidder will be required to file a mineral conveyance application with the Montrose District Manager simultaneously with the final payment of the purchase price for the parcel. The mineral conveyance application must be accompanied by a $50.00 fee.

### Post Sale Instructions

If the final purchase price payment and the mineral conveyance application and $50.00 fee are not received within the specified 180 days, the high bid will be rejected, the deposit will be forfeited, and the land will be offered to the second highest bidder, subject to the same terms and conditions. All unsuccessful sealed bids will be returned within 30 days of the sale.

The BLM may accept or reject any and all offers, or withdraw any land or interest in land from sale if, in the opinion of the authorized officer, consummation of the sale would not be fully consistent with FLPMA or other applicable laws.

The patent issued for this land will contain a reservation to the United States of rights-of-way for the construction of ditches and canals (26 Stat. 391; 43 U.S.C. 945), and be subject to valid existing rights.

Detailed information regarding this sale, including the planning documents and Environmental Assessment, is available for review in the Montrose District Office.

**DATE:** For a period of 45 days from the date of the publication of this Notice in the **Federal Register**, interested parties may submit comments to the District Manager, Montrose District Office.

**ADDRESS:** Comments should be sent to: Montrose District Manager, Bureau of Land Management, 2465 South Townsend, Montrose, Colorado 81401.

Any adverse comments will be evaluated by the District Manager, who may vacate or modify this Realty Action and issue a final determination. In the absence of any action by the District

Manager, this Realty Action will become the final determination of the Department of the Interior.

Paul W. Arrasmith,

*Montrose District Manager.*

February 14, 1985.

[FR Doc. 85-4397 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-JB-M

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[Group 649]

## California; Filing of Plat of Survey

February 12, 1985.

1. This plat of survey of the following descibed land will be officially filed in the California State Officer, Sacramento, California, effective 7:30 a.m. on April 9, 1985.

Mount Diablo Meridian, Modoc County

T. 41 N., R. 17 E.

2. This plat representing the dependent resurvey of a portion of the Eighth Standard Parallel North, north boundary and subdivisonal lines, the survey of a portion of the north boundary and subdivisional lines, and the meander line of Middle Alkali Lake in section 16, Township 41 North, Range 17 East, Mount Diablo Meridian, California, under Group No. 649, California, was accepted December 31, 1984.

3. The plat will at and after 7:30 a.m. for the above date, become the basic record for describing the land for all authorized purposes. Until this date and time, the plat has been placed in the open files and is available to the public for information only.

4. This plat was executed to meet certain administrative needs of the Bureau of Land Management.

5. All inquiries relating to this land should be sent to the California State Office, Bureau of Land Management, Federal Office Building, 2800 Cottage Way, Room E-2841, Sacramento, California 95825.

Herman J. Lyttge,

*Chief, Records and Information Section.*

[FR Doc. 85-4401 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-40-M

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[Group 908]

## California; Filing of Plat of Survey

February 12, 1985.

1. These plats of survey of the following described land will be officially filed in the California State Office, Sacramento, California, immediately:

San Bernardino Meridian, San Bernardino County

T. 9 N., R. 22 E.
T. 10 N., R. 22 E.

2. These plats, representing the dependent resurvey of a portion of the subdivisional lines, and the metes-and-bounds survey of Lot 5, in section 2, Township 9 North, Range 22 East, and the metes-and-bounds survey of Lots 8 and 10, and the survey of the Right-of-Way Access Road to Lot 10, in section 35, Township 10 North, Range 22 East, San Bernardino Meridian, California, under Group No. 908, California, were accepted January 17, 1985.

3. These plats will immediately become the basic record for describing the land for all authorized purposes. These plats have been placed in the open files and are available to the public for information only.

4. These plats were executed to meet certain administrative needs of the Bureau of Land Management.

5. All inquiries relating to this land should be sent to the California State Office, Bureau of Land Management, Federal Office Building, 2800 Cottage Way, Room E-2841, Sacramento, California 95825.

Herman J. Lyttge,

*Chief, Records and Information Section.*

[FR Doc. 85-4402 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-40-M

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[Group 767]

## California; Filing of Plat of Survey

February 12, 1985.

1. These plats of survey of the following described land will be officially filed in the California State Office, Sacramento, California, effective 7:30 a.m. on April 9, 1985:

Humboldt Meridian, Humboldt County

T. 1 S., R. 5 E.
T. 2 S., R. 5 E.

2. These plats representing the dependent resurvey of a portion of the subdivisional lines, the survey to complete sections 11, 14, 23, and 24, and the survey of the subdivision of section 3, 11, 23, and 24, T. 2 S., R. 5 E. Humboldt Meridian; and the dependent resurvey of a portion of the south boundary and a portion of the subdivisional lines, the survey to complete sections 23 and 26, and the survey of the subdivision of sections 22, 23, 26, 27, 34, and 35, T. 1 S., R. 5 E., Humboldt Meridian, under Group No. 767, California, were accepted December 18, 1984.

3. These plats will at and after 7:30 a.m. of the above date, become the basic record for describing the land for all authorized purposes. Until this date and time, the plats have been placed in the open files and are available to the public for information only.

4. These plats were executed to meet certain administrative needs of the U.S. Forest Service and the Bureau of Land Management.

5. All inquiries relating to this land should be sent to the California State Office, Bureau of Land Management, Federal Office Building, 2800 Cottage Way, Room E-2841, Sacramento, California 95825.

Herman J. Lyttge,

*Chief, Records & Information Section.*

[FR. Doc. 85-4403 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-40-M

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[Group 817]

## California; Filing of Plat of Survey

February 12, 1985.

1. This plat of survey of the following described land will be officially filed in the California State Office, Sacramento, California, effective 7:30 a.m. on April 9, 1985:

Mount Diablo Meridian, Trinity County

T. 34 N., R. 10 W.

2. This plat representing the retracement of portions of the south boundary and subdivisional lines, and the dependent resurvey of a portion of the subdivisional lines, and the survey of a portion of the subdivisional lines, the subdivision of sections 13 and 33, and the metes-and-bounds survey of Tract 39, Township 34 North, Range 10 West, Mount Diablo Meridian, California under Group 817, California, was accepted January 9, 1985.

3. This plat will at and after 7:30 a.m. of the above date, become the basic record for describing the land for all authorized purposes. Until this date and time, the plat has been placed in the open files and is available to the public for information only.

4. This plat was executed to meet certain administrative needs of the U.S. Forest Service, The Southern Pacific Land Company, and the Bureau of Land Management.

5. All inquiries relating to this land should be sent to the California State Office, Bureau of Land Management, Federal Office Building, 2800 Cottage Way, Room E-2841, Sacramento, California 95825.

Herman J. Lyttge,

*Chief, Records & Information Section.*

[FR Doc. 85-4404 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-40-M

[Group 841]

## California; Filing of Plat of Survey

February 12, 1985.

1. This plat of survey of the following described land will be officially filed in the California State Office, Sacramento, California, immediately:

**Mount Diablo Meridian, Mendocino County**

T. 23 N., R. 13 W.

2. This plat, representing the dependent resurvey of portions of the east and north boundaries, subdivisional lines, and the subdivision of section 24, and the survey of the subdivision-of-sections, 2, 11, 13, and 24, and the survey of the center line of Mina Road through certain Indian lands, Township 23 North, Range 13 West, Mount Diablo Meridian, California, under Group No. 841, California, was accepted January 9, 1985.

3. This plat will immediately become the basic record for describing the land for all authorized purposes. This plat has been placed in the open files and is available to the public for information only.

4. This plat was executed to meet certain administrative needs of the Bureau of Indian Affairs and the Bureau of Land Management.

5. All inquiries relating to this land should be sent to the California State Office, Bureau of Land Management, Federal Office Building, 2800 Cottage Way, Room E-2841, Sacramento, California 95825.

**Herman J. Lyttge,**

*Chief, Records & Information Section.*

[FR Doc. 85-4405 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-40-M

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[W-83358]

## Proposed Continuation of Withdrawal; Wyoming

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** The Bureau of Land Management proposes that the existing withdrawals of 295,313 acres for Stock Driveway purposes continue for an additional 20 years. Although the lands are to remain open to mineral location, any claims initiated are subject to special regulations found in 43 CFR 3815. The lands have been and will remain open to mineral leasing.

**DATE:** Comments should be received by May 23, 1985.

**ADDRESS:** Comments should be sent to: Chief, Branch of Land Resources, Bureau of Land Management, P.O. Box 1828, Cheyenne, Wyoming 82003.

**FOR FURTHER INFORMATION CONTACT:** Scott Gilmer, Wyoming State Office, 307-772-2089.

The Bureau of Land Management proposes to continue the existing withdrawals of the following public lands for a 20 year period pursuant to Section 204 of the Federal Land Policy and Management Act of October 21, 1976, 90 Stat. 2751, 43 U.S.C. 1714. The lands were withdrawn by the following orders: Secretarial Orders of May 24, and June 20, 1918, July 15, and August 21, 1919, March 18, 1920, December 21, 1925, June 14, 1926, January 28, 1927, July 18, 1929, and June 21, 1939. The above orders will be continued insofar as they affect the following described lands:

**Sixth Principal Meridian**

T. 23 N., R. 73 W.,
Sec. 20, S½NW¼, N½SW¼.
T. 22 N., R. 74W.,
Sec. 18, lots 2, 3, SE¼NW¼, NE¼SW¼.
T. 25 N., 4. 74W.,
Sec. 30, E½NE¼.
T. 22 N., R. 75 W.,
Sec. 28, NW¼NE¼, NE¼NW¼.
T. 23 N., R. 75 W.,
Sec. 2, S½SW¼;
Sec. 28, W½NE¼.
T. 21 N., R. 76 W.,
Sec. 12, E½NE¼.
T. 15 N., R. 87 W.,
Sec. 6, lots 6, 7;
Sec. 7, lots 1-4, SE¼NW¼, E½SW¼;
Sec. 18, lots 1-4, E½NW½, NE¼SW¼.
T. 21 N., R. 87 W.,
Sec. 30, lots 1-4, NW¼NE¼, NE¼NW¼, SE¼SW¼;
Sec. 32.
T. 22 N., 87 W.,
Sec. 18, lots 3, 4;
Sec. 30.
T. 13 N., R. 88 W.,
Sec. 7, lots 5, 6, NE¼, E½NW¼, NE¼SE¼.
T. 15 N., R., 88 W.,
Sec. 1, lots 5-10, 15, 16, SW¼NE¼, S½NW¼, NW¼SE¼;
Sec. 2, lots 5-8, S½N½
Sec. 12, lots 1, 2, 5, 6, 7, 11, 12, NW¼ SE¼;
Sec. 13, lots 1, 2, 4, 5, 6, 8, W½SE¼.
T. 16 N., R. 88 W.,
Secs. 4, 9, 10, 11, 14;
Sec. 23, lots 1-7, NE¼NW¼, SE¼NE¼, N½NW¼, S½S½, NE¼SE¼;
Sec. 26, lots 4, 5, NE¼NE¼, S½SE¼;
Sec. 35.
T. 17 N., R. 88 W.,
Sec. 5, S½N½, S½
Sec. 6, N½, E½SW¼, SE¼;
Sec. 17;
Sec. 20, W½E½, W½;
Sec. 29;
Sec. 31, lots 3, 4, E½SW¼, SE¼;
Sec. 32;
Sec. 33, S½.
T. 18 N., R. 88 W.,
Sec. 10, W½;
Sec. 20, 28, 32.
T. 19 N., R. 88 W.,
Secs. 2, 14, 22, 26.
T. 20 N., R. 88 W.,
Secs. 2, 14, 26, 34.
T. 21 N., R. 88 W.,
Sec. 18, lot 4, SE¼SW¼, S½SE¼;
Sec. 20, S½S½NE¼NE¼, S½NW¼, NW¼NE¼, S½NW¼NE¼, S½NE¼, NW¼, S½;
Sec. 22, N½NE¼NE¼SE¼, S½N½S½, S½N½S½, S½s½;
Sec. 24, lots 50, 51, S½SW¼, SE¼;
Sec. 26.
T. 22 N., R. 88 W.,
Sec. 2, lots 2, 3, 4, SW¼NE¼, S½NW¼, S½;
Sec. 12, NW¼NW¼, S½NW¼, SW¼, SW¼SE¼;
Sec. 24, N½N½, SE¼NE½, SW¼, NE¼SE¼, S½SE¼.
T. 23 N., R. 88 W.,
Sec. 6;
Sec. 8, W½E½, W½;
Sec. 18;
Sec. 20, NE¼NE¼, S½NE¼, SE¼NW¼, S½;
Sec. 28, 34.
T. 13 N., R. 89 W.,
Sec. 2, SW¼;
Sec. 3;
Sec. 4, lots 1-3, S½N½, S½;
Sec. 5, lots 1-4, S½N½;
Sec. 6, lots 2-5, SE¼NW¼;
Sec. 10, NE¼;
Sec. 11, NW¼;
Sec. 12, N½.
T. 14 N., R. 89 W.,
Sec. 31, lot 8;
Sec. 32, lots 3, 4.
T. 15 N., R. 89 W.,
Sec. 4, lot 8; SW ¼NW¼;
Sec. 5, lots 5, 6, S½NE¼.
T. 16 N., R. 89 W.,
Sec. 1, lots 11-14;
Sec. 2, lots 11,18, 19, E½SE¼;
Sec. 10, lots 1, 4, 5, 8, E½E½;
Sec. 11, N½N½;
Sec. 14, SW¼SW¼;
Sec. 15, lots 1, 2, W½NE¼; SE¼;
Sec. 23, W½W½;
Sec. 26, W½NW¼;
Sec. 27, lots 1-4, S½N½;
Sec. 28, lots 1-4, S½N½, W½SW¼;
Sec. 29, N½NE¼;
Sec. 33, W½W½.
T. 21 N., R. 89 W.,
Sec. 22, S½SE¼NE¼NE¼, SE¼NE¼, S½NE¼SW¼NE¼, S½N½SW¼NE¼, S½SW¼NE¼, S½S½SW¼NW¼, S½SE¼, S½;
Secs. 24, 26;
Sec. 28, N½, E½SW¼, SE¼;
Sec. 30, SE¼NW¼, S½NE¼ and S½ of lot 2, lots 3, 4, S½NE¼NE¼, S½S½N W¼NE¼, S½NE¼, SE¼NW¼, E½SW¼, SE¼.
T. 23 N., R. 89 W.,
Secs. 2, 12.
T. 24 N., R. 89 W.,
Secs. 8, 18, 22, 26, 28, 34.
T. 39 N., R. 89 W.,
Sec. 5, lots 1-4, S½N½;
Sec. 6, lots 2-7, S½NE¼, SE¼NW¼, E½SW¼;
Sec. 7, lots 1, 2, E½NW¼.
T. 40 N., R. 89 W.,
Sec. 21, E½NE¼, SE¼;

Sec. 28, E½;
Sec. 32, lots 1, 2, NE¼, S½SE¼;
Sec. 33, N½;
T. 13 N., R. 90 W.,
Sec. 1, lots 5–8, S½N½;
Secs. 2, 3, 4, 5, 6:
Tract 36.
T. 14 N., R. 90 W.,
Sec. 26, S½NE¼, S½;
Sec. 35.
T. 15 N., R. 90 W.,
Sec. 11, S½SE¼;
Sec. 14, NW¼NE¼, NE¼NW¼, S½NW¼;
Sec. 26, NW¼NW¼;
Sec. 27, N½N½;
Sec. 28, N½NE¼, NE¼NW¼, W½SW¼;
Sec. 29, 30.
T. 20 N., R. 90 W.,
Secs. 4, 6.
T. 21 N., R. 90 W.,
Sec. 26, S½SW¼SW¼SW¼, SE¼SW¼SW¼, S½NE¼SE¼SW¼, S½SE¼SW¼, SE¼NE¼SE¼, NE¼SW¼SE¼, S½NW¼SW¼SE¼, S½SW¼SE¼, SE¼SE¼;
Sec. 32, S½N½SW¼, S½N½SW¼, S¼SW¼, SE¼;
Sec. 34.
T. 24 N., R. 90 W.,
Secs. 3, 4, 5, 6.
T. 25 N., R. 90 W.,
Secs. 30, 31, 32.
T. 37 N., R. 90 W.,
Secs. 6, 7.
T. 38 N., R. 90 W.,
Sec. 6, lots 1–7, S½NE¼, SE¼NW¼, NE¼SW¼, N½SE¼;
Sec. 7, lots 1, 2, and lot 5 less 7.08 acres;
Sec. 31, E½.
T. 39 N., R. 90 W.,
Sec. 12, E½;
Sec. 13, N½, SW¼;
Sec. 14, E½;
Sec. 21, S½SE¼;
Sec. 22, E½, NE¼SW¼, S½SW¼;
Sec. 23, W½NE¼, NW¼, NW¼SW¼, N½SW¼SW¼, SW¼SW¼SW¼, N½SE¼SW¼SW¼, SW¼SE¼SW¼SW¼;
Sec. 27, N½, SW¼, N½SE¼, SW¼SE¼;
Sec. 28, NE¼, S½NW¼, S½;
Sec. 29, S½;
Sec. 30, NE¼SE¼, S½SE¼;
Sec. 31, E½, E½W½;
Sec. 32;
Sec. 33, N½N½;
Sec. 34, NW¼NE¼, N½NW¼.
T. 13 N., R. 91 W.,
Secs. 1, 2, 3;
Sec. 4, N½NE¼, SE¼NE¼, SW¼NW¼, SW¼, NE¼SE¼;
Sec. 5;
Sec. 6, W½;
Sec. 9, E½W½;
Sec. 15, SW¼NW¼, W½SW¼, SE¼SW¼;
Sec. 21, E½;
Sec. 22, NW¼NW¼.
T. 14 N., R. 91 W.,
Sec. 6, lots 1, 8, 9, S½NE¼, SW¼NW¼, NW¼SW¼, SE¼;
Sec. 7, E½, SW¼NW¼, W½SE¼;
Sec. 18, E½NE¼, E½W½;
Sec. 19, E½NE¼, E½W½, SW¼SE¼;
Sec. 29, E½, E½NW¼, SW¼SW¼;
Sec. 30, NW¼NE¼, S½NE¼, SE¼;
Sec. 32, NE¼NE¼, W½, W½SE¼;
Sec. 33, N½, N½SW¼, SE¼SW¼, SE¼.
T. 15 N., R. 91 W.,
Secs. 5, 6;
Sec. 7, N½NE¼, SE¼NE¼, NE¼NW¼, S½;
Secs. 8, 9, 10, 14, 15, 18, 19, 23, 24, 25, 30;
Sec. 31, N½, N½SW¼, SW¼SW¼, SE¼.
T. 16 N., R. 91 W.,
Sec. 14, E½SW¼;
Sec. 27, SW¼;
Sec. 28, NW¼NE¼, S½;
Sec. 29, S½;
Sec. 32.
T. 20 N., R. 91 W.,
Secs. 2, 4;
Sec. 6, S½ of SE¼SE¼NE¼ of lot 1, S½ of lot 5, lot 6, S½NE¼SW¼, SE¼SW¼, NE¼SE¼, NE¼NW¼SE¼, S½NW¼NW¼SE¼, S½NW¼SE¼, S½SE¼;
Secs. 8, 10, 12.
T. 25 N., R. 91 W.,
Secs. 3, 10, 14, 15;
Sec. 23, lots 1–15;
Secs. 25, 26.
T. 26 N., R. 91 W.,
Secs. 5, 8, 17, 20, 21, 28, 33, 34.
T. 33 N., R. 91 W.,
Sec. 3, lots 2–4, S½N½, SW¼, NW¼SE¼;
Sec. 10, E½NE¼, NW¼.
T. 34 N., R. 91 W.,
Sec. 3, lots 3, 4, S½NW¼, SW¼;
Sec. 10, W½;
Secs. 15, 22, 27;
Sec. 34, NE¼NE¼, W½E½, W½.
T. 35 N., R. 91 W.,
Secs. 5, 8;
Sec. 17, NE¼, N½NW¼, SW¼, N½SE¼, SW¼SE¼;
Sec. 20, NW¼,NE¼S½NE¼, W½, SE¼;
Sec. 28, W½;
Secs. 29, 33;
Sec. 34, E½E½, NW¼NE¼, SW¼NW¼, W½SW¼.
T. 36 N., R. 91 W.,
Secs. 4, 5, 8, 17, 20, 29, 32.
T. 37 N., R. 91 W.,
Secs. 12, 13, 14;
Sec. 23, N½N½, SW¼NW¼;
Sec. 24, lots 1–4, W½E½, N½NW¼;
Sec. 26, SW¼NW¼, S½;
Secs. 34, 35.
T. 38 N., R. 91 W.,
Sec. 1, SE¼NE¼, S½SW¼, SE¼;
Sec. 12, NE¼, N½NW¼, SE¼NW¼.
T. 13 N., R. 92 W.,
Secs. 1, 2, 8–11, 17, 19, 20.
T. 14 N., R. 92 W.,
Sec. 1, lots 5, 6, S½NE¼, SE¼;
Sec. 12, E½;
Sec. 13, E½.
T. 15 N., R. 92 W.,
Sec. 1, lots 5–8, S½N½, SW¼, NE¼SE¼;
Sec. 2;
Sec. 3, lots 5–8, SE¼NE¼, NW¼SW¼, S½S½; NE¼SE¼;
Sec. 4, lots 5–8, SW¼NE¼, S½NW¼, S½;
Secs. 5, 6;
Sec. 12, W½SE¼;
Sec. 13, lots 1–4, SE¼;
Sec. 24, E½;
Sec. 25, E½.
T. 16 N., R. 92 W.,
Sec. 7, lots 5, 6, 7–10, W½E½, E½W½;
Secs. 18, 19, 29, 30;
Sec. 31, E½;
Sec. 32.
T. 20 N., R. 92 W.,
Secs. 2, 4, 8, 10, 12, 18.
T. 13 N., R. 93 W.,
Secs. 19–24.
T. 15 N., R. 93 W.,
Secs. 1, 2;
Sec. 3, lots 1, 4, SE¼NE¼, S½NW¼, SW¼, NE¼SE¼, S½SE¼;
Sec. 4, lots 1–4, S½N½, N½SW¼, SW¼SW¼, SE¼;
Secs. 5, 6.
T. 16 N., R. 93 W.,
Secs. 1, 2, 12, 13, 24.
T. 17 N., R. 93 W.,
Secs. 4, 8, 10, 14, 22, 24, 26, 34.
T. 18 N., R. 93 W.,
Secs. 6, 8, 18, 20, 28, 30, 32, 34.
T. 20 N., R. 93 W.,
Secs. 8, 10, 12, 14, 18.
T. 35 N., R. 93 W.,
Secs. 3, 4, 5, 6;
Sec. 10, N½, SE¼;
Sec. 15, E½E½, NW¼NE¼, SW¼NW¼, SW¼;
Sec. 22, E½NE¼, NW¼, S½;
Sec. 27, N½, N½SE¼, SE¼SE¼.
T. 36 N., R. 93 W.,
Sec. 6, lots 2–6, E½SW¼, W½SE¼, SE¼SE¼;
Secs. 7, 18, 19, 30, 31.
T. 37 N., R. 93 W.,
Secs. 7, 17, 18, 20, 29;
Sec. 32, N½, SW¼, N½SE¼.
T. 13 N., R. 94 W.,
Secs. 19–24.
T. 18 N., R. 94 W.,
Secs. 2, 12.
T. 19 N., R. 94 W.,
Secs. 2, 4, 6, 8, 10, 14, 20, 22, 24, 26, 28, 34.
T. 20 N., R. 94 W.,
Secs. 2, 4, 8, 10, 12, 14, 20;
Sec. 22, E½, E½ W½, NW¼NW¼, E½SW¼NW¼, NE¼NW¼SW¼, S½NW¼SW¼, SW¼SW¼;
Secs. 26, 28, 32;
Sec. 34, NE¼SW¼, S½SE¼NW¼SW¼, S½SW¼.
T. 21 N., R. 94 W.,
Secs. 2, 4, 10, 14, 22, 26, 34.
T. 22 N., R. 94 W.,
Secs. 4, 10, 14, 22, 28, 34.
T. 23 N., R. 94 W.,
Secs. 6, 7, 18, 20, 28, 34.
T. 24 N., R. 94 W.,
Secs. 6, 7, 18, 19, 30, 31.
T. 31 N., R. 94 W.,
Secs. 5, 6.
T. 32 N., R. 94 W.,
Sec. 29, NW¼, S½;
Sec. 32.
T. 37 N., R. 94 W.,
Secs. 2, 3, 11, 12.
T. 38 N., R. 94 W.,
Sec. 34, N½N½, SW¼NW¼, S½;
Sec. 35, NE¼, N½NW¼, SE¼NW¼, S½.
T. 13 N., R. 95 W.,
Sec. 19, lots 2, 4, E½, E½W½;
Secs. 20–24.
T. 19 N., R. 95 W.,
Sec. 2;
Sec. 4, (less 5 A. in patent 1226269).
T. 20 N., R. 95 W.,
Sec. 32, N½, W½SW¼, SE¼SW¼, SE¼;
Sec. 34.

T. 29 N., R. 95 W.,
Secs. 2, 11;
Sec. 12, NE¼, NE¼NW¼, S½NW¼, S½.
T. 30 N., R. 95 W.,
Secs. 5, 7, 8;
Sec. 27, NW¼NW¼, SE¼NE¼NE¼SE¼, S½NE¼SE¼, S½SE¼;
Secs. 29, 30;
Sec. 34, NE¼, NE¼NW¼, S½NW¼, S½;
Sec. 35.
T. 31 N., R. 95 W.,
Secs. 1, 7, 11, 12, 14;
Sec. 17, N½N½, SW¼NW¼, SW¼, NE¼SE¼, S½SE¼;
Secs. 18, 20–23, 29, 32.
T. 13 N., R. 96 W.,
Sec. 19, lots 1–4, N½NE¼, SW¼NE¼, E½W½, SE¼;
Sec. 20, N½, N½SW¼, SW¼SW¼, SE¼;
Secs. 21–24.
T. 19 N., R. 96 W.,
Secs. 4, 6, 8.
T. 20 N., R. 96 W.,
Secs. 32, 34.
T. 29 N., R. 96 W.,
Sec. 6.
T. 30 N., R. 96 W.,
Secs. 12, 13, 21–25, 28, 29;
Sec. 31, lots 1, 2, 4, E½, E½W½;
Sec. 32.
T. 31 N., R. 96 W.,
Secs. 2, 11, 12.
T. 32 N., R. 96 W.,
Secs. 26, 27;
Sec. 28, N½, N½SW¼, SE¼SW¼, SE¼;
Sec. 29, NW¼SW¼;
Secs. 30, 35.
T. 13 N., R. 97 W.,
Sec. 6, lots 1–4, S½NE¼, SE¼NW¼, NE¼SW¼, SE¼;
Sec. 7, E½, E½W½;
Secs. 18–24.
T. 14 N., R. 97 W.,
Sec. 30, lots 3, 4, E½SW¼, SE¼;
Sec. 31, lots 1–4, NE¼, E½NW¼, NW¼SW¼, NE¼SE¼, S½SE¼.
T. 19 N., R. 97 W.,
Secs. 12, 14, 22, 28, 30, 32.
T. 29 N., R. 97 W.,
Secs. 1, 8–12, 17, 18.
T. 32 N., R. 97 W.,
Secs. 4, 9, 10, 15, 22–25.
T. 33 N., R. 97 W.,
Secs. 5, 8, 17, 20, 21, 28, 33, 34.
T. 34 N., R. 97 W.,
Sec. 32.
T. 12 N., R. 98 W.,
Sec. 4, lots 1–4, S½NW¼, SW¼, E½SE¼;
Sec. 9, NE¼NE¼, S½NE¼, W½NW¼, E½SW¼, SE¼.
T. 13 N., R. 98 W.,
Sec. 13, W½NE¼, W½, E½SE¼;
Sec. 24, SW¼NE¼, NW¼, N½SW¼, NE¼SE¼, S½SE¼;
Sec. 25;
Sec. 26, NW¼NE¼, N½NW¼, S½;
Sec. 27, N½, SW¼, NW¼SE¼, SE¼SE¼;
Sec. 33;
Sec. 34, E½E½, W½.
T. 14 N., R. 98 W.,
Secs. 3, 4;
Sec. 10, E½NE¼, W½, SW¼SE¼;
Sec. 15, W½NE¼, W½, NW¼SE¼, SE¼SE¼;
Sec. 22, NE¼NE¼, SW¼NE¼, W½, NW¼SE¼, SE¼SE¼;
Sec. 25, S½;
Sec. 26, S½;
Sec. 27, E½E½, NW¼, W½SW¼, SW¼SE¼.
T. 29 N., R. 98 W.,
Secs. 13, 19, 24;
Sec. 25, NW¼NW¼, S½N½, S½;
Secs. 26, 27;
Sec. 28, lots 1–15;
Secs. 29, 30, 31.
T. 34 N., R. 98 W.,
Secs. 25, 26.
T. 28 N., R. 99 W.,
Sec. 3.
T. 29 N., R. 99 W.,
Secs. 4, 9, 10, 11;
Sec. 12, lots 5–8;
Sec. 13;
Sec. 14, lots 1–7;
Sec. 24.
T. 30 N., R. 99 W.,
Sec. 20, N½, SW¼SW¼, N½SE¼, SE¼SE¼;
Sec. 29, SW¼NE¼, W½, SE¼;
Sec. 32, lots 1, 3, 4, 6–10, E½E½, W½NW¼, SW¼SE¼;
Sec. 33.

The area described aggregates 295,312.81 acres in Albany, Carbon, Fremont, and Sweetwater Counties.

The purpose of the withdrawal is to protect the stock driveways. The withdrawal segregates the land from operation of the public land laws generally, but not the mining and mineral leasing laws. No change is proposed in the purpose or segregative effect of the withdrawal.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments in connection with the proposed withdrawal continuation may present their views in writing to the Chief, Branch of Lands Resources in Wyoming State Office.

The authorized officer of the Bureau of Land Management will undertake such investigations as are necessary to determine the existing and potential demand for the land and its resources. A report will also be prepared for consideration by the Secretary of the Interior, the President, and Congress, who will determine whether or not the withdrawal will be continued and if so, for how long. The final determination on the continuation of the withdrawal will be published in the **Federal Register.** The existing withdrawals will continue until final determination is made.

Dated: February 12, 1985.

**David J. Walter,**

*Acting State Director.*

[FR Doc. 85–4345 Filed 2–21–85; 8:45 am]

BILLING CODE 4310-22-M

## Kingman Resource Area (Phoenix District) Grazing Advisory Board; Meeting

**AGENCY:** Bureau of Land Management, Phoenix District, Interior.

**ACTION:** Notice is hereby given in accordance with Pub. L. 92–463 of a meeting of the Kingman Resource Area (Phoenix District) Grazing Advisory Board.

**DATE:** Tuesday, March 19, 1985 at 9:00 a.m.

**ADDRESS:** 2475 Beverly Avenue, Kingman, Arizona 86041, BLM Conference Room.

**SUMMARY:** The agenda for the meeting will include:.

1. Status of the Bureau's Land Actions.
2. Update of Wilderness Program.
3. Allotment Boundary Adjustments in Subdivision Areas.
4. Recommendation to Adjudicate Grazing Preference—Greenwood Peak Community Peak Allotment.
5. Update on BLM's Programs.

This is a public meeting and BLM welcomes the presentation of oral statements or the submission of written statement that address the issues on the meeting agenda or related matters.

Summary minutes of the Board meeting will be maintained in the District Office and be made available for public inspection and reproduction (during regular business hours) within 30 days following the meeting.

Dated: February 13, 1985.

**Marlyn V. Jones,**

*District Manager.*

[FR Doc. 85–4323 Filed 2–21–85; 8:45 am]

BILLING CODE 4310-32-M

## Phoenix/Lower Gila Areas (Phoenix District) Grazing Advisory Board; Meeting

**AGENCY:** Bureau of Land Management, Phoenix District, Interior.

**ACTION:** Notice is hereby given in accordance with Pub. L. 92–463 of a meeting of the Phoenix/Lower Gila Resource Areas (Phoenix District) Grazing Advisory Board.

**DATE:** Thursday, March 21, 1985 at 9:00 a.m.

**ADDRESS:** 2015 West Deer Valley Road, Phoenix, Arizona 85027, BLM Conference Room.

**SUMMARY:** The agenda for the meeting will include:

1. Status of the Bureau's Land Actions.
2. Status of Lower Gila South Resource Management Plan.

3. Status of Southeastern Arizona Grazing Environmental Impact Statement.

4. Range Improvement Program—FY 1985.

5. Update on BLM's Programs.

This is a public meeting and BLM welcomes the presentation of oral statements or the submission of written statement that address the issues on the meeting agenda or related matters.

Summary minutes of the Board meeting will be maintained in the District Office and be made available for public inspection and reproduction (during regular business hours) within 30 days following the meeting.

Dated: February 13, 1985.

**Marlyn V. Jones,**

*District Manager.*

[FR Doc. 85-4322 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-32-M

## Phoenix District; Meeting

**AGENCY:** Bureau of Land Management, Phoenix District, Interior.

**ACTION:** Notice is hereby given in accordance with Pub. L. 92-195 of a meeting to discuss the removal plan on the Harquahala, Little Harquahala and Granite Wash Herd Management Areas, and the use of helicopters and motorized vehicles when conducting the wild burro capture.

**DATE:** Thursday, March 21, 1985 at 1:00 p.m.

**ADDRESS:** 2015 West Deer Valley Road, Phoenix, Arizona 85027, BLM Conference Room.

**SUPPLEMENTARY INFORMATION:** This is a public meeting and BLM welcomes the presentation of oral statements or the submission of written statements that address the issues on the meeting agenda or related matters.

Summary minutes of the meeting will be available for public inspection and duplication within 30 days following the meeting.

Dated: February 13, 1985.

**Marlyn V. Jones,**

*District Manager.*

[FR Doc. 85-4324 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-32-M

## Yuma District Advisory Council; Meeting

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Yuma (Arizona) District Advisory Council Meeting.

**SUMMARY:** Notice is hereby given in accordance with Pub. L. 94-579 and 43 CFR Part 1780, that a meeting of the Yuma District Advisory Council will be held Friday, March 15, 1985, at 9:00 a.m., in the Conference Room of the District office located at 3150 Winsor Avenue, Yuma, Arizona.

The agenda for the District Advisory Council meeting includes:

1. Resource Management Plan (RMP)—update.
2. Wild burro program—update.
3. Fire Management Program.
4. Long-Term Visitor Area Program—update.
5. District Manager's update.
6. Business from the floor.

The meeting is open to the public. Interested persons may make oral statements to the Council on March 15, or may file written statements for the Council's consideration. Anyone wishing to make an oral statement must notify the District Manager at the above address by March 14. Depending on the number of persons wishing to address the Council, a per person time limit may be considered.

Summary minutes of the District Advisory Council meeting will be maintained in the Yuma District Office and will be available for inspection and reproduction during regular business hours (7:45 a.m.-4:30 p.m.) within 30 days of the meeting.

Dated: February 11, 1985.

**J. Darwin Snell,**

*District Manager.*

[FR Doc. 85-4339 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-32-M

## Winnemucca District Grazing Advisory Board; Meeting

Notice is hereby given in accordance with Pub. L. 92-163 that a meeting of the Winnemucca District Grazing Board will be held on April 4, 1985. The meeting will begin at 10:00 a.m. in the conference room of the Bureau of Land Management Office at 705 East Fourth Street, Winnemucca, Nevada.

The agenda for the meeting will include:

1. Update on Wild Horse and Burro Land Use Plan Implementation.
2. Update on Current Range Improvement (8100) Projects.
3. Preliminary List of next year's Range Improvement (8100) projects.
4. Status Report on Monitoring Plans/Decisions and Allotment Management Plans.
5. Range Improvement Policy-Allotment Investment Ranking, Component No. 2.
6. Possible BLM/Forest Service Boundary Adjustments.
7. BLM/Animal Plant Health Inspection Service (APHIS) Roles' for Grasshopper Control.
8. Payment of Grazing Fee Billings.
9. Range Improvement Priorities as Related to Contributed Funds.
10. Public Comments.
11. Arrangements for next meeting and discussion of agenda items.

Summary minutes of the Board meeting will be maintained in the District Office and available for public inspection (during regular business hours) within 30 days following the meeting.

Dated: February 12, 1985.

**Frank C. Shields,**

*District Manager.*

[FR Doc. 85-4338 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-HC-M

[A-19126]

## Public Lands Exchange; Mohave County, AR

**AGENCY:** Bureau of Land Management (BLM), Interior.

**ACTION:** Notice of Realty Action—Exchange, Public Lands in Mohave County, Arizona.

**SUMMARY:** The following described lands and interests therein have been determined to be suitable for disposal by exchange under Section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716:

**Gila and Salt River Meridian, Arizona**

T. 24 N., R. 12 W.,
Sec. 4, lots 1 thru 4, S½S½.
Containing 296.92 acres, more or less.

In exchange for these lands, the United States will accquire the following described lands from William J. Robinson, of Peach Springs, Arizona.

**Gila and Salt River Meridian, Arizona**

T. 24 N., R. 13 W.,
Sec. 3, SW¼SW¼;
Sec. 7, SE¼NE¼;
Sec. 15, NW¼NW¼;
Sec. 17, NE¼NE¼;
Sec. 29, NW¼SE¼.
T. 24 N., R. 11 W.,
Sec. 25, NW¼NW¼;
Sec. 29, SE¼SE¼.
T. 23 N., R. 12 W.,
Sec. 19, lots 3 and 4;
Sec. 33, NE¼NE¼.
Comprising 398.99 acres, more or less.

The purpose of the exchange is to acquire the non-federal lands that contain critical mule deer habitat in and near the Music Mountains northeast of Kingman, Arizona. The exchange is consistent with the Cerbat Mountain

Management Framework Plan and the public interest will be well served.

The above lands will be subject to an appraisal to determine the value of the lands to be exchanged. The listed lands may change to reflect equal value following the completion of the appraisal.

Lands to be transferred from the United States will be subject to the following reservations:

1. A right-of-way for ditches and canals constructed by the authority of the United States, pursuant to the Act of August 30, 1890 (26 Stat. 391; U.S.C. 945).

2. Reserving to the United States the oil and gas and with it, the right to prospect for, mine and remove the same, subject to such conditions as are or may hereafter be provided by such laws reserving such deposits (30 U.S.C. 121–124).

3. Subject to such rights for telephone and telegraph right-of-way AR–0033346 as provided under the authority of the Act of March 4, 1911 (36 Stat. 1253; 43 U.S.C. 961).

4. Subject to such rights for telephone right-of-way A–9947 as provided under the authority of the Act of October 21, 1976 (90 Stat. 2776; 43 U.S.C. 1761).

Private lands to be acquired by the United States will be subject to the following reservations, terms and conditions:

1. All minerals in the subject are reserved to the Santa Fe Pacific Railroad Company as set forth in Book 73 of Deeds, page 80, and Book 28 of Deeds, page 239, Mohave County, Arizona.

Publication of this Notice will segregate the subject lands from all appropriations under the public land laws, including the mining laws, but not the mineral leasing laws. This segregation will terminate upon the issuance of a patent or two years from the date of this Notice, or upon publication of a Notice of Termination.

Detailed information concerning this exchange can be obtained from the Kingman Resource Area Office, 2475 Beverly Avenue, Kingman, Arizona 86401. For a period of forty-five (45) days from the date of this Notice, interested parties may submit comments to the District Manager, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027. Any adverse comments be evaluated by the District Manager who may vacate or modify this Realty Action, and issue a final determination. In the absence of any action by the District Manager, this Realty Action will become the final determination of the Department of the Interior.

Dated: February 14, 1985.

**Marlyn V. Jones,**

*District Manager.*

[FR Doc. 85–4332 Filed 2–21–85; 8:45 am]

BILLING CODE 4310-32-M

## Realty Action, as Amended Sale of Public Land, Shasta County, CA

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Amendment to notices of realty action, sale of public lands.

**SUMMARY:** This action amends notices of Realty Action proposing the sale of certain parcels of public land administered by the Redding Resource Area, originally published in the **Federal Register**, on September 22, 1983 (48 FR 185, page 43225) and April 10, 1984 (49 FR 70, page 14207). Twenty-five parcels remain available for sale. The current fair market value, sale methodology, segregative effect, and patent reservations are described herein.

The following described lands will be offered for sale, by sealed bid only, at 10:00 a.m. on May 1, 1985, and on subsequent first Wednesdays of each month at 10:00 a.m. until the parcels have been sold or the segregation expires.

The sealed bids bill be opened at 10:00 a.m. on the day of sale at the Redding Resource Area Office, Bureau of Land Management, 355 Hemsted Drive, Redding, California 96002. Sealed bids shall be considered only if received at the above address prior to 10:00 a.m. on the date of sale.

Each sealed bid shall be accompanied by certified check, postal money order, bank draft or cashier's check made payable to the Department of Interior—BLM, for not less than one-fifth of the bid. The sealed bid envelopes must be marked on the front left corner "Redding Resource Area, Shasta Land Sale, Parcel Number ———."

If 2 or more envelopes containing valid bids of the same amount are received, the determination of which is to be considered the highest bid shall be by supplemental biddings. The designated high bidders shall be allowed to submit oral or sealed bids as designated by the authorized officer. Interested parties and the public in general may attend the sealed bid sales to be held at the above referenced time and place.

A bid on parcels determined to contain "no known mineral value" will also constitute an application for conveyance of those mineral interests offered for conveyance in the sale. The declared high bidder will be required to deposit a $50.00 non-refundable filing fee (43 CFR 2720.1–2(c)), and the mineral estate will be sold simultaneously with the surface estate.

The successful bidder shall submit the remainder of the full bid price prior to the expiration of 180 days from the date of sale.

Upon publication of this Notice of Realty Action in the **Federal Register**, the subject public lands shall be segregated to the extent that they will not be subject to appropriation under the public land laws, including the mining laws. The segregtive effect shall terminate upon issuance of patent, upon publication in the **Federal Register** of a termination of the segregation or 270 days from the date of publication, whichever occurs first.

All other terms and conditions cited in the previously published Notice of Realty Action, and amendment remain in effect. All patents issued will be subject to prior existing rights.

Detailed information regarding these actions may be obtained from the Redding Resource Area Office, 355 Hemsted Drive, Redding, California 96002.

ENCUMBRANCES

| Case No | Acres | Fair market value | R-O-W | Mineral | Oil and gas lease | Powersite | Wetland/Riparian |
|---|---|---|---|---|---|---|---|
| CA 14247 | 40 | $12,600 | A-1 | B | | | |
| CA 14248 | 43.79 | 75,000 | A-1, and A-3 | B | C | | |
| CA 14249 | 40 | 40,500 | A-1, and A-6 | B | C | | |
| CA 14250 | 40 | 43,000 | A-1 | B | | | |
| CA 14251 | 40 | 36,000 | A-1 | B | C | E-2 | |
| CA 14252 | 80 | 62,000 | A-1 | B | C | | |
| CA 14253 | 40 | 30,000 | A-1 | B | C | | |
| CA 14254 | 40 | 36,000 | A-1 | B | C | | D-1 |
| CA 14255 | 40 | 36,800 | A-1 | B | C | | D-2 |
| CA 14256 | 60.60 | 58,500 | A-1, and A-3 | B | C | E-2 | |
| CA 14257 | 40.70 | 44,500 | A-1 | B | C | | D-3 |
| CA 14258 | 40 | 22,000 | A-1 | B | | | |
| CA 14260 | 40 | 26,500 | A-1, A-3,[1] and A-6 | B | | | |
| CA 14261 | 160 | 22,000 | A-1 | B | C | | |
| CA 14269(a) | 4.56 | 23,500 | A-1, A-3[1] | B | | | |
| CA 14269(b) | 22.67 | 39,710 | A-1, A-3,[1] and A-6[1] | B | | | |
| CA 14270(a) | 0.47 | 735 | A-1 | B | | | |
| CA 14271 | 0.08 | 100 | A-1 | B | | | |
| CA 14272 | 0.01 | 100 | A-1 | B | | | |
| CA 14273 | 5 | 26,000 | A-1, and A-3 | B | | | |
| CA 14274 | 7.5 | 59,000 | A-1, A-3,[1] and A-6 | B | | | |
| CA 14278 | 17.31 | 26,000 | A-1 | B | | | |
| CA 14282 | 14.74 | 1,500 | A-1 | B | | | |
| CA 14283 | 24.59 | 2,500 | A-1 | B | | | |
| CA 14285 | 10 | 14,500 | A-1 | B | | | |

[1] Indicates more than one (1) right-of-way

**Patent Reservations**

A–1. Excepting and reserving to the United States from the land so granted a right-of-way thereon for ditches or canals constructed by the authority of the United States. Act of August 30, 1890, 26 Stat. 391, 43 U.S.C. 945.

A–3. Subject to a right-of-way not exceeding . . . feet in width, for roadway and public utility purposes, to be located . . .

A–6. Subject to that (right-of-way) and all appurtenances thereto, constructed by the United States through, over, or upon the land herein described and the right of the United States, its agents or employees, to maintain, operate, repair, or improve the same so long as needed or used for or by the United States.

B. All minerals (or partial or specific mineral interests, where applicable) shall be reserved to the United States, together with the right to prospect for, mine and remove the minerals. A more detailed description of this reservation, which will be incorporated in the patent document, is available for review at this BLM office.

C. Subject to those rights granted by an oil and gas lease under the terms and provisions of the Act of February 25, 1920, 41 Stat. 437, 30 U.S.C. 181, as amended.

D–1. In accordance with Executive Order No. 11988 and 11990 and Shasta County Zoning Ordinance Code Sections 4353 and 5354, the patentee and his successors shall undertake no construction which is not in compliance with Shasta County floodplain zoning criteria in effect at the time such construction is undertaken or which will reduce the vegetative cover within the canyon containing the North Fork Battle Creek (i.e., all lands south of the creek to the rim and from the creek level to the 1,360 foot elevation level on the north side of the creek (approximately 200 feet).

D–2. In accordance with Executive Order No. 11988 and Shasta County Zoning Ordinance Code Sections 4353 and 5354, the patentee and his successors shall undertake no construction activities within 100 feet of the unnamed tributary to Lack Creek running from the north-east corner to the south-west corner of this parcel, which are not in compliance with Shasta County floodplain zoning criteria in effect at the time such construction is undertaken.

D–3. In accordance with Executive Order No. 11988 and 11990 and Shasta County Zoning Ordinance Code Sections 4353 and 5354, the patentee and his successors shall undertake no construction which is not in compliance with Shasta County floodplain zoning criteria in effect at the time such construction is undertaken or which will reduce the vegetative cover within the canyon containing Bailey Creek (i.e., all lands from the creek level to the 3,000 foot elevation level both north and south of the creek).

E–2. The right to the United States, its permittees or licensees, the right to enter upon, occupy and use, any part or all of (said land) (that portion of) lying within———— feet of the centerline of the transmission line right-of-way of the (named company) (project No., if any, or land office No. if any), for the purposes set forth in and subject to the conditions and limitations of section 24 of the Federal Power Act of June 10, 1920, 41 Stat. 1075, as amended (16 U.S.C. 818).

**DATE:** Comments should be submitted no later than April 1, 1985.

**ADDRESS:** Comments should be sent to: State Director, California State Office, Bureau of Land Management, Federal Office Building, 2800 Cottage Way, Sacramento, CA 95825.

Comments will be evaluated by the State Director who may vacate or modify this realty action and issue a final determination. In the absence of any action by the State Director, this realty action will become a final determination for the Bureau of Land Management.

**FOR FURTHER INFORMATION CONTACT:** Robert J. Bainbridge (916) 246–5325.

**Robert C. Korshage,**

*Acting Redding Area Manager.*

[FR Doc. 85–4400 Filed 2–21–85; 8:45 am]

BILLING CODE 4310–84–M

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**[AA–6673–A2]**

## Alaska Native Claims Selection; Alaska Penninsula Corp.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that the decision to issue conveyance (DIC) to Alaska Penninsula Corporation, notice of which was published in the **Federal Register** (49 FR 32800) on August 16, 1984, is modified by changing two reserved easements.

Upon issuance, the modified DIC will be published once a week, for four (4) consecutive weeks, in the Anchorage Daily News. Copies of the modified DIC can be obtained by contacting the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513.

Any party claiming a property interest which is adversely affected by the decision shall have until March 25, 1985 to file an appeal on the issue in the modified DIC. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management, Division of Conveyance Management (960), address identified above, where the requirements for filing an appeal can be obtained. Parties who do not file an appeal in accordance with the requirements in 43 CFR Part 4, Subpart E (1983) (as amended, 49 FR 6371, February 21, 1984) shall be deemed to have waived their rights.

Except as modified, the decision of August 16, 1984, notice of which was given August 16, 1984, stands as written.

**Barbara A. Lange,**

*Section Chief, Branch of ANCSA Adjudication.*

[FR Doc. 85–4415 Filed 2–21–85; 8:45 am]

BILLING CODE 4310–JA–M

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**[F–14852–A; F–14852–B]**

## Alaska Native Claims Selection; Dot Lake Native Corp.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that the decision to issue conveyance (DIC) to Dot Lake Native Corporation, notice of which was published in the **Federal Register** 48 FR 56650–56651 on December 22, 1983, is modified by adding F–025780, F–025784 and F–025788 material site rights-of-way under "The grant of the above-described lands shall be subject to:".

Upon issuance, the modified DIC will be published once a week, for four (4) consecutive weeks, in the Tundra Times. Copies of the modified DIC can be obtained by contacting the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513.

Any party claiming a property interest which is adversely affected by the decision shall have until March 25, 1985 to file an appeal on the issue in the modified DIC. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeals. Appeals must be filed in the Bureau of Land Management, Division of Conveyance Management (960), address identified above, where the requirements for filing an appeal can be obtained. Parties who do not file an appeal in accordance with the requirements in 43 CFR Part 4, Subpart E (1983) (as amended, 49 FR 6371, February 21, 1984) shall be deemed to have waived their rights.

Except as modified, the decision, notice of which was given December 22, 1983, is final.

**Helen Burleson,**

*Section Chief, Branch of ANCSA Adjudication.*

[FR Doc. 85–4416 Filed 2–21–85; 8:45 am]

BILLING CODE 4310–JA–M

[F-21901-52 [1]]

## Alaska Native Claims Selection; Doyon, Ltd.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that the decision to issue conveyance (DIC) to Doyon, Limited notice of which was published in the **Federal Register**, 49 FR 32805–32806, on August 16, 1984, and modified in part on October 5, 1984, and published in the **Federal Register**, 49 FR 39919, on October 11, 1984, is further modified by deleting easement EIN 2 C5, D1, D9.

Upon issuance, the modified DIC will be published once a week, for four (4) consecutive weeks, in the Tundra Times. A copy of the modified DIC can be obtained by contacting the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaksa 99513.

Any party claiming a property interest which is adversely affected by the decision shall have until March 25, 1985 to file an appeal on the issue in the modified DIC. However, parties receiving service by certified mail shall have 30 days from the date of receipt of file an appeal. Appeals must be filed in the Bureau of Land Management, Division of Conveyance Management (960), address identified above, where the requirements for filing an appeal can be obtained. Parties who do not file an appeal in accordance with the requirements in 43 CFR Part 4, Subpart E (1983) (as amended, 49 FR 6371, February 21, 1984) shall be deemed to have waived their rights.

Except as modified, the decision, notice of which was given August 16, 1984 and October 11, 1984, is final.

**Helen Burleson,**

*Section Chief, Branch of ANCSA Adjudication.*

[FR Doc. 85–4418 Filed 2–21–85; 8:45 am]

BILLING CODE 4310–JA–M

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[F-14913-B]

## Alaska Native Claims Selection; Gana-a 'Yoo, Ltd.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that the decision to issue conveyance (DIC) to Gana-a 'Yoo, Limited, notice of which was published in the **Federal Register**, 50 FR 4817, on February 1, 1985, is modified to clarify the land description.

Upon issuance, the modified DIC will be published once a week, for four (4) consecutive weeks, in the Fairbanks Daily News-Miner. A copy of the modified DIC can be obtained by contacting the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513.

Any party claiming a property interest which is adversely affected by the decision shall have until March 25, 1985 to file and appeal on the issue in the modified DIC. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management, Division of Conveyance Management (960), address identified above, where the requirements for filing an appeal can be obtained. Parties who do not file an appeal in accordance with the requirements in 43 CFR Part 4, Subpart E (1983) (as amended, 49 FR 6371, February 21, 1984) shall be deemed to have waived their rights.

Except as modified, the decision, notice of which was given February 1, 1985 if final.

**Helen Burleson,**

*Section Chief, Branch of ANCSA Adjudication.*

[FR Doc. 85–4417 Filed 2–21–85; 8:45 am]

BILLING CODE 4310–JA–M

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[F-19329-B]

## Alaska Native Claims Selection Mendas Cha-ag Native Corp.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance (DIC) under the provisions of Sec. 12 of the Alaska Native Claims Settlement Act of December 18, 1971 (ANCSA), 43 U.S.C. 1601, 1611 (1976), will be issued to Mendas Cha-ag Native Corporation for approximately 2,872 acres. The lands involved are in the vicinity of Healy Lake.

**Fairbanks Meridian, Alaska**

T. 11 S., R. 14 E.
T. 13 S., R. 16 E.

A notice of the decision will be published once a week, for four (4) consecutive weeks, in the Fairbanks Daily News-Miner. Copies of the decision may be obtained by contacting the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513. ((907) 271–5960).

Any party claiming a property interest which is adversely affected by the decision shall have until March 25, 1985 to file an appeal. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management, Division of Conveyance Management (960), address identified above, where the requirements for filing an appeal can be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E (1983) (as amended, 49 FR 6371, February 21, 1984) shall be deemed to have waived their rights.

**Helen Burleson,**

*Section Chief, Branch of ANCSA Adjudication.*

[FR Doc. 85–4414 Filed 2–21–85; 8:45 am]

BILLING CODE 4310–JA–M

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[AZ-027-85-30]

## Lower Gila North Draft Management Framework Plan Amendment; Environmental Assessment Phoenix District, AZ; Availability and Public Comment

**AGENCY:** Bureau of Land Management (BLM), Interior.

**ACTION:** Notice of Availability of the Draft Management Framework Plan Amendment/Environmental Assessment and Public Comment Periods.

**SUMMARY:** Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1976, a draft Management Framework Plan Amendment/ Environmental Assessment (MFP Amendment/EA) has been prepared for the Lower Gila North Planning Area in parts of Maricopa, La Paz, and Yavapai Counties, Arizona.

The Proposed Action changes the MFP Land Tenure Adjustment Section (L-4). The proposed change provides management the opportunity to implement a broader-scoped land tenure adjustment program than is currently in effect.

More specifically, the Land Tenure Adjustment section of the Lower Gila North MFP would be amended by changing the last paragraph to read: "Public lands within the planning area not identified in this list will be considered for disposal to accommodate the following lands actions only: 1. State land selections and State exchanges; 2. mineral estate exchanges; 3. and special legislation."

Compliance with the National Environmental Policy Act of 1969 (NEPA) will not change. Compliance with all requirements regarding environmental assessments, clearances, and public input will be insured prior to

[1] F-21901-54, F-21901-55, F-21901-76, F-21901-80, F-21901-81, F-21901-84, F-21905-99, F-21906-00, F-21906-03.

making a decision to accommodate a disposal action of this type.

This proposal would enhance BLM's multiple use management by ensuring consistency with the State of Arizona's expanded State exchange program. The proposal would also allow the BLM to accommodate more easily any special legislative action such as the Navajo-Hopi Relocation Act.

**Public Participation**

Copies of the draft MFP Amendment/EA are available upon request from the Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027. Public reading copies may be reviewed at the following locations:

Bureau of Land Management, Arizona State Office, 2707 North 7th Street, Phoenix, Arizona 85019; Telephone (602) 241–5504

Bureau of Land Management, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027; Telephone (602) 863–4464

The draft MFP Amendment/EA will be available for review through March 27, 1985. Written comments should be sent by this date to the MFP Amendment/EA Team Leader, Bureau of Land Management, Phoenix District Office, 2015 W. Deer Valley Road, Phoenix, Arizona 85027.

All comments received during the review period relating to the adequacy of the draft MFP Amendment/EA will be considered in preparing the Lower Gila North MFP Amendment/EA.

**SUPPLEMENTARY INFORMATION:** Two alternatives are described and analyzed in the draft MFP Amendment/EA. The proposed action to change the Land Tenure Adjustment section of the MFP was briefly discussed in this notice summary.

The second alternative of no action would limit all disposal actions to previously identified lands only in the existing MFP. This would make consistency with the State exchange program extremely difficult or non-existent, and would interfere with programs initiated under special legislation.

**FOR FURTHER INFORMATION CONTACT:** William T. Childress, Area Manager; Bureau of Land Management; Phoenix District Office; 2015 W. Deer Valley Rd.; Phoenix, Arizona 85027; Telephone (602) 863–4464.

Dated: February 15, 1985.

Marlyn V. Jones,

*District Manager.*

[FR Doc. 85–4387 Filed 2–21–85; 8:45 am]

BILLING CODE 4310-32-M

## Bureau of Reclamation

## DEPARTMENT OF ENERGY

## Western Area Power Administration

### Spring Canyon Pumped Storage Project, Arizona; Non-Federal Participation in Proposed Planning Investigation and Expression of Peaking Power Needs

On April 27, 1984, the Bureau of Reclamation (Reclamation) published a **Federal Register** notice (49 FR 18,189) requesting non-Federal participation in proposed planning investigations for the Spring Canyon Pumped Storage Project and Solar/Hydro Integration Project. The future of these planning investigations is contingent upon non-Federal upfront funding (a goal of 50 percent).

Minimum interest was shown in the potential Solar/Hydro Integration Project and Reclamation has decided to postpone the solicitation of upfront funding for that project.

To date, the following entities have expressed an intent to participate in the Spring Canyon Planning Investigation:

| Entity | Upfront funding ($1,000) | Specified amount of capacity (MW) |
|---|---|---|
| Arizona Electric Power Cooperative | 30 | 20 |
| Arizona Public Service Company | 150 | 100 |
| Colorado River Commission of Nevada | 22.5 | 15 |
| Imperial Irrigation District | 37.5 | 25 |
| Nevada Power Company | 375 | 250 |
| Public Service Co. of New Mexico | 150 | 100 |
| Riverside, City of | 45 | 30 |
| Salt River Project | 300 | 200 |
| San Diego Gas & Electric Company | 300 | 200 |
| Tucson Electric Power Company | 300 | 200 |
| Wellton-Mohawk Irrigation and Drainage District | 7.5 | 5 |

Because of the favorable response to the Spring Canyon Project, Reclamation is seeking to make certain all potential participants have been identified and has requested the Western Area Power Administration (Western) to identify peaking power needs that should be recognized as the detailed plan is formulated.

As indicated in the April 27 **Federal Register** notice, all planning study participants will have first right of refusal to upfront fund the construction of their share of the project. Because of the large potential generating capacity available from the Spring Canyon Pumped Storage Project, additional potential participants should have no impact on those entities who have already expressed their intent to participate in the project prior to the issuance of this supplemental **Federal Register** notice. The United States' current objective is for potential participants, electing to participate in the construction of the project, to provide 100 percent upfront financing for the project.

As discussed in a Special Report completed in 1982 (copies available upon request), the Spring Canyon Pumped Storage Project has a potential of new offstream generating capacity of 1,000 to 4,000 megawatts (MW) to meet peaking power requirements. The project site is in Mohave County, Arizona, offstream of Lake Mead. Project features could include a dam and upper reservoir with maximum capacity of about 200,000 acre-feet, an underground powerhouse and appurtenant structures, and transmission lines to be built within existing transmission line corridors. The rated reservoir head would be about 750 feet with Lake Mead serving as the lower reservoir. Project planning investigations costs are estimated to be $1.5 million. Planning and construction could be completed by the late 1990's.

In addition, preliminary investigations by Western indicate that the proposed Mead-Phoenix and Mead-Los Angeles transmission lines offer enhanced capability to bring offpeak coal-fired power from the inland Southwest and use the Spring Canyon facility to make the power available to the oilburning areas of the West Coast onpeak. In the event that a line from the Pacific Northwest to Mead is constructed, this same time-shifting ability of Spring Canyon could be made available for Northwest off peak surpluses.

In accordance with Administration policy on Federal and non-Federal participation in resource planning, Reclamation and Western are continuing the public process to identify participants and needs that may be associated with peaking power development in the Lower Colorado River Basin at the Spring Canyon site. Reclamation and Western will, therefore, hold a series of public information forums to fully explain the project and process and a public comment forum to receive public input on the proposal. Notice of the forums will be published in the **Federal Register**.

During the public process, Reclamation and Western will seek additional participants interested in any remaining uncommitted capacity. These participants would be required to contribute a proportionate share of the planning costs and would have first right of refusal to upfront fund their proportionate share of construction

costs. Reclamation and Western will then contract with interested parties for up-front funding of at lest one half the costs of the required preliminary planning investigation.

During the planning investigations process, Reclamation will coordinate among participants regarding planning, design, and construction of generating equipment; interface with water operations on Lake Mead; and interface with the Lake Mead National Recreation Area resource and the National Park Service. Western, pursuant to existing statutory marketing authority, will determine final allocations of the entire output of the powerplant, subject to a recognition of the planning study participants' rights of first refusal to acquire a proportionate share of the project (if constructed), and, if necessary, establish power rates sufficient to recover the annual costs of operating the facility. In addition, Western will coordinate among participants regarding planning, design, and construction of transmission systems; related power transmission operaton activities; and the market analysis of that share of the project pan financed by the United States during the planning process. Western will also conduct an additional marketing process for any remaining uncommitted capacity in the project and will seek additional participants who would be interested in purchasing such capacity if third party financing can be made available.

Letters of interest in participating in planning investigations, or expressing a need for peaking capacity, are invited and should be sent by March 28, 1985, to: Regional Director, Lower Colorado Regional Office, Bureau of Reclamation, Attention: Code LC-600, P.O. Box 427, Boulder City, Nevada 89005, with a copy to: Area Manager, Western Area Power Administration, Attention: Code G6000, P.O. Box 200, Boulder City, Nevada 89005. Those entities that submitted a letter of intent in response to the April 27 **Federal Register** notice need not submit any additional information in response to this notice. Entities that are not certain at this time about committing to participate in the project through the planning process are requested to indicate peaking capacity needs in the 1990–2010 time frame so that the optimum project can be evaluated.

For additional project information, please contact Don Esgar of Reclamation's Lower Colorado Regional Office in Boulder City, Nevada at (702) 293–8106. Power marketing questions should be directed to Tom Carter of Western's Boulder City Area Office at (702) 293–8855.

Dated: January 16, 1985.

**Robert A. Olson,**

*Acting Commissioner, Bureau of Reclamation.*

**William H. Clagett,**

*Acting Administrator, Western Area Power Administration.*

[FR Doc. 85–4419 Filed 2–21–85; 8:45 am]

BILLING CODE 4310-09-M

## Minerals Management Service

### Outer Continental Shelf; Development Operations Coordination Document; Mark Producing Inc.

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Notice of the Receipt of a Proposed Development Operations Coordination Document (DOCD).

**SUMMARY:** Notice is hereby given that Mark Producing Inc. has submitted a DOCD describing the activities it proposes to conduct on Leases OCS–G 4742 and 6226, Blocks A–476 and A–477, High Island Area, offshore Texas. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Galveston, Texas.

**DATE:** The subject DOCD was deemed submitted on February 12, 1985.

**ADDRESS:** A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

**FOR FURTHER INFORMATION CONTACT:** Mr. Michael J. Tolbert; Minerals Management Service; Gulf of Mexico OCS Region; Rules and Production; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (504) 838–0875.

**SUPPLEMENTARY INFORMATION:** The purpose of this Notice is to inform the public, pursuant to Sec. 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs 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 revised § 250.34 of Title 30 of the CFR.

Dated: February 15, 1985.

**John L. Rankin,**

*Regional Director, Gulf of Mexico OCS Region.*

[FR Doc. 85–4373 Filed 2–21–85; 8:45 am]

BILLING CODE 4310-MR-M

### Outer Continental Shelf; Tenneco Oil Exploration and Production; Development Operations Coordination Document (DOCD)

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Notice of the receipt of a Proposed Development Operations Coordination Document (DOCD).

**SUMMARY:** Notice is hereby given that Tenneco Oil Exploration and Production has submitted a DOCD describing the activities it proposes to conduct on Leases OCS–G 3145 and 1196, Blocks 60 and 61, respectively, South Marsh Island Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Intracoastal City, Louisiana.

**DATE:** The subject DOCD was deemed submitted on February 13, 1985.

**ADDRESS:** A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

**FOR FURTHER INFORMATION CONTACT:** Ms. Angie Gobert; Minerals Management Service; Gulf of Mexico OCS Region; Rules and Production; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (504) 838–0876.

**SUPPLEMENTARY INFORMATION:** 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 DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs 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 revised § 250.34 of Title 30 of the CFR.

Dated: February 13, 1985.

John L. Rankin,

*Regional Director, Gulf of Mexico OCS Region.*

[FR Doc. 85-4386 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-MR-M

## Outer Continental Shelf; Development Operations Coordination Document; Tenneco Oil Exploration and Production

**AGENCY:** Minerals Management Service, Interior.

**ACTION:** Notice of the receipt of a proposed development operations coordination document (DOCD).

**SUMMARY:** Notice is hereby given that Tenneco Oil Exploration and Production has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 4186, Block 424, Galveston Area, offshore Texas. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an onshore base located at Sabine Pass, Texas.

**DATE:** The subject DOCD was deemed submitted on February 8, 1985.

**ADDRESSES:** A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

**FOR FURTHER INFORMATION CONTACT:** Ms. Angie D. Gobert; Minerals Management Service; Gulf of Mexico OCS Region; Rules and Production; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (504) 838-0876.

**SUPPLEMENTARY INFORMATION:** The purpose of this Notice is to inform the public, pursuant to Sec. 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs 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 revised § 250.34 of Title 30 of the CFR.

Dated: February 8, 1985.

John L. Rankin,

*Regional Director, Gulf of Mexico OCS Region.*

[FR Doc. 85-4370 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-MR-M

## National Park Service

## Fishing Bridge Area; Environmental Impact Statement for the Development Concept Plan, Yellowstone National Park, WY

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice of intent to prepare an environmental impact statement for the Fishing Bridge Area Development Concept Plan, Yellowstone National Park.

**SUMMARY:** The National Park Service intends to prepare an Environmental Impact Statement (EIS) for the Fishing Bridge area Development Concept Plan (DCP). The EIS, although not required by the National Environmental Policy Act, will be prepared due to two controversial issues: (1) Grizzly bear habitat versus existing development and; (2) economical effect on Cody, Wyoming. Existing development within the Fishing Bridge area consists of a campground, a trailer village and concession facilities. Existing heavy public use creates a conflict with a prime wildlife habitat area located between Pelican Creek, Yellowstone Lake and the Yellowstone River. This area has been identified as prime grizzly bear habitat. The community of Cody, Wyoming has expressed concern that the removal of public use facilities from the Fishing Bridge area will create a severe economic impact on Cody. The EIS will address the economic impact on all gateway communities to Yellowstone National Park.

The Master Plan and accompanying Environmental Impact Statement (FES 74-31) directs the removal of development from the Fishing Bridge area after an interim period. An interim period of ten years has passed since the master plan was approved. Grizzly bear biological data has been assembled for Yellowstone National Park that identifies the Fishing bridge area as a prime grizzly bear habitat.

The environmental impact statement will address the relocation of visitor use facilities from the Fishing Bridge Area to other locations within Yellowstone National Park. The same number of campsites and trailer village sites will be relocated within the park boundary. Socioeconomic effects on gateway communities due to the relocation of Fishing Bridge visitor use facilities will be analyzed and documented. Cumulative environmental effects concerning relocation of facilities within the park will also be analyzed and documented. An EIS for the DCP will be prepared prior to design, construction and site restoration.

Analysis and alternative studies, currently underway, will continue. Alternatives will be developed as part of a future public scoping package. To receive a scoping package, contact the Superintendent, Yellowstone National Park, Wyoming 82190.

Dated: February 8, 1985.

Lorraine Mintzmyer,

*Regional Director, Rocky Mountain Region.*

[FR Doc. 85-4425 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-70-M

## INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

## Agency for International Development

## Latin America and the Caribbean Region; Redelegation of Authorities

### Section 1. Definition

A. AID Missions subject to this redelegation of authorities shall be the AID Missions to Bolivia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Panama, and Peru, and the Regional Office for Central American Programs (ROCAP) and the Regional Development Office for the Caribbean (RDO/C).

B. "Project", for purposes of this delegation, includes project and non-project assistance.

C. "Project Assistance Completion Date" (PACD) is the estimated date by which all AID-financed goods are to have been delivered or all services performed under the Project Agreement. In non-project assistance, the equivalent date is the terminal date for requests for disbursement authorizations.

D. "Life of Project" is the planned length of the project as determined in project preparation. The life of project runs from the estimated date of signature of the Project Agreement or other obligating document to the PACD.

### Section II. Authorities

A. The authority to authorize a project, if the project:

1. Does not exceed $20 million over the approved life of project (except as provided in subparagraph (2) below);

2. Does not present significant policy issues:

3. Does not require issuance of waivers that may only be approved by the Administrator or Assistant Administrator, or if such waivers are required they are approved by them prior to such authorization; and

4. Does not have a life of project in excess of seven years.

B. The authority to amend project authorizations executed by any AID official, if the amendment:

1. Does not result in a total life of project funding of more than $30 million;

2. Does not present significant policy issues; and

3. Does not require issuance of waivers that may only be approved by the Adminjstrator or Assistant Administrator or if such waivers are required they are approved by them prior to such authorizations.

**Section III. Redelegation of Authority**

Pursuant to the authorities delegated to me as Assistant Administrator for Latin America and the Caribbean, I hereby delegate all the authorities set forth in Section II hereof, retaining for myself concurrent authority to exercise any of the functions herein redelegated.

**Section IV. Miscellaneous**

A. The authorities redelegated purusant to Section III hereof shall be exercised in accordance with applicable statutes and regulations, including the Foreign Assistance Act of 1961, as amended, and the AID Handbooks and after consultation with a Regional Legal Advisor or GC/LAC, as appropriate, and with appropriate technical and support personnel.

B. The authorities redelegated pursuant to Section III hereof shall not be further redelegated; provided, however, that they may be exercised by the person acting in the capacity of the respective Mission Director while the latter is out of the country (with my prior approval).

C. Nothing contained in this redelegation of authorities shall affect the authorities previously redelegated by me concerning waivers and excess property, such redelegated authorities to remain valid and in effect.

D. This redelegation of authorities shall become effective on the date of my execution of this document.

Dated: February 12, 1985.

**Marshall Brown,**

*Acting Assistant Administrator, Bureau for Latin America and the Caribbean.*

[FR Doc. 85-4384 Filed 2-21-85; 8:45 am]

BILLING CODE 6116-01-M

## INTERSTATE COMMERCE COMMISSION

### 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: Halliburton Company, 2600 Southland Center, Dallas, Texas 75201.

2. Wholly-owned subsidiaries (or divisions) which will participate in the operations and state(s) of incorporation:

(i) Alaska Constructors, Inc.—Alaska.
(ii) Avon Services, Inc.—Delaware.
(iii) Brown & Root, Inc.—Texas.
(a) Allied Industries, Inc.—Texas.
(b) Brown & Root Alaska, Inc.—Alaska.
(c) Brown & Root Development, Inc.—Texas.
(d) Brown & Root Engineering and Construction Corporation—Texas.
(e) Brown & Root, International—Texas.
(f) Brown & Root Marine Operators, Inc.—Texas.
(g) Brown & Root, U.S.A.—Texas.
(h) Fargo Engineering Company—Michigan.
(i) Flo-Tronics, Inc.—Texas.
(j) Houston Executive Air Service, Inc.—Texas.
(k) Mid-Valley, Inc.—Delaware.
(iv) DHS Corporation—Texas.
(v) Federal Ore & Chemical, Inc.—Delaware.
(vi) FreightMaster Division of Halliburton Company.
(vii) Halliburton Resource Management Division of Halliburton Company.
(viii) Halliburton Services Division of Halliburton Company.
(ix) Halliburton Telecommunications, Inc.—Delaware.
(x) Horn Construction Co., Inc.—New York.
(a) GIM Mechanical Associates, Inc.—Texas.
(b) Hornco General Contractors, Inc.—Nevada.
(xi) Howard Smith Screen Company—Texas.
(xii) Joe D. Hughes, Inc.—Texas.
(a) Greens Bayou Terminal, Inc.—Texas.
(xiii) IMCO Services Division of Halliburton Company
(xiv) Jackson Marine Corporation—Texas.
(xv) Jet Research Center, Inc.—Texas.
(xvi) Nova Pressure Services, Inc.—Delaware.
(xvii) Otis Engineering Corporation—Delaware.
(a) Sun Contractors, Inc.—Louisiana.
(b) Otis Overseas, Inc.—Delaware.
(c) Otis Latin-America, Inc.—Delaware.
(xviii) Wm. A. Smith Construction Co. Inc.—Texas.
(a) Wm. A. Smith Contracting Co., Inc.—Missouri.
(b) Wm. A. Smith International Contractors, Inc.—Delaware.
(c) Service and Commodity Corporation—Nebraska.
(d) Longwill-Scott, Inc.—Missouri.
(e) Sharp & Fellows Construction Co. Inc.—California.
(xix) Southwestern Pipe, Inc.—Texas.
(a) Alamo Explosives Company, Inc.—Texas.
(xx) Taylor Diving & Salvage Co., Inc.—Louisiana.
(xxi) Vernon Graphics, Inc.—Delaware.
(a) CYBEK—New Jersey.
(xxii) Welex Division of Halliburton Company.

1. Parent corporation and address of principal office: Masco Corporation, 21001 Van Born Road, Taylor, Michigan 48180.

2. Wholly-owned subsidiaries * which will participate in the operations, and their States of incorporation:

American Metal Products Company, Delaware
Aqua Glass Corporation, Tennessee
  Tombigbee Transport Corporation, Tennessee
Baldwin Hardware Corporation, Pennsylvania
Brass-Craft Manufacturing Company, Michigan
  Brass-Craft Holding Company, Michigan
    Brass-Craft International Sales, Inc. Michigan
  Brass-Craft Western Company, Texas
  Romar Manufacturing Corporation, New York
  Thomas Mfg. Company Inc. of Thomasville, North Carolina
Evans Rule Company, Inc., New Jersey
  Taylor Investments, Inc., New Jersey
    E-R Rule Co. of Puerto Rico, Inc., New Jersey
    Evans International, Inc., New Jersey
Fulton Manufacturing Corporation, Delaware

* Directly owned subsidiaries appear at the left hand margin, first tier and second tier subsidiaries are indicated by single and double indentation, respectively, and are listed under the names of their respective parent companies.

Marvel Metal Products Co., Delaware
Masco Corporation of Indiana, Indiana
Delta Faucet Company, Michigan
Peerless Sales Corporation, California
Reese Service Center of California, Inc., California
Trayco, Inc., Michigan

3. Divisions of parent corporation and location of principal office:

American Metal Products, California
Auto Flo Company, Michigan
Compac Corporation, New Jersey
Davis Manufacturing, Michigan
Gamco Products Company, Kentucky

4. Divisions of Masco Corporation of Indiana and location of principal office:

Delta Faucet Company, Indiana
EPIC, Incorporated, Indiana
Peerless Aire Company, Indiana
Peerless Faucet Company, Indiana
Reese Products Company, Indiana

1. Parent corporation and address of principal office: McLane Company, Inc., 2915 Center Street, P.O. Box 80; Temple, Texas 76503.

2. Wholly-owned subsidiaries which will participate in the operations and respective states of incorporation:

(i) McLane/Western, Inc., 3800 Wheeling, P.O. Box 39144, Denver, Colorado 80239, A Colorado corporation
(ii) McLane/Pacific, Inc., 3876 Childs Ave., P.O. Box 2107, Merced, California 95344, A Texas corporation
(iii) McLane/Eastern, Inc., d/b/a McLane/Northeast, 621 East Brighton, P.O. Box 250, Syracuse, New York 13205, A Texas corporation
(iv) McLane/Food Service, Inc., 1301 South Treadaway, P.O. Box 2160, Abilene, Texas 79604, A Texas corporation
(v) McLane/Sunwest, Inc., 655 West McDowell Road, P.O. Box 1409, Goodyear, Arizona 85538, A Texas corporation
(vi) Merit Distribution Services, Inc., 2915 Center Street, P.O. Box 80, Temple, Texas 76503, A Texas corporation

James H. Bayne,
*Secretary.*

[FR Doc. 85-4340 Filed 2-21-85; 8:45 am]
BILLING CODE 7035-01-M

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[Docket No. AB-55 (Sub-129X); Finance Docket No. 30623]

## Rail Carriers; Seaboard System Railroad, Inc.; Exemption; Abandonment and Discontinuance of Service in Chattanooga, TN and Southern Railway Co. Lease Exemption

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Notice of exemption.

**SUMMARY:** The Interstate Commerce Commission grants an amended petition for: (1) A temporary (90-day) exemption from 49 U.S.C. 11343, for the sublease by Seaboard System Railroad, Inc. (SSR) to Southern Railway Company (SOU) of 215 feet of rail line owned by the State of Georgia; and (2) permanent exemption: (a) From 49 U.S.C. 10901, for SOU to lease 215 feet of rail line from Georgia; (b) from 49 U.S.C. 10903 *et seq.*, for SSR to immediately discontinue service over two segments of a rail line owned by Georgia totalling 0.72 miles; and (c) from 49 U.S.C. 10903 *et seq.*, for SSR to discontinue service over 215 feet of rail line owned by Georgia only after SOU consummates its lease of the same line with Georgia, all in Chattanooga, TN, and subject to appropriate labor protective conditions. The Commission also dismiss SSR's petition for exemption from 49 U.S.C. 10903 *et seq.*, with respect to its proposed abandonment and reclassification of an SSR-owned line of railroad in Chattanooga and its proposed abandonment of 2 other segments of rail line, on behalf of Georgia.

**DATES:** These exemptions are effective on February 19, 1985. Petitions to reopen must be filed by March 14, 1985.

**ADDRESSES:** Send pleadings referring to Docket No. AB-55 (Sub-No. 129X) and Finance Docket No. 30623 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423

and

Petitioners' representatives:

(2) Nancy S. Fleischman, Norfolk Southern Corporation, 1050 Connecticut Avenue NW., Suite 740, Washington, DC 20036

and

(3) Charles M. Rosenberger, Seaboard System Railroad, Inc., 500 Water Street, Jacksonville, FL 32202.

**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, write to T.S. InfoSystems, Inc., Interstate Commerce Commission, Room 2227, Washington, DC 20423, or call toll free (800) 424-5403, or 289-4357 (DC Metropolitan area).

Decided: February 13, 1985.

By the Commission, Chairman Taylor, Vice Chairman Gradison, Commissioners Sterrett, Andre, Simmons, Lamboley, and Strenio. Commissioner Lamboley concurred with a separate expression.

**James H. Bayne,**
*Secretary.*

[FR Doc. 85-4341 Filed 2-21-85; 8:45 am]
BILLING CODE 7035-01-M

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## DEPARTMENT OF JUSTICE

### National Institute of Justice

### Program Announcement; National Institute of Justice Solicited Research Programs; Fiscal Year 1985

The National Institute of Justice announces the publication of its research program plan for 1985. "Solicited Research Programs, Fiscal Year 1985" describes the thirteen core programs which comprise the 1985 research plan, gives application procedures, and outlines selection criteria.

For a copy of the plan, write to the National institute of Justice, NCJRS, Box 6000, Rockville, Maryland 20550, or call 301/251-5500. Ask for the NIJ Solicited Research Program Plan, and refer to document number 96131.

Dated: February 12, 1985.

**James K. Stewart,**
*Director.*

[FR Doc. 85-4334 Filed 2-21-85; 8:45 am]
BILLING CODE 4410-18-M

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### Drug Enforcement Administration

[Docket No. 84-27]

### Joseph A. Greco, M.D.; Hearing

Notice is hereby given that on August 24, 1984, the Drug Enforcement Administration, Department of Justice, issued to Joseph A. Greco, M.D., an Order To Show Cause as to why the Drug Enforcement Administration should not deny his application for registration executed on October 21, 1983, for registration as a practitioner under 21 U.S.C. 823(f).

Thirty days having elapsed since the said Order To Show Cause was received by Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 10:00 a.m. on Thursday, February 28, 1985, in Courtroom No. 10, Room 309, U.S. Claims Court, 717 Madison Place, NW., Washington, D.C.

Dated: February 15, 1985.

**Francis M. Mullen, Jr.,**

*Administrator, Drug Enforcement Administration.*

[FR Doc. 85-4377 Filed 2-21-85; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 84-29]

### Jeffery Pharmacy, Chicago, IL; Hearing

Notice is hereby given that on June 28, 1984, the Drug Enforcement Administration, Department of Justice, issued to Jeffery Pharmacy, an Order To Show Cause as to why the Drug Enforcement Administration should not revoke its DEA Certificate of Registration, AE4078045, as a retail pharmacy under 21 U.S.C. 823(f).

Thirty days having elapsed since the said Order To Show Cause was received by the Respondent, and written request for a hearing having been filed with the Drug Enforcement Administration, notice is hereby given that a hearing in this matter will be held commencing at 9:30 a.m. on Tuesday, March 5, 1985, in Moot Courtroom, Room 310, East Building, John Marshall Law School, 315 South Plymouth Court, Chicago, Illinois.

Dated: February 15, 1985.

**Francis M. Mullen, Jr.,**

*Administrator, Drug Enforcement Administration.*

[FR Doc. 85-4376 Filed 2-21-85; 8:45 am]

BILLING CODE 4410-09-M

## DEPARTMENT OF LABOR

### Employment and Training Administration

[TA-W-13,054]

### Amstar Corp., Spreckles Sugar Division, Factory No. 1, Spreckles, CA; a Further Determination on Remand

Pursuant to the U.S. Court of International Trade remand of December 28, 1984 in (*Sugar Workers Union, Local 180* v. *Donovan*, USCIT No. 83-3-00346) allowing plaintiff an opportunity to offer a further submission (the Frazier submission of November 24, 1982) so as to permit the Secretary to reconsider the denial of certification for workers of Amstar Corporation, Spreckles, California plant in light of any new evidence.

The claims contained in the Frazier submission do not materially rebut the Department's initial denial or its affirmation of that denial for reconsideration nor do they provide a basis for certification. The claims regarding the competitiveness of imported sugar and sugar refined from beets were addressed in the Department's reconsideration and its initial denial.

The Frazier submission implies that the U.S. International Trade Commission's (USITC) findings of June 28, 1982 are sufficient to certify workers for trade adjustment assistance. The Department's investigation deals with the Spreckles plant. The Group Eligibility Requirements set at section 222 of the Trade Act provides certification criteria for individual firms or subdivisions of firms while the USITC findings are based on different criteria that apply industry wide and as such are not controlling in this case for workers at the Spreckles plant.

The Department's review of its initial denial shows that the Spreckles plant processed sugar beets from independent growers into refined sugar mainly for beverage companies, canneries, bakeries and candy manufacturers. Initially, the Department found that the Spreckles worker petition did not meet the increased import criterion of the Trade Act of 1974, since U.S. imports of refined sugar decreased both absolutely and relative to domestic production in each year from 1978 through 1981.

The Department, on its first reconsideration, found that the Spreckles plant of Amstar Corporation closed on July 31, 1982. Company officials stated that the closure resulted from the high cost of transporting the raw material (sugar beets) to the refinery. At this time the Department considered imports of cane and beet sugar despite the fact the Spreckles plant could not convert raw sugar cane into refined sugar without modifications to the plant and even if it did Amstar would compromise its competitive position vis a vis other domestic refining facilities since Spreckles was not located near a deep water port.

Further findings on reconsideration showed that the market conditions were substantially different in 1981 than the earlier period in 1978 when the Spreckles workers were certified for trade adjustment assistance under an earlier petition, TA-W-5302. Of great significance was the dramatic inroads high fructose corn syrup (HFCS) made in one of the sugar refiners' largest markets, soft drinks. Industrial users of sweeteners, the principal market of the Spreckles Sugar Division, have shifted from refined sugar to a greater use of HFCS. In the 1977/1978 period, HFCS replaced about 38 percent of the decline in refined sugar consumption; in the 1980/1981 period HFCS consumption increased to 107 percent of the decline in refined sugar consumption. The trend of industrial users to substitute HFCS for refined sugar has continued to present as consumption of HFCS has risen 61 percent since 1981 to 4.3 million short tons in 1984.

Other findings on reconsideration show that not only has the share of raw cane and beet sugar imports of U.S. consumption declined since the period applicable to the earlier certification but that the per capital consumption of sugar also decreased. Further, U.S. production of raw cane and beet sugar increased more in 1981 compared to 1978 than did U.S. imports of raw cane and beet sugar.

Reconsideration findings also showed that U.S. imports of HFCS and refined sugar are negligible and do not impact on the domestic market.

Facts not presented by the Department in its reconsideration notice but relevant to the Frazier submission and supportive of the Department's findings are the matter of "drawbacks" (refunds on duties of imported raw sugar if refined for export purposes) and raw sugar imports refined in the U.S. going to industrial markets not served by the Spreckles plant.

Findings developed in this reconsideration show that virtually the entire increase of U.S. imports of raw cane and beet sugar in 1981 compared to 1980 resulted from U.S. refiners who took advantage of "drawbacks". U.S. exports of refined sugar amounted to 1,048,000 short tons, raw value, in 1981 compared to 588,000 short tons, raw value, in 1980. Drawbacks have a beneficial effect on employment for sugar refiners. Finally, much of the remaining raw sugar imports refined in the U.S. go to industrial markets (polyhydrdric alcohols and other industrial uses) not served by the Spreckles plant.

**Conclusion**

After further reconsideration, I reaffirm the original denial of eligibility to apply for adjustment assistance for workers at Amstar Corporation's Factory No. 1 at Spreckles, California.

Signed at Washington, D.C., this 14th day of February 1985.

**Robert O. Deslongchamps,**

*Director, Office of Legislation and Actuarial Services, UIS.*

[FR Doc. 85-4447 Filed 2-21-85; 8:45 am]

BILLING CODE 4510-30-M

## Mine Safety and Health Administration

### Task Force on Two-Entry Mining Systems; Public Meeting

**AGENCY:** Mine Safety and Health Administration, Labor.

**ACTION:** Notice of public meeting.

**SUMMARY:** The Mine Safety and Health Administration (MSHA) will hold a public meeting to gather information on the development of two-entry mining systems.

**DATE:** The public meeting will be held on March 12, 1985, beginning at 9:00 a.m. MST.

**ADDRESSES:** The public meeting will be held in the Golden Room, Holiday Inn-West, 14707 West Colfax Avenue, Denver, Colorado 80401.

Written information may be sent to: Robert Ferriter, Chairman, MSHA Task Force on Two-Entry Mining Systems, Safety and Health Technology Center, P.O. Box 25367, Denver, Colorado 80225.

**FOR FURTHER INFORMATION CONTACT:** Monte Christo, Mining Engineer, MSHA Safety and Health Technology Center, P.O. Box 25367, Denver, Colorado 80225, (303) 236-2642.

Persons wishing to speak at the meeting should contact Mr. Christo to register prior to the date of the meeting. Any person wishing to speak who has not made prior arrangements may register to do so at the beginning of the meeting.

**SUPPLEMENTARY INFORMATION:** The Assistant Secretary for Mine Safety and Health has established a Task Force to study two-entry mining systems. The purpose of the meeting is to afford the public an opportunity to present the Task Force with information concerning safety and health aspects, and experience with two-entry mining systems.

There will be no verbatim transcript made at the meeting. Persons who plan to speak are encouraged to provide the Task Force with written statements prior to or at the meeting. In the event that a large number of persons desire to speak, the presiding MSHA official at the meeting may limit the time for presentations.

Dated: February 20, 1985.

**David A. Zegeer,**

*Assistant Secretary for Mine Safety and Health.*

[FR Doc. 85-4520 Filed 2-21-85; 8:45 am]

BILLING CODE 4510-43-M

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[85-10]

### Intent To Grant an Exclusive Patent License

*Correction*

In FR Doc. 85-3957 beginning on page 7016 in the issue of Tuesday, February 19, 1985, make the following correction on page 7017: In the first column, the **DATE** paragraph should have read:

**DATE:** Comments to this notice must be received by April 22, 1985.

BILLING CODE 1505-01-M

## NATIONAL SCIENCE FOUNDATION

### Advisory Committee for Physics; Subcommittee for Review of the NSF Atomic, Molecular, and Plasma Physics Program; Meeting

In accordance with the Federal Advsisory Committee Act, as amended, Pub. L. 92-463, the National Science Foundation announces the following meeting:

Name: Advisory Committee for Physics: Subcommittee for the Review of the NSF Atomic, Molecular, and Plasma Physics Program.

Date and Time: March 11-12, 1985; 9:00 a.m. to 5:00 p.m., each day.

Place: Room 341, National Science Foundation, 1800 G Street NW., Washington, D.C. 20550.

Type of Meeting: Closed.

Contact Person: Dr. Marcel Bardon, Director, Division of Physics, Room 341, National Science Foundation, Washington, D.C. 20550, Telephone (202) 357-7985.

Purpose of Subcommittee: To provide oversight concerning NSF support and planning for research in atomic, molecular, and plasma physics.

Agenda: To review the NSF Atomic, Molecular, and Plasma Physics Program, including examination of proposal jackets, reviewer comments, and other privileged material.

Reason for Closing: The meeting will deal with a review of grants and declinations in which the Subcommittee will review materials containing the names of applicant institutions and principal investigators and privileged information from the files pertaining to the proposals. The meeting will also include a review of the peer review documentation pertaining to applicants. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority to Close Meeting: This determination was made by the Committee Management Officer pursuant to provisions of Section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Director, NSF, on July 6, 1976.

**M. Rebecca Winkler,**

*Committee Management Officer.*

February 19, 1985.

[FR Doc. 85-4427 Filed 2-21-85; 8:45 am]

BILLING CODE 7555-01-M

### Program Announcement for Teacher Enhancement and Informal Science Education

The effective date of this Announcement is April 1, 1985. Proposals already submitted to the programs included in this Announcement need not be resubmitted, but this Announcement should be used in preparing all future proposals to these programs. Other NSF programs directed toward precollege mathematics and science education are included in the Division of Materials Development and Research. These programs, described in detail in NSF Brochure 85-10, are: Instructional Materials Development; Materials and Methods for Teacher Preparation; Applications of Advanced Technologies; and Research in Teaching and Learning.

#### I. INTRODUCTION

The National Science Foundation has specific responsibility to initiate and support programs to strengthen science education at all levels. Since most people acquire their basic science education in grades kindergarten through twelve, strong precollege education in mathematics, science, and technology education is essential. For many people, college and university programs for nonspecialists as well as prospective mathematicians, scientists, engineers, and science educators extend this early development.

Parallel to with and beyond formal education in the schools and colleges, opportunities for education in mathematics, science, and technology education in out-of-school settings, for example, through electronic and print media, museums and nature centers, and local continuing education possibilities, are needed to build upon, review, and consolidate formal school exposure.

The National Science Board Commission on Precollege Education in Mathematics, Science, and Technology has stated that a primary national goal should be to strengthen precollege science and mathematics education to provide all the Nation's youth with a level of education in mathematics, science, and technology that is both the highest quality attained anywhere in the world and reflects the particular and

peculiar needs of our Nation. The Foundation's initial response has been expanded support for precollege programs.

*Beginning in 1985, the Foundation is focussing especially on projects that will strengthen science and mathematics eduation for students at the middle/junior high school and elementary level, the critical early years when concepts and attitudes are shaped for life.* Proposals relating to the high school years will still be welcome; there is no intent to exclude such proposals. Both public and private school teachers are eligible to participate in NSF-funded projects.

The Foundation has, for some time, also been concerned about the underrepresentation of women, minorities, and the physically-handicapped in careers in mathematics, science, and technology. Projects involving women, minorities, and/or physically-handicapped persons as part of the staff or the target audience are especially encouraged, particularly if they represent models for increasing the numbers of qualified young people in these groups who are encouraged to choose careers in mathematics, science, and technology.

Strengthening education in mathematics, science, and technology at any level requires (1) preparing, motivating, and recognizing the teachers who are central to the motivation and learning of students; (2) exchanging and replicating effective teaching materials and techniques for their use; and (3) providing appropriate parallel out-of-school reinforcement for what has been learned.

The concerns of the Division of Teacher Enhancement and Informal Science Education include:

- Activities that enrich teachers' experiences and provide background for leadership and peer teaching;
- Activities that provide incentives for teachers and enhance and develop their capabilities;
- Activities that provide dissemination opportunities, including local and regional resource-sharing networks, that actively involve teachers in exchanging and integrating successful approaches, materials, and curricula into their own teaching; and
- Activities aimed at reaching a braod segment of the public through more effective use of non-school setting to increase understanding of the principles and issues in mathematics, science, and technology.

In pursuing these concerns, the Division of Teacher Enhancement and Informal Science Education will:

- Make use of the Foundation's unique familiarity and relationship with the scientific research and education community—in schools, colleges, and universities; in industry; and in other scientific organizations and institutions;
- Exert leadership to bring together complementary resources from all sectors—stimulating cooperative ventures and collaboration among partners including the Federal government, colleges and universities, state and local education agencies, business and industry in the private sector, cultural institutions and media, scientists and science educators, and active teachers and school administrators;
- Encourage projects that result in self-sustaining networks among these varied elements—cooperative patterns that will continue to function, supported by non-Federal funds, after NSF-support has concluded;
- Focus resources on projects that exert high leverage, that are effective and widely applicable problem-solving approaches to strengthening science and mathematics education; and
- Select projects and activities on the basis of the principles of excellence and scientific and educational merit, as assessed by peer review.

The Foundation is committed to the principle of cost sharing for the educational projects it supports, especially cost sharing that involves cooperative and collaborative partnerships among local and state education agencies, business and industry, colleges and universities, and cultural and professional institutions and societies. Such partnerships could involve in-kind contributions of space, equipment, computer time, personnel, etc., as well as financial contributions. Bearing in mind that it takes time to develop these collaborations, projects that have little initial contribution from such partnerships, but a well-developed plan to organize them as they proceed, and, hence, to reduce the overall NSF share of the project cost, are encouraged as a way to catalyze these cooperative efforts.

To be most effective, the partnerships and the human resources identified and deveoped in NSF-funded projects must be geographically distributed to reflect, at least reasonably, the population density of the country. Since the available resources and needs are different in different regions of the country, projects will vary in their scope and intent, but should be based on assessments of the needs and resources peculiar and particular to a region. The Foundation will give preference to projects that help develop the nationwide distribtion of resource-sharing partnerships that is desirable for the continuing professional development of teachers and availability of a wide range of mutually reinforcing recreational science and mathematics opportunities for the general public.

The program descriptions in this announcement are guidelines. They are designed to provide information about the Foundation interests in the areas of science and engineering education and to help those who are developing proposals to sharpen their focus.

Programs are flexible; projects that cut across program or division boundaries to help solve a well-documented problem efficiently and effectively are welcome. In such cases, proposal writers are urged to submit preliminary inquiries and/or to contact one of the Divisions to determine the program to which the proposal should be initially directed. In all cases, the Directorate staff is available for advice and counsel as ideas and proposals are being developed.

The Foundation will consider proposals for support in any field of science, including but not necessarily limited to: astronomy, atmosheric sciences, biological and behavioral sciences, chemistry, computer sciences, earth sciences, engineering, information science, mathematical sciences, materials sciences, oceanography, physics, and the social sciences. Interdisciplinary and multidisciplinary proposals also are eligible for consideration.

## II. PROGRAMS

### Leadership Activities for Precollege Teachers

*Objectives of the Program*

- Identify a cadre of well-trained and highly skilled elementary and secondary school master teachers.
- Provide teachers experience with up-to-date content, developments in educational technology, teaching methods, and research in teaching and learning they can use to enrich and improve instruction.
- Provide effective opportunities for in-service, peer teaching supported and encouraged by school administrations and community resources in the region from which the teachers are drawn.
- Provide the teaching community with people trained to implement improved education in mathematics, science, and technology effectively and widely.
- Recognize and honor precollege teaching professionals and provide role models, including women, minority, and

physically-handicapped master teachers.

• Provide an incentive to establish cooperative and collaborative regional partnerships among schools, colleges and universities, the private sector, and others that will continue to use the human resources developed and that will build upon projects initially funded in part by the NSF.

• Develop leadership programs that serve as a magnet for attracting the most talented individuals into the education.

*Scope of the Program*

Apropriate project activities may include, but are not limited to, seminars, conferences, research participation opportunities, and workshops designed to expand the scientific and/or mathematical knowledge base of teachers who have a solid foundation in these areas. Projects should provide the training for participant teachers to take leadership roles in in-service training of their peers in their home schools and communities.

Projects should be designed to engage teachers, school administrations, and the community as meaningful collaborators with a commitment to extend the impact of the master teachers when they return to their home schools. It is expected that support and encouragement will be forthcoming from the home school and project staff and be part of the project plan as the master teachers conduct training sessions for their colleagues.

*Characteristics of Leadership Activities*

Effective project planning and development will usually involve precollege teachers with appropriate expertise and background to help guide program design.

Projects should provide for intensive, hands-on sessions for teachers to learn in depth about one or more recent developments in their fields of specialization, including the results of research on teaching and learning that might have an impact on their instrucion. Teachers should have the opportunity to work with the best instructional materials, educational technology, and teaching methods related to the content of the knowledge-intensive sessions and time to adapt these materials and methods for use both in their own classrooms and laboratories and for the instruction of their peers. Adequate time should be scheduled to allow for teachers to interact in a meaningful way, professionally, with the other teacher participants and project staff. Several weeks of sustained effort will probably be required to provide adequate time for these activities.

The outcomes of these projects should include:

• Teachers of science and mathematics who are confident of their grasp of the new knowledge and methods obtained;

• Teachers prepared to carry what they have learned back into their own teaching and to conduct staff development and in-service continuing education for their colleagues. Such cadres of master teachers, as they are developed, should play significant roles in local and regional teacher development projects; and

• Improved materials and methods, collected and adapted by the participants, for use in their classes and in presentations in their home schools.

*Participant Selection*

Participants teaching at the elementary level should have taught at the precollege level for three years and be able to demonstrate their interest in and knowledge about science and/or mathematics through completion of appropriate training and evidence of strong science and/or mathematics instruction in their classroom or be science or mathematics specialists in their school systems.

Participants teaching science or mathematics at the secondary level (7–12) should have a bachelors or advanced degree in the scientific or mathematical discipline for which they have primary teaching responsibility and have taught at the precollege level for at least three years.

Demonstrations of leadership ability and performance should be evident, such as involvement in materials development or assistance to other colleagues. Further, the appropriate administrator from the teacher's home school should supply evidence of a commitment to allow the participant teacher to use the project materials and ideas for classroom instruction and to support the teacher in providing in-service, continuing education opportunities for her or his peers.

All selection processes should assure that access is available to qualified women, minority, and physically-handicapped teachers.

There are some circumstances where a program could be more effective if some of its participants were school administrators, school board members, and/or community leaders, in addition to teachers. Proposals for such a program should present plans for involving all participants in the project activities.

*Target Date's for proposal Submission*

Proposals for this program are evaluated by a combination of mail and panel peer review followed by review analysis. Although proposals are accepted at any time, the following target dates for submitting proposals should be noted:

• December 15 for projects with starting dates near the middle of the calendar year. These will include projects with participant activities beginning during the academic year or during the summer, if lead time is, for some reason, unnecessary.

• April 1 for projects with starting dates in the last quarter of the calendar year.

• August 15 for projects with starting dates near the first of the following calender year. This will include most projects for the following summer where lead time for announcements and participant selection are necessary.

*Proposal Evaluation Criteria*

In addition to the general criteria for proposal evaluation given in Section IV below, the following more specific factors will be given substantial weight in the review process and these questions posed for reviewers.

*Staff qualifications:* Is the proposed Project Director knowledgeable in the content and methods of the area(s) of mathematics, science, or technology on which the project will focus? Have appropriate additional principal staff been selected to complement and extend the expertise of the Project Director? Are the Project Director and/or staff acquainted with pedagogical research, methods, and techniques appropriate to the project?

*Scientific and educational merit:* Are the mathematical, scientific, or technological concepts upon which the project will focus timely and appropriate for adaptation to classroom use and for the instruction of the teachers' peers? Have members of the target audience—precollege science and mathematics teachers—been involved at the proposal and project planning stages or as part of the project staff to help assure appropriate program design?

Is there evidence that the proposers are knowledgeable about and have given attention to prior projects, studies, *etc.* that offer isights for their project? Are appropriate developments in educational technology, teaching methods, and research in teaching and learning incorporated as instructional strategies in the project to give participants opportunities to experience and make informed choices about

adopting them? What evidence is there that positive efforts have been or will be made to include women, minorities, and the physically-handicapped among the project staff and participants and to address their special needs and concerns?

*Follow-up activities:* Do the plans for supporting and encouraging participating teachers as they use the project materials and provide in-service continuing education for their peers take into account the sponsoring institution's location and the locations from which the teachers are selected? (Possibilities for continuing interaction might include personal visits by project instructional staff or by faculty from higher education institutions or other appropriate persons in the region closer to the teachers' own schools.)

Is there evidence that the teachers' home school systems recognize the extra effort and time that will be required to carry out academic-year project activities? (Evidences of this recognition might be reduced teaching and/or non-classroom duties, more paraprofessional help, and convenient scheduling.) Have arrangements been made to provide appropriate opportunities for other teachers to take advantage of the human resources represented by the master teachers?

*Partnerships:* What cooperative or collaborative arrangements have been formed among schools, colleges and universities, the private sector, cultural institutions, and others to support this project? Is there evidence that these arrangements will continue to function and flourish in the absence of NSF funding?

**Local and Regional Teacher Development**

*Objectives of the Program*

- Assist local and regional communities in their efforts to provide appropriate continuing education and professional development opportunities for elementary and secondary teachers who lack mathematics and science background for the courses they teach.
- Assist in identifying and developing creative approaches, including telecommunication and computer networks, to improve the science and mathematics knowledge base of elementary school teachers and non-certified secondary school teachers.
- Provide teachers experience with developments in educational technology, teaching methods, and research in teaching and learning they cn use to enrich and improve instruction.
- Provide an incentive to establish cooperative and collaborative partnerships among schools, colleges and universities, the private sector, and others that will continue and build upon the projects initially supported in part by the NSF.
- Provide an incentive to examine the roles that women, minorities, and the physically-handicapped are playing in the local and regional educational setting and to develop ways to increase their access to activities and careers in mathematics, science, and technology.

*Scope of the Program*

Appropriate project activities include, but are not limited to, part-time and full-time courses, seminars, and workshops dealing with:

- Content in mathematics, science, and technology;
- Application of education technology, such as computers and telecommunications, to the teaching and learning process;
- New or improved instructional activities, delivery systems, or teaching practices in mathematics and science; and
- Procedures to increase teacher effectiveness with various groups of students, including women, minorities, and the physically-handicapped.

In addition to classroom-oriented approaches, activities might include, for example, delivery via electronic media, using museums and science centers, or research experiences in a college, university, industrial, or national laboratory in carefully designed programs to provide effective education and professional development.

*Characteristics of Local and Regional Teacher Development*

Effective project planning and development will usually involve precollege teachers with appropriate expertise and background to help guide program design.

Projects should be designed to address local and regional problems or needs, and evidence for such need should be included. The proposal should explain why this project is particularly appropriate to these needs. Proposed solutions should draw upon the best available approaches, adapted to local circumstances, and all available resources, including local and regional cadres of master teachers, as appropriate. Projects designed to increase teachers' knowledge of content and/or methods new to them should provide intensive, hands-on practice.

Activities may vary in length according to their scope and the type of participants. They may be conducted during the academic year, the summer, or both. At least several weeks of sustained effort will probably be required at some point to provide adequate depth for lasting professional development. There should be a plan for the instructional staff and/or local master teachers to support, encourage, and advise the teachers as they begin to use their new knowledge in the classroom and laboratory. Methods for assessing how well the development and teaching improvement goals of a project are met are an integral part of its plan.

Activities may take place at a college or university, a local or state educational facility, an academic or industrial laboratory, a museum or nature center, or in other appropriate settings. Academic credit, or the equivalent, for teacher participation is encouraged, where appropriate. The activities in which the teachers participate should be designed to be appropriate for their needs. Where standard undergraduate or graduate courses are part of a project, their inclusion should be justified on the basis of the assessed needs of the target audience and the local problem(s) to be addressed.

In some cases the projects may run over two or more years, perhaps even continuing indefinitely. In all cases, local and regional support from partnerships of colleges and universities, local and state education agencies, business and industry, cultural institutions, and others is expected to be combined with Federal support for the projects. For longer term projects, proposals should contain an explicit plan for decreasing Federal support and increasing local and regional support—toward the goal of full and sustaining local and regional support.

*Participant Selection*

Participants in these projects will generally be elementary or secondary teachers whose background in particular science or mathematics content or methods needs strengthening. These might be teachers with very limited formal science training, crossover teachers, teachers with a general certificate or provisional certificate, etc.

There are many circumstances where a program can be more effective if some (or all) of its participants are school administrators, school board members, and/or community leaders, in addition to teachers. Proposals should present plans for involving all participants in the project activities.

All selection processes should assure that access is available to qualified

women, minority, and physically-handicapped teachers.

*Target Dates for Proposal Submission*

Proposals for this program are evaluated by a combination of mail and panel peer review followed by review analysis. Although proposals are accepted at any time the following target dates for submitting proposals should be noted:

- December 15 for projects with starting dates near the middle of the calendar year. These will include projects with participant activities beginning during the academic year or during the summer, if lead time is, for some reason, unnecessary.
- April 1 for projects with starting dates in the last quarter of the calendar year.
- August 15 for projects with starting dates near the first of the following calendar year. This will include most projects for the following summer where lead time for announcements and participant selection are necessary.

*Proposal Evaluation Criteria*

In addition to the general criteria for proposal evaluation given in Section IV below, the following more specific factors will be given substantial weight in the review process and these questions posed for reviewers.

*Staff qualifications:* It the proposed Project Director Knowledgeable in the content and methods of the area(s) of mathematics, science, or technology on which the project will focus? Have appropriate additional principal staff been selected to complement and extend the expertise of the Project Director? Are the Project Director and/or staff acquainted with the pedagogical research, methods, and techniques appropriate to the project?

*Needs assessment:* Have appropriate persons and agencies in the project target audience, been involved in an assessment of its educational needs in mathematics, science, and technology? Does the proposed project address the particular and peculiar needs identified? How will the outcomes of the project be assessed?

*Scientific and educational merit:* Are the mathematical, scientific, and technological concepts upon which the project will focus appropriate for the target audience? Do the concepts represent timely topics treated in sufficient, but appropriate, depth to provide the proposed teacher-development outcomes?

Have members of the precollege science and mathematics teaching community been in on the project planning and development to help assure effective program design and execution? Will peer teachers be used to some extent in the project as instructors, role models, and knowledgeable practitioners? Are appropriate developments in educational technology, teaching methods, and research in teaching and learning incorported as instructional strategies in the project to give participants opportunities to experience and make informed choices about adopting them? What evidence is there that positive efforts have been or will be made to include women, minorities, and the physically handicapped among the project staff and participants and to address their special needs and concerns?

*Follow-up activities:* Are plans included for supporting, encouraging, and advising teacher participants as they begin to use their new knowledge? Are there plans to build upon, consolidate, and share the experiences the teachers have as they use what they have learned?

*Long-term plans* (if approporiate): Is a realistic funding plan proposed that will make the project self-sustaining when NSF funding is over? Does the plan provide for a graduated phase of NSF funding? What evidence is there that the required local and regional funding levels are attainable in the time allotted?

*Partnerships:* What cooperative or collaborative arrangements have been formed among local and regional schools, colleges and universities, the private sector, cultural institutions, and others to support this project? Is there evidence that these arrangements will continue to function and flourish in the absence of NSFD funding?

**Presidential Awards for Excellence in Science and Mathematics Teaching** [1]

This is a Presidential initiative to provide national recognition for distinguished secondary school teachers of science and mathematics. Teachers whose primary responsibility is classroom teaching of science or mathematics aat grade 7 through 12 in an accredited school in any of the fifty states, Puerto Rico, or the District of Columbia are eligible for this award. In addition, a minimum of five years' teaching experience in science of mathematics is required. Awardees receive national recognition and their schools receive $5,000 to be used under the awardees' direction for instructional purposes in their school districts.

**Science and Mathematics Education Networks**

*Objective of the Program*

- Encourage the development of substantial local and regional resources-sharing networks and collaborations that may include, among others, teachers, schools, local and state education agencies, colleages and universities, business and industry, and cultural and professional organizations, designed to accomplish the objectives of this activity. Collaborations that take advantage of available curricula and materials, methods, and human resources and expertise and, as necessary, appropriate communications technology for dissemination are encouraged, and an information brokering role is assumed by the NSF in helping them develop.
- Provide opportunties for teachers, school administrators, educational decision-makers, and local and state educational agencies to learn about new and alternative instructional materials, classroom teaching techniques, and recent research findings that may have meaningful classroom applications for teaching mathematics and science at the precolleage level.
- Provide professional support to local mathematics and science teachers by introducing them to new materials and teaching techniques—and by providing a continuing source of information and advice on how these innovations may be put to practical classroom use.
- Build bridges between educational product developers and distributors and users, including teachers and local and state education agencies responsible for product selection, to help producers better meet the needs for effective mathematics and science instructional materials.
- Establish mechanisms for disseminating information about resource materials for efficient and effective classroom instruction.
- Initiate collaborative, coherent, and constructive programs to help teachers, school administrators, and school board members translate the results of research on teaching and learning into classroom practice.
- Develop resource-sharing networks augmented by effective and appropriate use of telecommuncations and computer networks, that will serve the scientific and instructional needs of local school districts will continue after Federal support has terminated.

[1] This description is provided for information purposes only. No applications or proposals are sought for Presidential awards via this announcement.

*Characteristics of the Program*

Resource-sharing networks for dissemination of information on the successful curricula, methods, materials, and human resources available in well-defined geographical regions of the country are encouraged. The planning, execution, and support of these networking activities will involve collaboration and cooperation among many people (precollege and college teachers, administrators, parents, businesspersons, etc.) and institutions (local and state education agencies, colleges and universities, business and industry, professional societies, and cultural institutions). Cooperative efforts will be based on sharing and using identified strengths found in the region to meet needs and improve mathematics and science education throughout the region.

Networking projects developed in this way are likely to consist of a substantial number of individual, correlated but independent activities that, together, meet the overall needs of a particular region. Discrete projects that focus more narrowly on a particular need and consist of relatively few activities are also supported by this program.

Whether in discrete projects or as part of a collaborative network, this program encourages sharply focused individual project activities designed to engage the participants actively with the information presented. The individual activities in an information project will often be of relatively short duration, a few days to a week or so, and concentrated on a specific topic to insure depth of coverage can be accomplished in a short period of time. Projects might embody a coherent collection of such activities that provide broad coverage of a topic, but extended over a longer period of time, for example, a series of weekend workshops each focusing on a different problem solving technique. The timing, extent of coverage of topic, and rate of engagement of participants should be a function of the project's stated needs.

Other characteristics of networking projects include, but are not limited to:

- Helping to define and respond to the educational needs of specific geographic regions;
- Providing a continuing source of information and advice to the teachers, principals, and others as training is put into practice in the classroom;
- Exchanging information about demonstrated collaborative efforts among teachers, schools, local and state education agencies, professional societies, colleges and universities, business and industry, cultural institutions, and others in the planning, execution and support of the project;
- Helping educators and planners develop long and short term priorities for gaining and using information; and
- Demonstrating alternative solutions, increasing the participants' awareness to possible alternatives, and helping them to develop their strategies for choice among them.

*Participant Selection*

Whenever possible, the individual activities in networking projects should be available to all members of the target audiences. If, for example, a workshop for science specialists and school principals is planned, it should be open and publicized to all specialists and principals in the area served by the project. Participation in all networking projects should be at the option of the possible participants, except in some cases where enrollment is limited. This is necessary to make information in mathematics, science, and technology education as widely available as possible.

All selection processes should assure that access is available to qualified women, minority, and physically-handicapped teachers.

*Project Activities*

The Foundation encourages a wide variety of individual activities, so that a broad spectrum of options will be available to teachers, administrators, education decision-makers and others. Examples of the activities eligible for support might be: Information conferences structured along subject matter lines by grade levels, e.g., a conference on mathematics in middle schools; activities built around available technologies and pedagogical practices; teleconferenced information exchange sessions providing opportunities for information dissemination of considerable classroom utility; or resource centers for teaching materials and ideas, in-service seminar programs, and support services.

Activities designed to provide administrators, subject matter specialists, teacher-leaders, school board members, parents and other policy makers with the requisite knowledge to make more informed choices in mathematics and science education are encouraged. Activities that focus on timely issues and topics could also be proposed specifically for key state education personnel.

The Foundation is particularly interested in projects directed at the dissemination of information on materials, applications of the new technologies, and instructional practices designed to increase the access of women, minorities, and the physically-handicapped to careers in mathematics, science, and technology.

*Project Content*

The content of project activities should be selected from the vast array of materials, practices, research finds, and educational technologies currently available to assist instruction in mathematics and science. Those materials selected for inclusion in projects should show clarity of purpose, scientific accuracy, and educational soundness. Evidence for acceptability should be documented from such resources as journal articles, published reviews, evaluations and use studies, and other reliable sources of information dealing with educational products and research. The content of the proposal should also reflect a balanced perspective on the available alternatives.

*Proposal Submission and Review*

The Science and Mathematics Education Networks program uses a combination of brief preliminary inquiries, with rapid staff responses to these new ideas, and peer review of formal proposals by mail reviewers.

The preliminary inquiry process is not elaborate, but it provides an opportunity for proposers to explore a new idea or suggestion without the elaborate investment of time and effort that are involved in a formal proposal. A preliminary inquiry has no significance or role in any subsequent review, but it helps to clarify the project goals and to focus the resources of both proposers and reviewers on the ideas that show the most promise.

Formal proposals require a substantial effort on the part of both the authors and the review process. This review process can require six to nine months and often involves debate on priorities, needs within the field, probable impact, and the most cost-effective investment of resources. To focus this formal review effort as much as possible, *the program requires a preliminary inquiry and staff opinion of the prognosis for funding, before considering a formal proposal.*

*Preliminary Inquiries:* These should be no longer than 5 pages and should address the following topics:

- What are the needs and how were they assessed?
- What, in broad outline, is the proposed solution?
- Why was this solution chosen over others?
- Who can and will carry out the work?

• What are the expected outcomes?
• How will it be known that the outcomes have been achieved?
• Approximately how much will it cost?

Preliminary inquiries and staff opinions have no bearing on the peer review process for a formal proposal. No information concerning the preliminary inquiry is available to peer reviewers.

Three copies of a preliminary inquiry should be sent directly to: Science and Mathematics Education Networks Program, Division of Teacher Enhancement and Informal Science Education, Directorate for Science and Engineering Education National Science Foundation, Washington, DC 20550

**Please Note.**— Only preliminary inquiries are to be sent directly to the Division. Formal Proposals, as described in Section III, must be addressed to the Data Support Services Section of the Foundation; see Section III.

Preliminary inquiries may be submitted at any time and the Program will make every effort to respond within eight weeks of their receipt.

*Proposal Evaluation Criteria*

In addition to the general criteria for proposal evaluation given in Section IV below, the following more specific factors will be given substantial weight in the review process and these questions posed for reviewers.

*Needs assessment:* Have appropriate persons and agencies in the region to be served by the project been involved in an assessment of its educational resources and needs in mathematics, science, and technology? Does the proposed project represent an effective approach for using the available resources to address the particular and peculiar needs identified? Is there justification for any proposed use of educational resources from outside the region? Is Federal support necessary and clearly justified?

*Project plan:* Does the proposal articulate a realistic plan for a local or regional resource-sharing network and/or collaboration to accomplish the project objectives? Will all the available telecommunications and other educational techniques, including computers, be used appropriately and effectively? Does the plan take advantage of the expertise of master teachers, leading administrators, and community leaders as well as material resources? Have all the relevant teachers, administrators, local and state education agencies, colleges and universities, business and industry, and cultural and professional organizations been involved in the planning? Are these the appropriate individuals, groups, and institutions to carry out the plan successfully?

*Scientific and educational merit:* Are the mathematical, scientific, and technological concepts involved in the project the appropriate ones for the target audience(s). Will peer teachers and members of the community with particular expertise to share be involved as instructors, role models, and knowledgeable practitioners? Are appropriate developments in educational technology, teaching methods, and research in teaching and learning incorporated as instructional strategies and/or in other ways that will provide teachers, administrators, and the communities opportunities to experience them and make informed choices about adopting them? What evidence is there that positive efforts have been or will be made to include women, minorities, and the physically-handicapped in all aspects of the project and to address their special needs and concerns?

*Staff qualifications:* Has the proposed Project Director the administrative experience, as well as knowledge of the content and educational methods in mathematics, science, and technology, required to coordinate all the elements being brought together in this project? Have appropriate additional principal staff been selected to complement and extend the expertise of the Project Director? Is there evidence that the staff have knowledge and understanding of other information and dissemination efforts and their possible relation to the proposed project?

*Evaluation and dissemination:* Are the goals of the project clearly stated? Has a plan been formulated for assessing the intermediate as well as final outcomes of the project? Does the proposal clearly and specifically indicate how the project staff will use the results of intermediate assessments to alter and improve the project? If relevant, have specific, effective plans been formulated for disseminating the content, methods, etc., from this project that could be of value to others?

*Partnerships:* What cooperative or collaborative arrangements have been formed among local and state educational agencies, colleges and universities, the private sector, cultural institutions, and others to support this project? Is a realistic funding plan proposed that will make the project self-sustaining when NSF funding is over? Does the plan provide for a graduated phase out of NSF funding? What evidence is there that the local and regional funding levels are attainable in the time allotted?

**Informal Science Education**

*Objectives of the Program*

• Provide greater and mutually reinforcing opportunities for the public to make use of the rich resources for scientific, mathematical, and technological learning which exist outside the formal educational systems.
• Allow for increased interactions between the formal educational systems and the resources and staff of museums, zoos, and other institutions responsible for the preservation and exhibition of scientific phenomena and specimens.
• Encourage communications media to take a more intense and greater interest in imparting knowledge about scientific, mathematical, and technological concepts to both the public at large and selected groups.
• Encourage private supporters of the media to focus efforts on increasing the scientific and technological literacy of the American public.
• Encourage local-membership groups to provide mathematics- and science-based activities for their members or groups served by them, in order to increase the amount of active engagement in out-of-school mathematics and science.
• Provide an incentive to examine the roles of women, minorities, and the physically-handicapped in mathematics, science, and technology and to develop ways to encourage their full participation.

*Scope of the Program*

This program supports projects that help to provide a rich and stimulating environment for informal learning, for a wide variety of audiences, in a cost effective manner.

A principal characteristic of informal learning is its highly personal and internalized acquisition. Each person visiting a museum, watching a television program, or pursuing a science hobby develops different insights and understanding—and the pattern of understanding that develops is the result of many overlapping impressions and experiences.

For this reason, the program supports activities in a variety of media—broadcasting, museums, clubs, and other sources of direct science experience. A principal goal of the program is to encourage projects that are both cost effective and mutually reinforcing. At the same time the overall pattern must serve the needs of a full spectrum of age and interest.

Representative projects include museum, zoo, and other activities that encourage personal interactive learning

about science, mathematics, and technology. In addition to exhibits and special programs, these include outreach activities, such as training teachers to use museum and zoo resources effectively, offering special out-of-school programs for students and parents, or designing innovative ways to take the museum to the schools and the public rather than the reverse.

Other projects, in print and broadcast mass-media, are able to reach extremely large and varied audiences, providing an intriguing overview of the scope and excitement of science—on a scale that cannot be matched by any other means. NSF is particularly interested in encouraging a well balanced array of such large-scale communication activities. This includes science series for both children and adults, via both radio and television. The NSF is also interested in periodic series on major areas of science and technology, especially when these promise to have lasting value.

A parallel development of interest in science activities within local-membership clubs (for example, Girl and Boy Scouts, the "Y," amateur science societies, and service clubs) is necessary to encourage early and continued learning outside of school. Not only students, but parents, teachers, and all citizens, need to have opportunities to experience the joy and enthusiasm of exploration and discovery for themselves.

In all cases, projects should lead to programs or print materials that are bias-free, scientifically and educationally sound, and cost effective in terms of their ultimate audience and impact. Synergistic projects among the institutions involved in informal science education are particularly welcome—projects that will encourage further personal involvement in reading and hands-on activities—cooperative activities between broadcasting and museums as a center of community interest in science.

Each area of activity has complementary strengths and purposes.

- Broadcasting reaches uniquely large audiences, providing an initial stimulus and overview that is unmatched by any other means.
- Museums provide a direct personal experience with the phenomena and principles of science and technology.
- Personal activities develop a depth of insight and involvement that cannot be matched by any less involving presentation.

The strategy of the Informal Education Program is to encourage all three, especially, in modes where they complement and reinforce each other.

*Characteristics of the Program*

Because the range of possible out-of-school learning experiences in mathematics, science, and technology is so large, the Division has chosen to focus its selection of projects on the following strategic considerations:

- *A balance of key projects:* The program is a pragmatic effort to improve the environment and opportunities for out-of-school learning. A balance is maintained between support for major activities that have national impact and significance and support of more limited projects that serve to explore special needs and opportunities.
- *Linking and strengthening the media of informal education:* Projects that will strengthen the institutions of informal education by recognizing their strengths and weaknesses, and by encouraging cooperative and complementary activities are emphasized.
- *Significance and urgency:* Projects that have a significant effect on the overall pattern and quality of informal education, as well as the strength of its institutions and their relation to formal learning are emphasized.
- *Contribution to the pattern of general education:* Informal learning as an integral component of general education is encouraged. Informal education should provide stimulus, awareness, and background before school, support and reinforcement during formal education, and an opportunity to continue learning and awareness when formal study ends. Lifelong learning should be a habit of all persons regardless of age or role.

In its support of television and radio projects, the Foundation is committed to the development of high quality programming made widely available to all children, youth, and adults. Under normal circumstances, the Foundation requires that:

- NSF retain the right to use the programs for government purposes in perpetuity;
- Off-the-air recording rights by educational agencies or institutions shall be guaranteed for a minimum of three years;
- All television programs must have closed captions encoded on the master broadcast tape and all programs must be broadcast with closed captions;
- All broadcasts, exhibits, and other materials must include a clear indication of the source(s) of support (both NSF and any other contributions), and should include the NSF logo;
- A copy of all materials, e.g., videotapes of programs and copy of teacher's guide, be provided to the NSF; and
- A quarterly letter-report on the activities of the project be submitted.

*Proposal Submission, Review, and Deadlines*

The Informal Education program uses a combination of brief preliminary inquiries with rapid staff responses to these new ideas and peer review of formal proposals by a combination of mail reviewers and a standing review panel.

The preliminary inquiry process is not elaborate, but it provides an opportunity for proposers to explore a new idea or suggestion without the elaborate investment of time and effort that are involved in a formal proposal. A preliminary inquiry has no significance or role in any subsequent review, but it helps to clarify the project goals and to focus the resources of both proposers and reviewers on the ideas that show the most promise.

Formal proposals require a substantial effort on the part of both the authors and the review process. This review process can require six to nine months and often involves debate on priorities, needs within the field, probable impact and, the most cost-effective investment of resources. To focus this formal review effort as much as possible, *the program requires a preliminary inquiry and staff opinion of the prognosis for funding, before considering a formal proposal.*

*Preliminary Inquiries:* These should be no longer than 5 single-spaced pages and should address the following topics:

- What are the needs and how were they assessed?
- What, in broad outline, is the proposed solution?
- Why was this solution chosen over others?
- Who can and will carry out the work?
- What are the expected outcomes?
- How will it be known that the outcomes have been achieved?
- Approximately how much will it cost?

Preliminary inquiries and staff opinions have no bearing on the peer review process for a formal proposal. No information concerning the preliminary inquiry is available to peer reviewers.

Three copies of a preliminary inquiry, should be sent directly to:

Informal Science Education Program, Division of Teacher Enhancement and Informal Science Education, Directorate for Science and Engineering Education, National Science Foundation, Washington, DC 20550.

**Please Note.**—Only preliminary inquiries are to be sent directly to the Division. Formal proposals, as described in Section III, must be addressed to the Data Support Services Section of the Foundation; see Section III.

Preliminary inquiries may be submitted at any time and the Program will make every effort to respond within eight weeks of their receipt. Formal proposals are reviewed three times each year.

*Formal proposal target dates:* The target dates for submitting formal proposals are April 1, August 1, and December 1 of each year.

*Proposal Evaluation Criteria*

In addition to the general criteria for proposal evaluation given in Section IV below, the following, more specific factors will be given substantial weight in the review process and these questions posed for reviewers.

*Rationale:* Are the project objectives clear and relevant to the goals of NSF? Has the proposer identified an important need, problem, or issue in public understanding of science? Have the proposers demonstrated knowledge of the area of concern that is pertinent, current, and complete? Is the rationale for supporting the project adequate to justify the investment of Federal funds?

*Project Design:* Does the proposal articulate a well-formulated plan of attack on the problem identified? Is the proposed approach a practical and effective way to solve the problem? Are the management plan and the dissemination plan appropriate? Are the special needs and concerns of women, minorities, and the physically handicapped recognized and accounted for?

*Impact:* Is there evidence that project outcomes will have an effect on the target audience? Is the character and size of the audience significant? Is the target audience one that is not effectively reached by existing formal and/or informal education programs? Will the project explore innovative modes of communication that have potential for transfer or adaptation in other settings?

*Cost-Effectiveness:* Is it likely that project outcomes will be cost-effective? Will the improvements in public understanding justify the cost?

*Monitoring and Evaluation:* Is there a good procedure for assessing the outcome of the project? Are there suitable plans for obtaining reliable and unbiased information on the effectiveness of the project? Are adequate funds included in broadcast projects to obtain information on national ratings and audience share?

*Personnel and Institutional Resources:* Is the staff qualified to carry out the roles assigned to them? Are the services and conditions necessary to support the project activities available? What other source(s) of funds will support the project?

*Budget:* Are the costs of the project (salaries, services, and other expenses) reasonable? Does the budget reflect understanding of the magnitude of the task?

*Quality:* Does the activity have intrinsic merit? Does the conceptualization of the problem and the proposed solution show imagination and creativity? Are high quality resources to be employed in attacking the problem? Will the results promised significantly improve some aspects of the public understanding of science?

## III. PREPARATION AND SUBMISSION OF PROPOSALS

This announcement sets forth basic information needed to initiate planning for a formal proposal and to submit it. More detailed information is available in the publication *Grants for Scientific and Engineering Research* (GSER), NSF 83–57. This publication is available from the Forms and Publications Unit, National Science Foundation, 1800 G Street, N.W., Washington, D.C. 20550. The GSER should be used with the following understandings:

- For "research" substitute "science education" or "science education project" according to the context;
- The terms "new discoveries" or "fundamental advances" included development of the science and engineering infrastructure directed toward those goals.

*In the event that the submitting organization has never been the recipient of an NSF award,* it is recommended that appropriate administrative officials become familiar with the NSF policies and procedures contained in the *NSF Grant Policy Manual, Revised* (NSF 77–47, available through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402) which are applicable to most NSF awards. If a proposal is recommended for an award, the NSF Division of Grants and Contracts *will request* certain organizational, management, and financial information. These requirements are contained in Chapter III of the *Manual.*

### Who May Submit

Organizations with a scientific or educational mission are eligible to submit proposals. Among these are: colleges and universities; state and local educational agencies; professional societies; science museums and zoological parks; research laboratories; private foundations; private industry; and other public and private organizations, whether for profit or non-profit. Proposers are encouraged to involve representation from more than one of these areas.

### When To Submit

Proposals to the Division of Teacher Enhancement and Informal Science Education may be submitted at any time. However, to ensure the most efficient processing of proposals, there are target dates suggested in Section II for some programs.

### What To Submit

Proposals should be prepared in accordance with the guidelines contained in the GSER, page 1–8. Fifteen (15) copies of the proposal and three (3) additional copies of the Cover Sheet and Project Summary are required. The notes here provide some further interpretation. *See Appendix 1 for the order of assembly of the proposal.*

*Cover Page*

Use a photocopy of the cover page form, Appendix 2, as the "original."

In the upper left hand block labeled "For Consideration by NSF Organizational Unit," identify, if clearly defined, the specific program to which the proposal is directed, e.g., "Leadership Activities" or "Science and Mathematics Education Networks" (see reverse side of Appendix 3). For proposals that involve more than one program, prior discussion with staff should be held to determine the appropriate program to which the proposals should be directed. If, after the receipt of a proposal, staff examination suggests that it would be more appropriately and effectively considered in a program other than the one to which it has been submitted, the principal investigator will be contacted to determine whether the change is acceptable and the change made, if the principal investigator agrees.

All required signatures (principal investigator, co-principal investigator(s), and organizational representative) with dates must appear in the appropriate location(s) on the cover page of the original copy.

### Table of Contents

*Project Summary*

Use the form in Appendix 3 to provide a required 200-word summary, as well as the rest of the information requested on that form. The summary should be

understandable by an intelligent but nonspecialist reader and should be free of jargon and technical terminology that would obscure its meaning. Indicate what is going to be done, why, who and how many will be affected, and the desired outcomes.

*Data Sheet*

The Data Sheet, Appendix 5, must be completed and assembled as the fourth page, following the Project Summary, of the proposal. Some projects may be more complicated than is allowed for on this sheet; please contact the appropriate program to determine the best way to complete it.

*Supplementary Information Sheet*

See Appendix 4. (PLEASE NOTE: One copy only of this sheet is to be clipped to the face page of the Signature Copy; this information sheet is *NOT* to be assembled as part of each copy of the proposal.)

*Project Description*

This main body of the proposal should be a detailed, but succinct, statement of the project to be carried out. The project description should normally not exceed 15 single-spaced pages. (The equivalent of 30 double-spaced pages is acceptable.) The description can be amplified by material in appendixes, but the body should stand alone to give a complete picture of the project.

The project description should describe the particular and peculiar needs to be met by the project and how they were determined. The solution proposed should be sketched in broad outline together with a rationale for this choice over any others that might be available. A detailed description of the project activities should be presented that shows how each part is related to the overall project and the expertise required to carry out each part. A timetable, including personnel time commitments, for the project activities is useful as a summary. There should be concrete statements concerning the expected outcomes of the project and the means that will be used to assess whether they have been achieved.

Use the suggested proposal evaluation criteria provided with the description of each program and the more general criteria in Section IV to determine the sort of details that need to be provided to facilitate effective review.

*Bibliography of Pertinent Literature*

The objective is to determine whether proposers are familiar with the work of others that has bearing on the proposed project's design, methods, aims, and content.

*Biographical Sketches*

A complete vita for each principal investigator should be submitted as well as abbreviated vitae for other personnel who will perform major roles in the implementation of the project. In the interests of brevity and relevance, only the last five years' activities and publications should be stressed for all personnel.

*Budget*

A budget for each year of support requested, as well as a cumulative budget for the full term of the project, must be presented. These budgets must be on the prescribed form, Appendix 6. Additional pages for budget explanation and amplification are necessary and should be attached directly following the budget form(s) in the proposal. The categories and data in the budget explanation must be consistent with those on the form(s). The direct costs of the project should be reasonable with respect to the tasks proposed. All budget requests need to be documented and justified.

As an expression of commitment to the project and the collaborative and cooperative efforts the Foundation seeks to promote, information on cost-sharing by the grantee institution and/or others with which it has formed partnerships should be provided in as much detail as possible. Contributions to cost-sharing must be in categories that are eligible for Foundation funding in these programs; for example, instructional salaries and supplies are eligible, whereas capital expenditures and office equipment are not.

*Stipends*: A direct stipend to participants of *up to* $40 per day for *full-time* project activity is allowable from NSF funds or as a cost-sharing contribution. The amount of the stipend should be justified in the proposal. In arriving at the figure, the project director should take into account various factors that may be involved in a particular project including the answers to questions such as: Is the level of activity part-time or full-time? Does participation in the project preclude summer employment? Is academic credit being awarded?

Funds to defray the costs for participant room and board and travel from home to the project site may be requested from NSF or included as a cost-sharing contribution. Requests for other participant support must be strongly justified.

*Tuition:* Tuition is not allowed as a project cost, if the NSF is already paying instructional costs. Similarly, if the NSF is paying instructional costs, tuition waiver cannot be counted as an institutional contribution to the project. In no case may participants be charged tuition for credits obtained based on project activities.

*Current and Pending Support*

See Appendix 7 for the appropriate form. All support for research and education projects that occupy the time of the Project Director and principal staff must be included. You may find that extensive footnotes are necessary to explain your activities and their support. This form is applicable to *all* projects, since item I.B.1. asks for a listing of the proposal being submitted and failure include this form can slow up the award of a grant.

**Appendixes**

**How and Where to Submit**

*Intergovernmental Review*

Many states have elected to review proposals submitted to Federal agencies by prospective grantees from that state. Pursuant to Executive Order 12372 ("Intergovernmental Review of Federal Programs") and the implementing NSF regulations **Federal Register**, Volume 48, No. 123, June June 24, 1983, pp. 29358–29366), the NSF has established a procedure for ensuring review of proposals by states when applicable. Programs described in this announcement are eligible for review by electing states under E.O. 12372.

Proposers from states electing to review proposals must submit their proposals to the state's single point of contact (SPOC) for review prior to or simultaneously with submission to the NSF. (See Appendix 8 of this program announcement for a list of states electing to review and their SPOC.) No grant award will be made by the NSF unless the state has had an opportunity to review the proposal for a period of 60 days. Please supply the number assigned by the state to your proposal at the bottom of the Data Sheet, Appendix 5.

Questions relating to NSF's implementation of E.O. 12372 should be directed to the NSF Intergovernmental Review Officer at (202) 357–7880.

*Proposal Submission*

Fifteen (15) complete copies of the proposal and three (3) additional copies of the Cover Sheet and Project Summary should be prepared and sent to:

Data Support Services Unit, National Science Foundation, Washington, DC 20550.

**Grant Administration**

NSF grants are administered in accord with the terms and conditions of NSF Form Letter 200, Grant General Conditions, copies of which may be requested from the NSF Forms and Publications Unit.

Beacuse of the nature of some precollege projects, proposers may wish to familiarize themselves with NSF policy in two particular areas:

• Where educational materials are outcomes, the GSER should be consulted with respect to inventions, software, and copyrights.

• Where precollege students are to be inolved in research or in the development of materials, awards are subject to the provisions of 2 U.S.C. 1869 (a) and (b) ("Myers Amendment" and "Dornan Amendment"). The provisions of law require appropriate grantee coordination with parents, guardians, and school district officials.

The awardee is wholly responsible for the conduct of projects, including the research and development of materials and the preparation of project results for publication. The Foundation does not assume responsibility for such findings nor their interpretation, but expects an acknowledgement of support in all published materials resulting from funded projects.

**Inquiries**

Questions not addressed in this publication may be directed to the NSF staff by writing to:

Division of Teacher Enhancement and Informal Science Education, Directorate for Science and Engineering Education, National Science Foundation, Washington, DC 20550.

For telephone inquiries (Area Code: 202):

| | |
|---|---|
| Leadership Activities for precollege teachers program | 357–7074 |
| Local and regional teacher development program | 357–7539 |
| Science and mathematics education networks program | 357–7078 |
| Informal Science Education Program | 357–7076 |
| Division Office | 357–7073 |

**Related Programs**

Information on other NSF programs in science education may be obtained by contacting: (1) The *Division of Materials Development and Research* (for information on Instructional Materials Development, Materials and Methods for Teacher Preparation, Applications of Advanced Technologies, and Research in Teaching and Learning); (2) *Office of College Science Instrumentation* (for information on the College Science Instrumentation Program); (3) *Office of Studies and Program Assessment* (for information on the Studies and Analyses Program; or (4) the *Division of Research Career Development* (for information on graduate and minority graduate research fellowships, NATO postdoctoral fellowships, Presidential Young Investigator Awards, and other graduate and postdoctoral programs).

**IV. PROPOSAL EVALUATION**

NSF evaluates proposals on the basis of the four general criteria below. Also indicated are additional factors to be considered. These are intended to amplify the general criteria, where appropriate.

1. *Instrinsic Merit* This criterion is used to assess the likelihood that the project will advance or have substantial impact on precollege mathematics, science, and technology education.

2. *Performance Competence* This criterion relates to the capability of the proposers, the soundness of the proposed approach, and the adequacy of the resources available to carry out the project. With respect to this criterion, consider such factors as:

• *Plan:* Does the project appear workable, cost-effective, and appropriate relative to the target problems and the impact anticipated? Are factors like the selection of participants and the provision of academic credit, or the equivalent, provided to successful participants adequately described and thought out? Is the plan integrated with other local efforts to improve the quality of mathematics or science education? Is the plan for continuation of the project beyond NSF support credible? Are the evaluation plans reasonable? Does the proposed project include realistic mechanisms which will lead to widespread dissemination of instructional materials or other project results?

• *Personnel:* Are needed personnel, such as mathematicians, scientists, engineers, active teachers, science educators, officials of state and local education agencies, and persons from the private sector (such as industrial scientists) included in the project?

3. *Utility or Relevance of the Project* This criterion is used to assess the likelihood that the project can contribute to meeting specific needs in precollege mathematics, science, and technology education. Consider such factors as:

• *Impact:* Does the project have potential for significantly strengthening the Nation's science and mathematics education? Is the approach scientifically and educationally sound? Have the cooperating school system adequately examined and defined their teachers' needs? Is the project likely to deal effectively with the problem(s) and improve the quality of teaching? Does the project employ a particularly creative approach that might serve as a model for others with similar problems?

• *Products:* Will the project result in quality products such as instructional materials or models and plans for wider impact?

4. *Effect on the Infrastructure of Science and Engineering* This criterion relates to the potential of the proposed project to contribute to better understanding or improvement of the quality, distribution, or effectiveness of the Nation's scientific and engineering research, education, and manpower base. Consider such factors as:

• *Cooperative Relationships:* Has a reasonable working relationship among the cooperating parties been defined? Does the proposal contain letters of agreement or other evidence of workable relationships? Will the project encourage and facilitate better working relationships between cooperating school systems and their teachers and the scientists and educators of cooperating colleges, universities, cultural institutions, the media, and industry? Will the project develop long-term relationships with institutions that can supplement and support the quality of precollege mathematics and science teaching?

• *Contributions:* Does the proposal include appropriate contributions from the private sector, state or local educational agencies, colleges or universities, scientific or teaching professional societies, and other sources?

• *Balance:* does the project reflect awareness of the needs and potential of the diverse teacher and student population of the Nation such as the gifted and talented, women, minorities, and physically disabled, disadvantaged, and students not intending careers in science and engineering?

Proposals will be reviewed for scientific and educational merit by scientists, science educators, and others knowledgeable in the fields represented by the proposal. Until a decision is announced, no information can be provided on the probability of support. Every effort is made to reach a decision and inform the applicant promptly. Notification of award is made in writing by the Foundation. Organizations whose proposals are unsuccessful will be the Foundation. Organizations whose proposals are unsuccessful will be advised as promptly as possible. Verbatim copies of reviews not

including the identity of the reviewers, will be made available to prospective project directors.

Dated: February 15, 1985.

**Alan I. Leshner,**

*Acting Division Director, Teacher Enhancement and Informal Science Education.*

[FR Doc. 85-4302 Filed 2-21-85; 8:45 am]

BILLING CODE 7555-01-M

## NUCLEAR REGULATORY COMMISSION

**[Docket Nos. 50-317 and 50-318]**

### Baltimore Gas and Electric Co. (Calvert Cliffs Nuclear Power Plant Unit Nos. 1 and 2); Exemption

I

The Baltimore Gas and Electric Company (the licensee) is the holder of Facility Operating License Nos. DPR-53 and DPR-69 which authorize operation of the Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2. These licenses provide, among other things, that they are subject to all rules, regulations and Orders of the Commission now or hereafter in effect.

The facility comprises two pressurized water reactors at the licensee's site located in Calvert County, Maryland.

II

Appendix J to 10 CFR Part 50, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors," includes schedular and technical requirements for the conduct of "Type A" reactor containment Integrated Leak Rate Tests (ILRTs). With regard to schedule for ILRTs, Appendix J, section II.D.1.(a) requires that ". . . three Type A tests shall be performed, at approximately equal intervals during each 10-year service period. The third test of each set shall be conducted when the plant is shutdown for the 10-year plant inservice inspections."

The currently scheduled 10-year Inservice Inspection (ISI) outage would be in the fall of 1986 for Unit 1 and in the spring of 1987 for Unit 2. Performance of the third ILRT during the 10-year ISI outage, which is required by Appendix J, would result in the violation of the 40±10-month interval which is also required by Appendix J. Accordingly, by application dated September 14, 1984 the licensee requested a "one time only" change to the ILRT schedule, as specified in Appendix J, section III.D.1.(a) to allow the third ILRT to be conducted during the spring 1985 and fall 1985 refueling outages for Units 1 and 2, respectively. The proposed schedule would satisfy the 40±10-month inspection interval requirement of Appendix J which is deemed to be of primary importance in the maintenance of containment integrity via the ILRT program. The coincidence of the third ILRT with the 10-year ISI outage is of clearly secondary importance for this "one time only" schedule change.

III

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, an exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest and hereby grants the following exemptions with respect to the requirements of Appendix J to 10 CFR Part 50:

With regard to the third ILRT of the first 10-year service period, this test shall be conducted on the following schedule:

- Unit 1—during the spring 1985 refueling outage.
- Unit 2—during the fall 1985 refueling outage.

Pursuant to 10 CFR 51.32 the Commission has determined that the issuance of the exemption will have no significant impact on the environment (50 FR 4284).

Dated at Bethesda, Maryland this 14th day of February 1985.

For the Nuclear Regulatory Commission.

**Frank J. Miraglia,**

*Acting Director, Division of Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 85-4434 Filed 2-21-85; 8:45 am]

BILLING CODE 7590-01-M

**[Docket No. 374]**

### Commonwealth Edison Co.; Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF-18, issued to Commonwealth Edison Company (the licensee), for operation of the LaSalle County Station, Unit 2 located in LaSalle County, Illinois.

The amendment would revise License Condition 2.C.(5) to incorporate a November 30, 1985 deadline for the environmental qualification of all safety-related electrical equipment. Section 50.49(i) of the Commission's Regulations, which is applicable to the LaSalle County Station, Unit 2, does not require the March 31, 1985 deadline currently in the license. The licensee indicates that the total number of components requiring qualification for Unit 2 to 10 CFR 50.49 requirements are 745, 656 of which will be qualified prior to March 31, 1985. Specifically, an extension up to November 30, 1985 is being requested for the following items:

1. Fifty (50) Limitorque Valve Motor Operators,
2. Four (4) S&K Flow Elements,
3. Two (2) Delphi Hydrogen-Oxygen Analyzer Panels,
4. The Atomics International Hydrogen Recombiner,
5. Six (6) Klockner-Moeller AC Motor Control Centers,
6. Eight (8) Magnetrol Level Switches, and
7. Eighteen (18) General Electric Terminal Boards.

For the above items, the licensee has previously submitted Justification for Interim Operation (JIO's) which have addressed the requirements of 10 CFR 50.49 and will remain valid through November 30, 1985. The discussions in these JIO's ensure that the plant can be safely operated pending completion of equipment qualification. The staff has concluded that the licensee has demonstrated conformance with the qualification requirements of 10 CFR 50.49 (Supplement No. 5 to the LaSalle County Station, Units 1 and 2 Safety Evaluation Report NUREG-0519, section 3.11). Precedents have been set regarding recently issued operating licenses that included November 30, 1985 qualification deadline. In particular, Facility Operating License NPF-23 for Byron Station, Unit 1, issued subsequent to NPF-18 (LaSalle Unit 2), has a November 30, 1985 environmental qualification deadline. This amendment is in accordance with the licensee's application for amendment dated January 8, 1985.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from

any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee, in its letter of January 8, 1985, stated that the proposed change does not involve a significant increase in the probability or consequences of an accident or other adverse condition over previous evaluations; nor create the possibility of a new or different kind of accident or condition over previous evaluations; nor involve a significant reduction in a margin of safety. Based on the foregoing, the requested amendment does not present a significant hazard. The Commission has provided guidance concerning the application of the Standards in 10 CFR 50.92 by providing certain examples (48 FR 14870). This amendment request is similar to the example of an action involving no significant hazards consideration which relates to a change to make the license conform to regulations, where the license amendment results in very minor changes to facility operations clearly in keeping with the regulations. The staff has made a significant hazards determination and has concluded that this amendment request does not result in a significant hazards consideration because previously submitted JIO's which have addressed the requirements of 10 CFR 50.49(i) will remain valid through November 30, 1985. The discussions in these JIO's ensure that the plant can be safely operated pending completion of equipment qualification.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Comments should be addressed to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attn: Docketing and Service Branch.

By March 25, 1985, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to A. Schwencer: Petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this Federal Register notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Isham, Lincoln, and Burke, Suite 840, 1120 Connecticut Avenue, NW., Washington, D.C. 20036, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions,

supplemental petitions and/or requests for hearing will not be entertained absent as a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the Public Library of Illinois Valley Community College, Rural Route No. 1, Ogelsby, Illinois 61348.

Dated at Bethesda, Maryland, this 19th day of February 1985.

For the Nuclear Regualtory Commission.

**Byron Siegel,**

*Acting Chief, Licensing Branch No. 2, Division of Licensing.*

[FR Doc. 85–4436 Filed 2–21–85; 8:45 am]

BILLING CODE 7590-01-M

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**[Docket No. 50-389]**

## Florida Power and Light Company, et al., St. Lucie Plant, Unit No. 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Operating License No. NPF–16 to Forida Power and Light Company, Orlando Utilities Commission of the City of Orlando, Florida, and Florida Municipal Power Agency (the licensees), for St. Lucie Plant, Unit No. 2 located in St. Lucie County, Florida.

### Environmental Assessment

*Identification of Proposed Action:* The amendment would consist of a change to the TS appended to Facility Operating License No. NPF–16 that would allow changing the power level at which the unit can operate from 2560 Mwt to 2700 Mwt.

The proposed amendment would be responsive to the licensee's application for amendment dated November 21, 1984.

*The Need for the Proposed Action:* St. Lucie Plant, Unit No. 2 was designed, like its sister unit, St. Lucie Plant, Unit No. 1, to operate at 2700 Mwt. Historically, licensees have applied for their operating licenses at a power level of about 5% below the design power level. This is done with an intent to ask for the increase to design power after a period of operation at the lower level. St. Lucie 1, with an identical Nuclear Steam Supply System, was authorized to increase its operating power level to 2700 Mwt in Amendment No. 48 dated November 23, 1981.

*Environmental Impacts of the Proposed Action:* The environmental impacts of operating St. Lucie 2 at 2700 Mwt were addressed in the Final Environmental Statement issued in conjunction with the construction permit review. The Final Environmental Statement was issued in May 1974 and was based on operating both units at St. Lucie at 2700 Mwt. Since there will be no increase in the release of either radiological or non-radiological substances over those used in the May 1974 Final Environmental Statement, the conclusions in that statement are still valid. The Final Environmental Statement for the operation of St. Lucie 2 was issued in April 1982. The assessments found in the April 1982 statement supplement those described in the May 1974 Final Environmental Statement.

The Notice of Consideration of Issuance of Amendment and Opportunity for Prior Hearing in connection with this action was published in the **Federal Register** on December 26, 1984 (49 FR 50131). Since the proposed change involves an increase in the operating level from 2560 Mwt to 2700 Mwt, the Commission did not propose to determine that this action involved no significant hazards considerations. No request for hearing or petition for leave to intervene was filed following this notice.

The Commission has reviewed this proposed action relative to the requirements set forth in 10 CFR Part 51. Based upon this review, the Commission has concluded that post-accident radiological releases would not be greater than previously determined nor does the proposed change otherwise affect radiological plant effluents, and there is no significant increase in occupational exposures. Therefore, the Commission concludes that there are no significant radiological environmental impacts associated with this proposed amendment.

With regard to potential non-radiological impacts, the proposed change to the TS involves systems located entirely within the restricted area as defined in 10 CFR Part 20. It does not affect non-radiological plant effluents and has no other environmental impact. Therefore, the Commission concludes that there are no significant non-radiological environmental impacts associated with the proposed amendment.

*Alternative to the Proposed Action:* Since we have concluded that there is no measureable environmental impact associated with the proposed change to the TS, any alternatives to this change will have either no environmental impact or greater environmental impact.

The principal alternative would be to deny the requested amendment. This would not reduce environmental impacts of plant operation and would result in reduced operational flexibility.

*Alternate Use of Resources:* This action does not involve the use of resources not previously considered in connection with the NRC Final Environmental Statements issued in May 1974 and April 1982 related to this facility.

*Agencies and Persons Consulted:* The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

### Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed license amendment.

Based upon the foregoing environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see (1) the application for amendment dated November 21, 1984, (2) the Final Environmental Statement (Construction Permit Stage) dated May 1974, and (3) the Final Environmental Statement (Operating License Stage) dated April 1982, which are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the Indian River Junior College Library, 3209 Virginia Avenue, Fort Pierce, Florida.

Dated at Bethesda, Maryland this 15th day of February 1985.

For the Nuclear Regulatory Commission.

**Gus C. Lainas,**

*Assistant Director for Operating Reactors, Division of Licensing.*

[FR Doc. 85–4435 Filed 2–21–85; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-388]

## Pennsylvania Power & Light Co.; Consideration of Issuance of Amendment to Facility Operating License and Propose No Significant Hazards Consideration Determination and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF-22, issued to Pennsylvania Power & Light Company (the licensee), for operation of the Susquehanna Steam Electric Station, Unit 2 located in Luzerne County, Pennsylvania.

The proposed amendment is to revise License Condition 2.C.(7) of Facility Operating License NPF-22 to incorporate a November 30, 1985 deadline for the environmental qualification of certain safety-related electrical equipment. Section 50.49(i) of the Commission's Regulation, which is applicable to the Susquehanna Steam Electric Station, Unit 2, does not require the March 31, 1985 deadline currently in the license. The licensee in their letter of January 30, 1985 stated that the equipment for which qualification will not be completed by March 31, 1985 can be divided into two categories: (1) equipment for which testing will not be completed, and (2) equipment for which modification is required in order to satisfy qualification requirements.

Specifically an extension up to November 30, 1985 is being requested for the following items:

1. Conduit Seals;
2. Silicon Rubber Insulated Cable;
3. Anaconda NSIS FR-EP Cable;
4. SGTS Radiation Monitors;
5. PDSL Switches in Common Plenum
6. Solenoid Valve SV-22651;
7. Sensor and Converter D12-NO17A&B; and
8. Differential Pressure Switch PDSL07544A,B.

For the above items, the licensee has previously submitted and iterated again in their letter of January 30, 1985, the Justification for Interim Operation (JIO's) which have addressed the requirements of 10 CFR 50.49 and will remain valid through November 30, 1985. The discussion of these JIO's insure that the plant can be safely operated pending completion of equipment qualification. The staff has concluded that the licensee has demonstrated conformance with the qualification requirements of 10 CFR 50.49 (Supplement No. 6 to Susquehanna Steam Electric Station, Units 1 & 2 Safety Evaluation Report, NUREG-0776, sections 3.11). Precedents have been set regarding recently issued operated licenses that included November 30, 1985 qualification deadline. In particular, Facility Operating License NPF-23 for Byron Station, Unit 1, issued subsequent to NPF-22 (Susquehanna, Unit 2), has a November 30, 1985 environmental qualification deadline.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability of consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluted; or (3) involve a significant reduction in a margin of safety.

The Commission has provided guidance concerning the application of the Standards in 10 CFR 50.92 by providing certain examples (48 FR 14870). This amendment request is similar to example (vii) of amendments that are not likely to involve significant hazards considerations. Specifically, example (vii) relates to a change to make the license conform to changes in the regulations, where the license amendment results in very minor changes to facility operations clearly in keeping with the regulations. Since previously submitted JIO's which have addressed the requirements of 10 CFR 50.149(i) ensure that the plant can be safely operated pending completion of equipment qualification and will remain valid through November 30, 1985, and because this amendment request is similar to example (vii), the staff has concluded that this amendment request does not result in a significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Comments should be addressed to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Docketing and Service Branch.

By March 25, 1985, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petitions for leave to intevene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these

requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325–6000 (in Missouri (800) 342–6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to A. Schwencer: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Jay Silberg, Esquire, Shaw, Pittman, Potts & Trowbridge, 1800 M Street, Washington, D.C. 20036, attorney for the licensee.

Nontimely filings of petitions for leave to invervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701.

Dated at Bethesda, Maryland, this 19th day of February 1985.

For the Nuclear Regulatory Commission.

**Byron Siegel,**

*Acting Chief, Licensing Branch No. 2, Division of Licensing.*

[FR Doc. 85–4432 Filed 2–21–85; 8:45 am]

BILLING CODE 7590-01-M

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**[Docket No. 50-397]**

## Washington Public Power Supply System; Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–21, issued to Washington Public Power Supply System (the licensee), for operation of the WNP–2 located in Richland, Washington.

The purpose of the proposed amendment request is to revise License Condition 2.C.(16), Attachment 2, Item 3(b) of Facility Operating License NPF–21 to incorporate a change in deadline for the Regulatory Guide 1.97, Rev. 2 implementation requirements. The revised license condition will read as follows: "The licensee shall implement (installation or upgrade) requirements of Regulatory Guide 1.97, Rev. 2 for flux monitoring prior to startup following the first refueling outage." The licensee in a letter dated August 3, 1983, requested to defer installation of qualified source range monitors (SRM's) until first refueling. The basis was that qualified replacements for the existing SRM's did not then exist in the industry, and that a delay would allow sufficient time to complete qualification of one of several designs being developed at the time. At the time of licensing in December, 1983, the staff approved a fifteen month deferral, to March 31, 1985, instead of the first refueling outage because, in part that was the goal for final environmental qualification of electrical equipment for operating reactors.

The staff recognizes that environmental qualification of SRM's has required an industry research and development program, and has allowed delays in meeting the Commission's requirements on this basis. The licensee's previously-submitted Justification for Interim Operation (JIO) for this equipment remains valid and, in the staff's view, assures safe operation pending installation of a qualified SRM.

Before issuance of the proposed license amendment, the Commission will have made finding required by the Atomic Energy Act of 1985, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee, in its letter of January 11, 1985, stated that the proposed change does not involve a significant increase in the probability or consequences of an accident or other adverse condition over previous evaluations; nor create the possibility of a new or different kind of accident or condition over previous evaluation; nor involve a significant reduction in a margin of safety. The Commission has provided guidance concerning the application of the Standards in 10 CFR 50.92 by providing

certain examples (48 FR 14870). This amendment request is similar to the example of an action involving no significant hazards consideration which relates to a change to make the license conform to regulations, where the license amendment results in very minor changes to facility operations clearly in keeping with the regulations. The staff has made a significant hazards determination and has concluded that this amendment request does not result in a significant hazards consideration because previously submitted JIO which addressed the analysis requirements of 10 CFR 50.49(i) will remain valid through first refueling outage. On this basis the staff concludes that the plant can be safely operated pending installation of qualified SRM's.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Comments should be addressed to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attn: Docketing and Service Branch.

By March 25, 1985, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satifies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to A. Schwencer: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Nicholas Reynolds; Bishop, Cook, Liberman, Purcell and Reynolds, 1200 Seventeenth Street, NW., Washington, D.C. 20036, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the Richland

City Library, Swift and Northgate Streets, Richland, Washington.

Dated at Bethesda, Maryland, this 19th day of February 1985.

For the Nuclear Regulatory Commission.

**Byron Siegel,**

*Acting Chief, Licensing Branch No. 2, Division of Licensing.*

[FR Doc. 85-4431 Filed 2-21-85; 8:45 am]

BILLING CODE 7590-01-M

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**[Docket No. 50-397]**

## Washington Public Power Supply System; Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF-21, issued to Washington Public Power Supply System (the licensee), for operation of the WNP-2 located in Richland, Washington.

The purpose of the proposed amendment request is to revise License Condition 2.C.(28) of Facility Operating License NPF-21 to incorporate a November 30, 1985 deadline for the environmental qualification of safety-related electrical equipment. The licensee in their letter of January 17, 1985 stated that due to recent design changes, delays in procurement, test complications, and installation problems, environment qualification for certain equipment will not be completed by March 31, 1985. Specifically, an extension is being requested for the following items:

1. Level Transmitters: MS-LITS-26A, 26B, 26C, and 25D;
2. Solenoid Valves: PSR-V-X77A/1 and -X77A/3;
3. Remote Manual Switch: RRA-RMS-FN/1, -FN/2 and -FN/3;
4. Electro/Pneumatic Converters: REA-E/P-1A and -1B;
5. Pressure Switch: LPCS-PIS-1;
6. Motor Operator: RCIC-MO-V/63;
7. Motor Operator: RCI-MO-V/1;
8. Valve CIA-V-39A; and
9. LPRM Detectors and Connectors.

For the above items, the licensee has previously submitted or has provided Justification of Interim Operation (JIO's), which have addressed the requirements of 10 CFR 50.49. The staff has reviewed these JIO's and agrees with the licensee' assertion that they will support continued operation pending completion of environmental qualification. In addition, the licensee has indicated that the qualification requirements of certain equipment in the Reactor Core Isolation Cooling System will not be completed by March 31, 1985. The licensee plans to complete the qualification of all equipment in accordance with the requirements of § 50.49 during the scheduled outage starting April, 1985 but no later than November 30, 1985.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The licensee, in his letter of January 17, 1985, stated that the proposed change does not involve a significant increase in the probability or consequences of an accident or other adverse condition over previous evaluations; nor create the possibility of new or different kind of accident or condition over previous evaluations; nor involve a significant reduction in a margin of safety. The Commission has provided guidance concerning the application of the standards in 10 CFR 50.92 by providing certain examples (48 FR 14870). This amendment request is similar to the example of an action involving no significant hazards consideration which relates to a change to make the license conform to regulations, where the license amendment results in very minor changes to facility operations clearly in keeping with the regulations. The staff has made a significant hazards determination and has concluded that this amendment request does not result in a significant hazards consideration because previously submitted JIO's and the additional information provided in the January 17, 1985 letter, which have addressed the requirements of 10 CFR 50.49(i) will remain valid through November 30, 1985.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Comments should be addressed to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attn: Docketing and Service Branch.

By March 25, 1985, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to praticipate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement ot the petition to intervene which must include a list of the contentions which are sought to be

litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should cirsumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram identification Number 3737 and the following message addressed to A. Schwencer: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Nicholas Reynolds, Bishop, Cook, Liberman, Purcell, and Reynolds, 1200 Seventeenth Street, NW., Washington, D.C. 20036, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the Richland City Library, Swift and Northgate Street, Richland, Washington, last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram identification Number 3737 and the following message addressed to A. Schwencer: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Nicholas Reynolds, Bishop, Cook, Liberman, Purcell, and Reynolds, 1200 Seventeenth Street, NW., Washington, D.C. 20036, attorney for the licensee.

Dated at Bethesda, Maryland, this 19th day of February 1985

For the Nuclear Regulatory Commission.

**Byron Siegel,**

*Acting Chief, Licensing Branch No. 2, Division of Licensing.*

[FR Doc. 85-4433 Filed 2-21-85; 8:45 am]

BILLING CODE 7590-01-M

## PACIFIC NORTHWEST ELECTRIC POWER AND CONSERVATION PLANNING COUNCIL

### State Agency Advisory Committee; Meeting

**AGENCY:** State Agency Advisory Committee of the Pacific Northwest Electric Power and Conservation Planning Council (Northwest Power Planning Council).

**ACTION:** Notice of meeting to be held pursuant to the Federal Advisory Committee Act, 5 U.S.C. Appendix I, 1–4. Activities will include:

- Outline of Intertie Access Policy.
- Planning Assumptions WNP–1 and –3.
- Preliminary Load Forecasts.
- Hand-out Most Current Issue Papers.

Status: Open.

**SUMMARY:** The Northwest Power Planning Council hereby announces a forthcoming meeting of its State Agency Advisory Committee.

**DATE:** Thursday, February 14, 1985, 9:00 a.m.

**ADDRESS:** The meeting will be held at the Council Conference Room at 850 SW. Broadway; Suite 1100, Portland, Oregon.

**FOR FURTHER INFORMATION CONTACT:** Jim Litchfield, (503) 222-5161.

**Edward Sheets,**

*Executive Director.*

[FR Doc. 85-4374 Filed 2-21-85; 8:45 am]

BILLING CODE 0000-00-M

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. IC-14370 (File No. 812-5561)]**

### Application and Opportunity for Hearing; Legg Mason Tax-Exempt Trust, Inc.

February 12, 1985.

Notice is hereby given that Legg Mason Tax-Exempt Trust, Inc. ("Applicant"), 7 East Redwood Street, Baltimore, MD 21202, registered under the Investment Company Act of 1940 ("Act") as an open-end, diversified, management investment company, filed an application on May 25, 1983, and

amendments thereto on May 14, 1984, and January 11, 1985, requesting an order of the Commission, pursuant to Section 6(c) of the Act, exempting Applicant from the provisions of Section 12(d)(3) of the Act to the extent necessary to permit Applicant to acquire rights to sell it portfolio securities to brokers or dealers ("Stand-by Commitments") and from the provisions of Section 2(a)(41) of the Act and Rules 2a–4 and 22c–1 thereunder to the extent necessary to permit Applicant to value such commitments in the manner described in the application. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below, and to the Act and the Rules thereunder for the complete text of the relevant provisions.

Applicant, states that it a no-load fund whose investment objectives are to provide investors with maximum current income exempt from federal income tax, to maintain liquidity, and to preserve capital. Applicant also states that it currently offers shares in a single investment portfolio which invests primarily in short-term, high quality municipal securities, the interest on which is exempt from federal income tax ("Municipal Securities"). Applicant intends to attempt to maintain a constant net asset value of $1.00 for each of its shares in reliance on Rule 2a–7 under the Act.

Applicant states that it is authorized to purchase Stand-by Commitments which give the Applicant a right to sell the principal amount of Municipal Securities it has purchased from a dealer or other financial institution back to the seller, at the Fund's option, at a specified price. Applicant represents that it intends to acquire Stand-by Commitments solely to facilitate portfolio liquidity. Applicant represents further that it offers its shareholders daily liquidity by ordinarily providing immediately available funds upon redemption of shares by an investor.

According to the application, the Stand-by Commitments will have the following features: (1) They will be in writing and will be physically held by the Applicant's custodian; (2) they may be exercisable by Applicant at any time or during specified periods prior to the underlying security's maturity; (3) they will be entered into only with banks, broker-dealers and other persons which in the investment adviser's opinion present a minimal risk of default; (4) Applicant's right to exercise them will be unconditional and unqualified; (5) although they may not be transferable, municipal obligations purchased subject to the commitments could be sold to a third party at any time, even though the commitment was outstanding; and (6) their exercise price will be (i) Applicant's acquisition cost of the municipal obligations which are subject to the commitment (exluding any accrured interest which Applicant paid on their acquisition), less any amortized market premium or plus any amortized market or original issue discount during the period Applicant owned the securities, plus (ii) all interest accrued on the securities since the last interest payment date during the period the securities were owned by Applicant.

According to the application, because Applicant values its municipal obligations on an amortized cost basis, the amount payable under a Stand-by Commitment will be equal to the value of the underlying security. Applicant submits that there is little risk of an event occuring which would make the amortized cost valuation of its portfolio securities inappropriate; however, in that event, Applicant expects that it may refrain from exercising the Stand-by Commitments to avoid imposing a loss on a dealer and jeopardizing Applicant's business relationship with that dealer.

If necessary and advisable, Applicant proposes to pay for Stand-by Commitments, either separately in cash or by paying a higher price for portfolio securities which are acquired subject to the commitment. Applicant represents that the total amount paid in either manner for outstanding Stand-by Commitments held in its portfolio will not exceed ½ of 1% of the value of its total assets calculated immediately after any Stand-by Commitment is acquired. Applicant states that the proposed acquisition of Stand-by Commitments will not affect Applicant's net asset value per share for purposes of sales and redemptions, but rather will improve its liquidity and ability to pay redemption proceeds. Applicant states further that it will value the Stand-by Commitments at zero, regardless of whether any direct or indirect consideration has been paid; however, if Applicant has paid for a Stand-by Commitment, its cost will be reflected as unrealized depreciation for the period during which it is held.

Applicant asserts that the acquisition of Stand-by Commitments will not meaningfully expose its assets to the entrepreneurial risks of the investment banking business. Applicant submits that its relationship with the dealer will be comparable to a fully collateralized broker-dealer repurchase agreement or security loan. Applicant further asserts that, while the failure of a broker or dealer to fulfill its obligation under the Stand-by Commitment could result in a loss to Applicant, this risk of loss is not different qualitatively from the risk of loss faced by any investment company which is holding securities pending settlement after having agreed to sell the securities to a broker or dealer in the ordinary course of business. Applicant states that its investment adviser will periodically evaluate the credit risks of dealers from whom it will purchase Stand-by Commitments. Applicant states that it will not acquire Stand-by Commitments to promote reciprocal practices, to encourage the sale of its shares or to obtain research services.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than March 11, 1985, at 5:30 p.m., do so by submitting a written request setting forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of the request should be served personally or by mail upon Applicant at the address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. After said date, an order disposing of the application will be issued unless the Commission orders a hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**John Wheeler,**

*Secretary.*

[FR Doc. 85–4347 Filed 2–21–85; 8:45 am]

BILLING CODE 8010–01–M

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**[File No. 22–13587]**

## Trans World Airlines, Inc.; Application and Opportunity for Hearing

February 15, 1985.

Notice is hereby given that Trans World Airlines, Inc. ("Applicant") has filed an application under clause (ii) of Section 310(b)(1) of the Trust Indenture Act of 1939, as amended (the "1939 Act"), for a finding by the Securities and Exchange Commission (the "Commission") that the trusteeships of The Bank of New York (the "Bank") under (i) a Trust Indenture and Mortgage, dated May 1, 1971 (the "Indenture") among Bankers Trust Company, as Owner-Trustee ("Bankers Trust"), Applicant as Guarantor and the

Bank as Indenture Trustee, (ii) an Equipment Trust Agreement, dated October 1, 1979 (the "Equipment Trust") between Applicant and the Bank which provides for the issuance of approximately $100 million aggregate principal amount of Equipment Trust Certificates due May 11, 1990 (the "Equipment Trust"), (iii) an Indenture of Mortgage, dated January 1, 1977 (the "Mortgage") among certain senior lenders, Applicant and the Bank, as Trustee (succeeding the original Trustee, Marine Midland Bank) and (iv) a Note Facility Indenture of Mortgage dated as of January 16, 1984 (the "Facility Mortgage") between the Applicant and the Bank as Trustee, as amended and restated in a Revolving Underwriting Facility Mortgage dated as of November 20, 1984 (the "Restated Facility Mortgage") for the benefit of holders of Promissory Notes, (v) an Indenture of Mortgage, dated as of June 29, 1984 (the "June 1984 Mortgage") between Applicant and the Bank as Trustee for the benefit of holders of Floating Rate Secured Notes due June 29, 1989 and issued under the Loan Agreement, and (vi) an Indenture of Mortgage dated as of December 20, 1984 (the "December 1984 Mortgage") between Applicant and the Bank as Trustee for the benefit of holders of a Second Series of Floating Rate Secured Notes due December 20, 1989 and issued under the Loan Agreement, and of certain additional such Notes which may be issued in the future under supplemental agreements and Chattel Mortgages in substantially the same form, are not so likely to involve a material conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify the Bank from acting as Trustee under the Indenture.

The Application alleges that:

(1) The Commission has previously considered the subject trusteeships, excepting the Restated Facility Mortgage and the December 1984 Mortgage trusteeship, in response to applications submitted on March 12, 1980 (the "1980 Application"), February 15, 1984 as amended on April 6, 1984 (the "February 1984 Application") and August 13, 1984 (the "August 1984 Application") of the Applicant, in each case under Section 310(b)(1), clause (ii), of the 1939 Act. By Orders dated May 28, 1980 in File No. 22–10302, March 30, 1984 as amended on May 17, 1984 in File No. 22–12976, and October 2, 1984 in File No. 22–13244, the Commission found that the Bank's trusteeships, as well as an agency appointment under a certain Pledge Agreement (which terminated by full payment of the secured obligation thereunder on August 15, 1983), were not so likely to involve a material conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify the Bank from acting as Trustee under the Indenture. Insofar as the Restated Facility Mortgage is concerned, the Commission's Order in response to the February 1984 Application specifically provided that the Facility Mortgage, which was defined to include "a possible, future long term facility arrangement", was also not so likely to involve such a material conflict of interest.

(2) The Indenture was qualified under the 1939 Act and filed with the Commission as Exhibit 4(a)–17 to the Registration Statement (Registration No. 2–40077) which Applicant filed to register the 11% Guaranteed Loan Certificates due June 1, 1986 (the "Loan Certificates") under the Securities Act of 1933, as amended (the "1933 Act"). There were outstanding, on December 31, 1984, $9,946,000 in aggregate principal amount of Loan Certificates, payment of which is guaranteed by the Applicant and is secured by the mortgage of three Boeing 747–131 aircraft which were purchased in part by the proceeds of the sale of the Loan Certificates. Additional funds were provided by certain banking and financial institutions (the "Owners") for whom Bankers Trust acts as Owner-Trustee. The three aircraft have been leased to Applicant by Bankers Trust for terms ending on May 31, 1986. After the Loan Certificates have been paid in full, the three aircraft will remain the property of the Owners subject to certain rights of Applicant to acquire them at fair market value when the lease expires. Thus, the Indenture will terminate in accordance with its terms in approximately sixteen months time.

(3) Applicant and the Bank, as trustee, entered into the Equipment Trust in connection with the purchase of three Boeing 747 SP–31 aircraft (the "Aircraft") delivered in March and April of 1980. The Equipment Trust covering the Aircraft secures the Equipment Trust Certificates which are guaranteed by Applicant and were issued in private placements on the respective delivery dates of the Aircraft. The Equipment Trust Certificates have not been registered under the 1933 Act since the sales thereof have not involved public offerings and are therefore exempt under the 1933 Act. The Aircraft are leased to Applicant by the Bank for terms ending in 1990. At the termination of the lease, the lease payments will be treated as payment in full of the purchase price of the Aircraft and title to all the Aircraft will vest in Applicant. On July 27, 1984, Applicant sold one of the three Aircraft and the aggregate principal amount of Equipment Trust Certificates outstanding was reduced on a pro-rata basis in accordance with the ratio that the original purchase price of such Aircraft bore to the original purchase price of all three Aircraft. A contract covering the sale of a second Boeing 747 SP–31 Aircraft has been executed by both the buyer and the seller and the Closing on this transaction is scheduled to take place on February 15, 1985. At that time, the aggregate principal amount of Equipment Trust Certificates outstanding will be further reduced on a pro-rata basis in the same manner as for the Aircraft sold on July 27, 1984. The one remaining Boeing 747 SP–31 Aircraft is "For Sale", thereby making it more than likely that the Equipment Trust will be terminated well in advance of its expiration date in 1990.

(4) The Bank is successor to Marine Midland Bank as Trustee for certain of Applicant's senior lenders under the Mortgage, by which Applicant has mortgaged substantially all aircraft and aircraft engines (together with appliances from time to time installed) owned by Applicant on March 1, 1977, as more particularly described in the granting clauses thereof. As of December 31, 1984, Applicant owned 38 jet aircraft subject to the lien of the Mortgage, and the aggregate principal amount of the outstanding Notes held by the senior lenders secured thereunder was approximately $3.3 million. The Mortgage is not qualified under the 1939 Act and was filed with the Commission as Exhibit 1 to the March 1, 1977 Form 8–K filed by Applicant. The Mortgage secures Applicant's senior indebtedness currently outstanding under, or that may be issued pursuant to, certain senior debt instruments. The Mortgage has been amended by six supplemental indentures, the first five being on file with the Commission as Exhibits 3(c)-2 and 3(c)-3 of Applicant's January 25, 1979 Form 8–B and Exhibit 4(b)-3 to File No. 2–77852. The sixth supplemental indenture is set forth in Exhibit B to the February 1984 Application.

(5) The Facility Mortgage established an additional trusteeship for the Bank commencing on February 1, 1984. It secured promissory notes issued under a Note Facility Agreement, dated as of January 16, 1984 with Merrill Lynch International & Co. (the "Note Facility"). The maturity date of the last of the promissory notes issued under the Facility Mortgage was June 21, 1984.

Thereafter, as contemplated by the parties to the Facility Mortgage and as set forth in Paragraph 6 of the February 1984 Application, Applicant entered into a Revolving Underwriting Facility Agreement dated November 12, 1984 (the "Revolving Note Facility") with Merrill Lynch International & Co. acting as Placing Agent for a syndicate of foreign International Banks, and the Facility Mortgage was replaced by the Restated Facility Mortgage between Applicant and the Bank as set forth in the preamble to the latter document. The Revolving Note Facility and the Restated Facility Mortgage provide for the issuance of promissory notes (the "Promissory Notes"), in an aggregate principal amount at any time outstanding of up to $75 million, subject to increase in accordance with the terms of the Revolving Note Facility, and as of December 31, 1984, such Notes in the amount of $17.5 million had been issued and were outstanding. Because the sale of Promissory Notes under the Revolving Note Facility does not involve a public offering, the offering is not required to be registered with the Commission under the 1933 Act and the Restated Facility Mortgage is not required to be qualified under the 1939 Act.

(6) The June 1984 Mortgage established an additional trusteeship for the Bank commencing on June 29, 1984 securing five year Floating Rate Notes of TWA (the "Floating Rate Notes") in the aggregate principal amount of $25 million issued under a Loan Agreement between C.C. Leasing Corporation and Goldome FSB as Lenders, and TWA. Because the sale of the Floating Rate Notes is a private replacement, the offering is not required to be registered with the Commission under the 1933 Act and the June 1984 Mortgage is not required to be qualified under the 1939 Act. The amount borrowed was not increased on or prior to December 31, 1984, the expiration date of Applicant's right to request such increases, and the property initially mortgaged under the June 1984 Mortgage is, as specified in Schedule I thereto, two used Boeing Model 727-31 aircraft and two used L-1011 aircraft.

(7) The December 1984 Mortgage transaction is virtually identical to that of June 1984. It establishes a new trusteeship for the Bank commencing on December 20, 1984 securing a second series of five year Floating Rate Notes of TWA (the "Second Series Notes") in an aggregate principal amount of $35 million issued under a Loan Agreement between Walter E. Heller & Company and The Philadelphia Saving Fund Society as Lenders, and TWA. Because the sale of the Second Series Notes is a private placement, the offering is not required to be registered with the Commission under the 1933 Act and the December 1984 Mortgage is not required to be qualified under the 1939 Act. Thus far, cash deposits in the Aviation Property Fund (as defined in the December 1984 Mortgage) have been made to secure the Second Series Notes on a one-to-one basis, but TWA has the right, at any time, to change the security for such Notes to aircraft, aircraft engines, or a combination of cash, aircraft and aircraft engines, on the terms and conditions specified in the December 1984 Mortgage. These include the substitution of aircraft and aircraft engines under certain circumstances.

(8) The December 1984 Mortgage may also in the future serve as the vehicle for a proposed additional credit facility to be created between Applicant and other financial institutions (not including the Bank), on or prior to June 30, 1985. That facility will also involve the issuance of additional Second Series Notes up to a maximum principal aggregate amount of $15 million, bringing the total maximum amount of all such Notes to $50 million. Any such additional Second Series Notes are to have maturity dates of December 20, 1989 and the December 1984 Mortgage provides flexibility for the addition or removal of mortgaged property, provided that 66⅔% of the appraised value thereof plus 100% of the cash included in an Aviation Property Fund is not less than the aggregate amount of Second Series Notes outstanding, except in the case of Applicant's making of certain prepayments or cash payments in connection therewith. Thus, additional aircraft or aircraft engines can readily be added to the December 1984 Mortgage to secure an increase in outstanding credit up to the $50 million maximum. Additional property to be placed under the December 1984 Mortgage would not be subject to any other mortgage or lien encumbrance for which the Bank has a trusteeship. In submitting this Application, TWA requests that the Commission issue its Order with respect to the Bank's role as Trustee under the December 1984 Mortgage, recognizing that it may, in the future, secure additional Second Series Notes.

(9) Applicant believes that no material conflict of interest will result from the Bank acting as Trustee under the Indenture, the Equipment Trust, the Mortgage, the Restated Facility Mortgage, the June 1984 Mortgage and the December 1984 Mortgage. Each covers, or in the case of the December 1984 Mortgage, will cover, wholly separate and distinct collateral consisting of identified aircraft and aircraft engines. In the event that the Bank should have the occasion to proceed against the security of any one or more of these instruments, such action would not affect the security, or the use of any security, under any of the others. As a result, Applicant believes that the Bank, in serving as Trustee under the Indenture, the Equipment Trust, the Mortgage, the Restated Facility Mortgage, the June 1984 Mortgage and the December 1984 Mortgage, and, more importantly, in taking action on behalf of the securityholders or the senior lenders with respect to their separate security under each of these instruments, will not be placed in a situation in which the potential for a material conflict of interest would arise.

(10) Applicant believes that the Bank's serving as Trustee in the subject trusteeships will be beneficial to the holders of the Loan Certificates, the holders of the Equipment Trust Certificates, the senior lenders, the holders of the Promissory Notes, the holders of the Floating Rate Notes and the holders of the Second Series Notes, in that the operations of the Equipment Trust, the Mortgage, the Restated Facility Mortgage, the June 1984 Mortgage and the December 1984 Mortgage would be simplified if the Trustee acting under the Indenture can act as the Trustee under those instruments as well. The specialized nature of the Indenture, the Equipment Trust, the Mortgage, the Restated Facility Mortgage, the June 1984 Mortgage and the December 1984 Mortgage, is such that Applicant believes that the holders of the Loan Certificates, the holders of Equipment Trust Certificates, the senior lenders, the holders of the Promissory Notes, the holders of Floating Rate Notes, the holders of Second Series Notes and Applicant would benefit by having a common trustee familiar with the operation of the Applicant under the Indenture, the Equipment Trust, the Mortgage, the Restated Facility Mortgage, the June 1984 Mortgage and the December 1984 Mortgage.

(11) The Indenture contains the provisions permitted by the proviso of Section 310(b)(1) of the 1939 Act which allow Applicant to make the application under Section 310(b)(1)(ii). Applicant is not in default under the Indenture, the Equipment Trust, the Mortgage, the Restated Facility Mortgage, the June 1984 Mortgage, the December 1984

Mortgage or any other indenture or equipment trust agreement.

Applicant has waived any hearing as well as notice of any hearing and all rights of specified procedures under the rules of practice of the Commission.

For a more detailed account of the matters of fact and law asserted, all persons are referred to said application, which is a public document on file in the offices of the Commission at the Public Reference Room 450, 5th Street NW., Judiciary Plaza, Washington, D.C. 20549.

Notice is further given that any interested person may, not later than March 11, 1985, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of law or fact raised by such application which he desires to controvert; or he may request that he be notified if the Commission should order a hearing theron. Any such request should be addressed to: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. At any time after said date, the Commission may issue an order granting the application upon such terms and conditions as the Commission may deem necessary or appropriate in the public interest and for the protection of investors, unless a hearing is ordered by the Commission.

For the Commission, pursuant to delegated authority, by the Division of Corporation Finance.

**Shirley E. Hollis,**

*Assistant Secretary.*

[FR Doc. 85-4346 Filed 2-21-85; 8:45 am]

BILLING CODE 8010-01-M

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**[Release No. 21748; SR-CBOE-85-2]**

## Self-Regulatory Organization; Chicago Board Options Exchange, Inc., Filing and Order Granting Accelerated Approval of Proposed Rule Change

February 12, 1985.

The Chicago Board Options Exchange, Incorporated ("CBOE") LaSalle at Van Buren, Chicago, IL 60605, submitted on January 24, 1985, copies of a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, to permit the sales personnel of a member organization who solicit or accept customer orders for options on government securities to qualify for such sales activity by successfully completing the CBOE's Interest Rate Options Qualification Examination ("Series 5 examination"). In addition, the rule provides that trading of government securities options within a branch office may be supervised by any Debt Registered Options Principal within the member organization.

Under Rule 21.19A, as amended, in order to conduct a public customer business in options on government securities, sales personnel will no longer be required to pass the General Securities Registered Representatives Examination ("Series 7 examination"), in addition to passing the Series 5 examination. The Exchange believes that, heretofore, the need to pass both examinations as a prerequisite to conducting a public customer business in government securities options, had the effect of discouraging many competent sales personnel in government securities from offering their customers the supplementary investment of options on these securities. The Exchange believes the rule change will permit more widespread public customer access to options on government securities.[1] CBOE indicates that the Series 7 examination would continue to be required if a sales person wishes to engage in a broader public customer securities business.

The rule change also would delete the requirement that every branch of a member organization where three or more registered representatives conduct a government securities option business have a principal supervisor who is a Debt Registered Options Principal. The Exchange believes that experience has shown this to be an unnecessary and burdensome requirement. The Exchange believes that member organizations, given their overall supervisory responsibilities, will assure that each registered representative with a government securities options business is appropriately supervised by a Debt Registered Options Principal.[2]

Interested persons are invited to submit written data, views and arguments concerning the proposed rule change within 21 days from the date of publication of the submission in the **Federal Register**. Persons desiring to make written comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549. Reference should be made to File No. SR-CBOE-85-2.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change which are filed with the Commission and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room, Washington, D.C. Copies of the filing and of any subsequent amendments also will be available at the principal office of the CBOE.

The Commission finds the proposed rule change consistent with the requirements of the Act and the rules and regulations thereunder applicable to a self-regulatory organization and, in particular, the requirements of Section 6. The Commission finds good cause for approving the proposed ruled change prior to the thirtieth day after the date of publication of notice of filing thereof, in that the Commission recently has approved a similar rule change proposed by the American Stock Exchange, Inc. (File No. SR-Amex-84-34, Release No. 21694, January 28, 1985) and this rule change will help ensure that member firms effected by this rule change will be able to operate under consistent rules at both the CBOE and the Amex.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change referenced above be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

**John Wheeler,**

*Secretary.*

[FR Doc. 85-4344 Filed 2-21-85; 8:45 am]

BILLING CODE 8010-01-M

[1] According to the CBOE, institutional investors account for the vast majority of trading in government securities options.

[2] Although a particular branch office manager may not be qualified as a Debt Registered Options Principal, the member organization must continue, of course, to provide adequate, effective supervision of all sales personnel, wherever they are located.

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**[Release No. 21749; SR-MSE-84-12]**

## Self-Regulatory Organizations; Midwest Stock Exchange, Inc.; Order Approving Proposed Rule Change

February 12, 1985.

The Midwest Stock Exchange, Inc. ("MSE") 120 South LaSalle Street, Chicago, IL, 60605, submitted on December 11, 1984, copies of a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, to modify Article XXX, Rule 1, Interpretations and Policies .01 (Specialist Assignment and Evaluation) of the MSE's rules. The proposed changes include the following: (1) In the event of a split-up and/or merger of specialist units, the MSE's Committee on

Specialist Assignment and Evaluation ("Committee") would be authorized to determine the assignment or re-assignment of securities of such units; (2) specialists and co-specialists of the same specialist unit would be authorized to terminate their relationship but only with Committee approval; and, upon such a split-up between a specialist and a co-specialist, the posting, if any, of their unit's stocks would depend on the facts of the particular situation, including past performance and capital considerations; and (3) the Committee would be authorized to review and approve any significant change in the organization of a specialist unit, including changes in percentage interest of a unit's partners or stockholders and changes of a unit's controlling partner or stockholder; and, in event of such changes, the Committee could determine whether to post the unit's stocks.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by the issuance of a Commission release (Securities Exchange Act Release No. 21600, December 24, 1984) and by publication in the **Federal Register** (50 FR 909, January 7, 1985). No Comments were received with respect to the proposed rule filing.

The Commission finds that the proppsed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of Section 6 and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

**John Wheeler,**

*Secretary.*

[FR Doc. 85-4338 Filed 2-21-85; 8:45 am]

BILLING CODE 8010-01-M

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**[Release No. 21743; SR-NASD-84-26]**

## Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change

February 12, 1985.

The National Association of Securities Dealers, Inc. ("NASD"), 1735 K Street, NW., Washington, D.C. 20006, on October 18, 1984 submitted copies of a proposed rule change (SR-NASD-84-26), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, that describes its Small Order Execution System ("SOES").[1]

The Commission believes that the proposed rule change accurately describes SOES. Accordingly, the Commission has determined to approve the rule change on a permanent basis. The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD, and in particular, the requirements of Sections 11A and 15A and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change be, and it hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

**John Wheeler,**

*Secretary.*

[FR Doc. 85-4351 Filed 2-21-85; 8:45 am]

BILLING CODE 8010-01M

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**[Release No. 21745; SR-NYSE-84-41]**

## Self-Regulatory Organizations; Filing and Ordering Granting Accelerated Approval of Proposed Rule Change

February 12, 1985.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1) and Rule 19b-4 thereunder, notice is hereby given that on December 3, 1984, the New York Stock Exchange, Inc., ("NYSE") 11 Wall Street, New York, NY, 10006, filed with the Securities and Exchange Commission the proposed rule change as described herein. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

NYSE proposes to commence opening rotations for index options promptly following the official time trading opens in the primary market for the majority of the underlying stocks that comprise the indext.[1] Under exiting rules, opening rotation for index options can be held only after securities comprising 50 percent of the aggregate market value of the index have opened on the primary market where they are traded.

NYSE states that the proposed rule change will address situations where the stock market moves dramatically early in the trading session, thereby resulting in delays in the opening of some of the more heavily weighted securities comprising NYSE's option indices. NYSE notes that on several occasions these delayed openings have prevented the index value from reaching the 50 percent level for an extended period of time, even though most other securities were open and the market was very active. Under the proposed rule change, investors will be able to take a position based on the new market direction, despite and delays that may occur in opening the underlying securities.[2]

Interested persons are invited to submit written data, views and arguments concerning the NYSE submission within 21 days, from the date of publication in the **Federal Register**. Person desiring to make written comments should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, 450 Fifth Street NW., Washington, D.C. 20549. Reference should be made to File No. SR-NYSE-84-41.

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change which are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those which may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for

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[1] *See* File No. SR-NASD-84-26. The proposed rule change was published for comment in Securities Exchange Act Release No. 21433 (October 29, 1984), 49 FR 44042. The NASD also submitted a proposed rule change setting forth the rules and fees governing SOES. *See* File No. SR-NASD-84-28, which was published for comment in Securities Exchange Act Release No. 21458 (November 2, 1984), 49 FR 44838. Finally, the NASD filed a proposed rule change that allowed SOES to operate on a temporary basis until February 11, 1985. *See* File No. SR-NASD-84-32. Notice of the filing and the order granting accelerated approval of the proposed rule change was published in Securities Exchange Act Release No. 21567 (December 14, 1984), 50 FR 1662. The Commission, today, has approved SR-NASD-84-28 until July 1, 1986. Securities Exchange Act Release No. 21742 (February 12, 1985).

[1] The official opening time for trading stocks on the NYSE is 10:00 a.m. The NYSE is the primary market for the stocks underlying NYSE's three index options (NYSE currently trades options on the Composite Index, Double Index, and Telephone Index). Accordingly, the rule change would permit opening rotations in the index options currently traded on the NYSE to commence promptly following the 10:00 a.m. opening.

[2] The NYSE notes that the market trend is usually clear, even when many of the "price-leader" securities have not begun trading. In addition, the NYSE states that when the delays are caused by order imblances, a range indicating the likely opening price of the stock is disseminated early, providing investors with a valid guide as to the "likely near-term direction of the market and the effect on the index value as these securities open."

inspection and copying at the Commission's Public Reference Room. Copies of the filing and of any subsequent amendments also will be available at the principal office of NYSE.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of Section 6 and the rules and regulations thereunder.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing thereof in that insofar as the proposal would alter the existing NYSE rule, it is substantially the same as a Chicago Board Options Exchange, Incorporated ("CBOE") rule recently published for comment and approved by the Commission.[3] In light of this fact, and to reduce the potential for confusion, accelerated approval is appropriate.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

**John Wheeler,**

*Secretary.*

[FR Doc. 85-4349 Filed 2-21-85; 8:45 am]

BILLING CODE 8010-01-M

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**[Release No. 21744; SR-Phlx-84-29]**

## Self-Regulatory Organizations; the Philadelphia Stock Exchange, Inc.; Order Approving Proposed Rule Change

February 12, 1985.

The Philadelphia Stock Exchange, Inc. ("Phlx") 1900 Market Street, Philadelphia, PA, 19103, submitted on December 13, 1984, copies of a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, to file as a rule the Phlx's interpretation of precedence as it pertains to options trading on the Phlx. New Rule 1067 is derived from the provisions of Rule 119 which govern precedence on the Phlx's equity floor. Rule 1067 provides that the highest bid and the lowest offer shall have precedence in all cases.

Notice of the proposed rule change together with the terms of substance of the proposed rule change was given by the issuance of a Commission Release (Securities Exchange Act Release No. 21611, December 28, 1984) and by publication in the **Federal Register** (50 FR 1154, January 9, 1985). No written comments were received with respect to the proposed rule change.

The Exchange asserts that the rule change is based on Section 6(b)(1) of the Act, which provides in part that an exchange have the capacity to enforce compliance by its members with its rules. The Commission finds that the proposed rule change is consistent with the reqirements of the Act and the rules and regulations thereunder applicable to a self-regulatory organization and, in particular, the requirements of Section 6 and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the above-mentioned proposed rule change be, and hereby is, granted.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

**John Wheeler,**

*Secretary.*

[FR Doc. 85-4350 Filed 2-21-85; 8:45 am]

BILLING CODE 8010-01-M

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**[Release No. 21750; SR-Amex-82-27]**

## American Stock Exchange, Inc.; Order Approving Proposed Rule Change

February 12, 1985.

The American Stock Exchange, Inc. ("Amex") 86 Trinity Place, New York, NY 10006, submitted on December 30, 1982, copies of a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, to allow options specialist firms and certain individuals and organizations associated with such specialist firms ("associated persons") to make recommendations for the purchase or sale of the securities underlying specialty options.[1] On April 2, 1984, Amex submitted Amendment No. 1 to the proposed rule change. Amendment No. 1 changed the proposed rule change by allowing an options specialist and his associated persons to make such recommendations only if the recommendations are contained in research reports similar to those described in paragraph (b) of Rule 139 under the Securities Act of 1933 ("1933 Act").[2] On November 5, 1984, Amex submitted Amendment No. 2 to the filing. The stated purpose of Amendment No. 2 was to conform the proposed rule change to the amendments to paragraph (b) of Rule 139 the Commission adopted in September 1984,[3] and to require options specialists and their associated persons, when making the recommendations allowed under the proposed rule change, to disclose, among other things, the fact that they are specialists or associated persons of the specialist in the option overlying the security whose purchase or sale is being recommended.[4] No comments were received with respect to the proposed rule change.

Amex's rules currently prohibit options specialists, their member organizations and associated persons from making any buy or sell recommendations regarding the securities underlying the specialists' specialty options. Amex proposes to allow its options specialists, their member organizations and associated persons to publish recommendations, opinions or information regarding securities underlying the specialists' specialty options if the recommendations, opinions or information are contained in research reports similar to those allowed under paragraph (b) of Rule 139 under the 1933 Act.[5] To comport with the rule, the

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[3] *See* CBOE Rule 24.13. The Commission approved the proposed changes to Rule 24.13 in File No. SR-CBOE-84-25, Securities Exchange Act Release No. 21580, December 18, 1984; 49 FR 50342, December 27, 1984. In the same order, the Commission also approved, on an accelerated basis, a similar rule change submitted by the American Stock Exchange, Inc. ("Amex") (File No. SR-Amex-84-38), which permits opening rotations for the Amex Major Market Index to commence at 10:00 a.m.

[1] The proposed rule change was noticed in Securities Exchange Act Release No. 19558, March 1, 1983, 48 FR 10186. In this same filing, Amex proposed to allow options specialists and their associated organizations to: (1) Engage in certain business transactions with the issuer or insiders of the security underlying a specialty option; (2) accept orders in the underlying stock from small pension and profit sharing funds; and (3) participate as selling group members in underwritings of non-convertible senior securities of issuers of the securities underlying specialty options. The Commission approved these three portions of the proposed rule change in Securities Exchange Act Release No. 21134, July 12, 1984, 49 FR 29183.

[2] 17 CFR 230.139(b) (1984). Under the original rule filing, recommendations by options specialists of purchases or sales of the securities underlying their specialty options could be made only if the firm had in place specified "Chinese Wall" procedures. Amendment No. 1 was noticed in Securities Exchange Act Release No. 20841, April 1, 1984, 49 FR 15040.

[3] *See* Securities Act Release No. 6550, September 19, 1984, 49 FR 37589 ("Rule 139 Release").

[4] Amendment No. 2 was noticed in Securities Exchange Act Release No. 21502, November 20, 1984, 49 FR 47143.

[5] Paragraph (b) of Rule 139 allows broker-dealers to publish specified types of research reports about certain issuers that are in the process of registering securities for public sale and disseminate research reports on industry or sub-industry groups while participating in a distribution of a security within the group. Paragraph (b) applies only if the issuer

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research reports must be distributed with reasonable regularity in the normal course of business, and must contain either a comprehensive list of the securities being recommended currently, or similar recommendations, opnions or information with respect to a substantial number of companies in the issuer's[6] industry or sub-industry. The discussion of the issuer could not be treated materially differently than that regarding other issuers, and only could include projections of sales or earnings if: (1) Such projections also are included for either a substantial number of companies in the issuer's sub-industry or for all companies in a comprehensive list that is contained in the publication; and (2) such projections cover the same time periods for the other companies as for the issuer. Amex's rule also would require that options specialists, their member organizations and associated persons disclose in such reports that: (1) The specialist specializes in options on the securities being recommended; (2) the specialist may have an inventory position either long or short in the option on the securities being recommended; and (3) the possibility that as a result of the specialist's function he may be on the opposite side of orders executed on the Amex in the option.[7] Amex specialists would be prohibited from making written recommendations in any other form and also would continue to be prohibited from making any oral recommendations concerning the stocks underlying their specialty options or the options themselves.

Amex's proposed rule change differs from paragraph (b) of Rule 139, as amended, in that the opinions and recommendations contained in research reports disseminated under Amex's proposed rule, unlike those contained in research reports published in accordance with paragraph (b) of Rule 139, could be more favorable than previously published opinions of recommendations. Because Amex's rule applies to an options specialist (and his associated persons) on a continuous basis, the incorporation into the Amex rule of Rule 139's prohibition against more favorable recommendations would prohibit options specialist (and their associated persons) from ever upgrading a recommendation. In contrast, paragraph (b) of Rule 139 applies only during a distribution, so that once the distribution is over, recommendations can be upgraded.[8] The upgrading of recommendations by the options specialist, its firm and associated persons, however, during a distribution of securities underlying the options specialist's specialty options in which the specialist, its firm or associated persons was a participant, would generally violate Rule 10b–6 under the Act.[9] In addition, the upgrading of recommendations could not be published during a distribution of certain securities (*i.e.*, generally ones not meeting the requirements for registration on Forms S–3 or F–3, *see* note 5, *supra*) underlying the options specialist's specialty options in which the specialist its firm or associated persons was a participant, because such publication would be in violation of paragraph (b) of Rule 139.[10]

The Commission previously has stated that existing bans on recommendations by a specialist of his specialty securities basically serve to prevent: (1) Manipulation of the specialty security; (2) the indirect passing on of inside market information available to the specialist due to his market position; and (3) recommendations when the specialist may have a conflict of interest.[11] The Commission finds that Amex's ban on options specialists making recommendations regarding the securities underlying their specialty options also serves these purposes.

The restrictions upon research reports found in paragraph (b) of Rule 139 limit the ability of a broker-dealer to target research to condition the secondary market price of a security during a distribution of securities.[12] The Commission finds that these same types of restrictions are equally useful in addressing potential manipulations of the prices of securities underlying specialty options by the options specialist through the dissemination of buy/sell recommendations. As noted above, the Amex proposal differs from paragraph (b) of Rule 139 in that it would permit the specialist (and his associated persons) to upgrade research reports. This arguably increases the opportunity for manipulation under the proposed rule change. The Commission finds, however, that the other limitations contained in the Amex proposal should reduce this danger. In addition, the ability of the Exchange to compare the specialist's options postion and trading activity at the time a recommendation is upgraded or downgraded, and thereby uncover possible incentives for manipulation or patterns of activity suggestive of manipulation, should be sufficient to protect against possible manipulation by Amex specialists via research reports. Accordingly, the Commission finds that the Amex proposal adequately serves the anti-manipulation purposes of the Act.

Furthermore, while Amex options specialists[13] may on occasion have, by reason of their market position, temporary informational advantages regarding the securities underlying their specialty options,[14] precisely because

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does not meet the registration requirements of Form S–3 (17 CFR § 239.13) or F–3 (17 CFR § 239.33) and the minimum float or investment securities provisions of either paragraph (B) (1) or (2) of General Instructions I of the respective forms. Paragraph (a) of Rule 139, which applies if the issuer does meet these requirements, requires only that information, opinions or recommendations published during a distribution by a broker-dealer be contained in publications distributed with "reasonable regularity in the normal course of business." The differences between Amex's rule and paragraph (b) of Rule 139 are discussed below. The Commission emphasizes that Amex draws upon Rule 139 only as a model for the restrictions contained in its proposed rule; compliance with Amex's amended rule will not relieve Amex options specialists and their associated persons of the obligation to comply with Rule 139 itself, when applicable, or any other provisions of the federal securities laws and the rules thereunder.

[6] "Issuer" as used here refers to the issuer of the stock underlying the options specialist's specialty options.

[7] Amex has indicated that it will inform its members that they will be required to make clear in the research reports to which specific issues covered by the reports this disclosure relates. Telephone conversation of January 16, 1984 between Michael Emen, Vice President, Legal and Regulatory Division, Amex and Alden Adkins, Attorney, Division of Market Regulation, SEC.

[8] The Rule 139 approach also is not directly applicable to the options specialist's situation for another reason. The Rule 139 limitation is predicated on the assumption that an underwriter has an incentive only to seek to manipulate upward the price of the security being offered; hence, it only restricts upgrading, not downgrading, of recommendations. An options specialist, however, can be on either side of the market, and thus arguably could profit from either an upgraded or downgraded recommendation with respect to the underlying security. Hence, to incorporate the Rule 139 approach in its entirety into the Amex rule would require that an Amex specialist (and his associated persons) never change their recommendations regarding the underlying security in any respect.

[9] 17 CFR 240.10b–6 (1964). *See* Rule 139 Release, *supra* note 3, at 37572.

[10] As a practical matter, the options specialist, his firm and associated persons will participate rarely, if ever, in distributions of securities underlying the specialist's specialty options because Amex rule, even as amended by this proposal, prohibits the type of selling activity entailed by such participation, unless the options specialist passes the limit order book during the distribution.

[11] *See* Securities Exchange Act Release No. 20456, December 7, 1983, 48 FR 55659.

[12] *See* the Rule 139 Release, *supra* note 3.

[13] The Amex does not allow options trading on its floor if the underlying stock also is traded on its floor (so-called "side-by-side" trading).

[14] Such informational advantages, for example, could result from a significant increase in investor demand for a security being manifested in an influx of options orders that preceded an increase in investor demand for the underlying stock itself.

any such advantages are temporary in nature they cannot be used in formulating and disseminating the written research reports allowed under Amex's proposal. Thus, the Commission finds that Amex's proposal adequately addresses concerns with the indirect passing on of inside market information.

The Commission also finds that, in light of the limitations placed on the types of recommendations which may be made under the proposed Amex rule, the disclosure that will be required under the Amex proposal should alert investors to the possible conflict of interest the options specialist may have in making recommendations regarding the securities underlying his specialty options. The fact that recommendations are limited to industry or comprehensive research reports, and that oral recommendations are not allowed, also should limit opportunities for abuse in this area. The Commission finds, therefore, that the Amex proposal also adequately responds to those conflict of interest concerns raised by the recommendations allowed by the Amex proposed rule.[15]

Finally, the Commission recognizes the importance to the Amex of being able to attract capital for specializing in its stock options from as many sources as possible, as well as the possible disincentive to such activity that could be imposed on retail-oriented broker-dealers so long as they are precluded from soliciting public interest in the stocks underlying specialty options by virtue of their activities as specialist. The Commission believes that the potential value of the involvement of such entities as specialist in stock options outweighs the potential regulatory concerns outlined above if such entities are permitted to specialize under the conditions set forth in the Amex proposal.

For these reasons, we find that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of Sections 6 and 11 and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act that the proposed rule change, as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

John Wheeler,

*Secretary.*

[FR Doc. 85-4353 Filed 2-21-85; 8:45 am]

BILLING CODE 8010-01-M

[15] We emphasize, however, that compliance with the disclosure provisions of Amex's proposed rule does not relieve the specialist or his member organization of their duty under Amex's suitability and related rules or to comply with any other applicable requirements of Amex's rules or the federal securities laws. *See, e.g.*, Amex Rule 411; and *In re* Smith, Barney, Harris Upham & Co., Incorporated, Securities Exchange Act Release No. 21242, 31 S.E.C. Doc. 200, August 15, 1984 (affirming Amex's finding of violation of Amex rules where a member organization effected options transactions for its own account before its research recommendations with respect to the underlying stock were disseminated to public investors).

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[Release No. 21742; SR-NASD-84-28]

## National Association of Securities Dealers, Inc., Order Approving Proposed Rule Change

February 12, 1985.

### Background

On October 19, 1984, the National Association of Securities Dealers, Inc. ("NASD"), 1735 K Street, NW., Washington, D.C. 20006, filed with the Commission a proposed rule change [1] pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b-4 thereunder, that sets forth the rules governing the operating procedures of its Small Order Execution System ("SOES"). It also proposes a fee to be charged market makers for SOES of one half of one cent per share executed in the system. In response to the Commission's request for comment on the proposed rule change, the Commission received comment letters from the Institutional Networks Corporation ("Instinet") [2] and the Midwest Stock Exchange, Inc. ("MSE").[3] Both Instinet and a subsidiary of the MSE operate automated execution systems for over-the-counter ("OTC") Securities.

Instinet said that SOES should be structured to allow competing systems to send orders to, and receive orders from, SOES. Instinet also said that the NASD had not demonstrated that the proposed SOES fees would recover costs, and argued that the one-sided fee (on market makers but not order entry firms) would limit Instinet's ability to attract order entry firms and market makers to its service. Thus, Instinet argued that the rule change should not be approved.

The MSE also argued against approval of the rule change because it had been unsuccessful up to that time in its efforts to obtain NASDAQ Level 1 service (the best bid and offer quotations in each NASDAQ security) from the NASD for purposes of pricing trades executed through its own OTC service.

After considering these comment letters, the Commission approved an NASD proposed rule change that allowed SOES to operate on a temporary basis until February 11, 1985.[4] Before taking this action, the Commission was informed by the NASD that it had agreed to provide the MSE subsidiary access to NASDAQ Level 1 service.[5] With respect to Instinet's concerns, the Commission believed that a temporary approval of SOES would not prejudice Instinet's service pending Commission study of the issues raised by the underlying SOES rule filing. The Commission also believed that any potential harm to Instinet or other competing systems while SOES operated on a temporary basis would be more than outweighed by the major order routing, execution, comparison and clearance efficiencies provided to the OTC market by SOES.

### Discussion

In Section 11A of the Act, Congress made a finding that "[n]ew data processing and communications techniques create the opportunity for more efficient and effective market operations" [6] and directed the Commission to facilitate the establishment of a National Market System for securities consistent with certain objectives, including the "economically efficient execution of securities transactions." [7] When a registered securities association such as the NASD provides a service such as SOES, Section 15A of the Act requires that "the association provide for the equitable allocation of reasonable dues, fees, and other charges among members . . . and other persons using any facility

[1] *See* File No. SR-NASD-84-28. The proposed rule change was published for comment in Securities Exchange Act Release No. 21458 (November 2, 1984), 49 FR 44838. The NASD also filed a proposed rule change that described SOES. *See* File No. SR-NASD-84-26, which was published for comment in Securities Exchange Act Release No. 21433 (October 29, 1984), 49 FR 44042.

[2] Letter to Shirley E. Hollis, Acting Secretary, SEC, from Daniel T. Brooks, Counsel to Instinet, dated November 30, 1984.

[3] Letter to Shirley E. Hollis, Acting Secretary, SEC, from Kenneth I. Rosenblum, President, MSE, dated December 7, 1984.

[4] *See* File No. SR-NASD-84-32. Notice of the filing and the order granting accelerated approval of the proposed rule change was published in Securities Exchange Act Release No. 21567 (December 14, 1984), 50 FR 1662.

[5] The Commission understands that the NASD and the MSE have agreed to all major terms relating to the MSE subsidiary's access to NASDAQ Level 1 service. Accordingly, the Commission no longer views this matter to be pertinent to the rule change.

[6] Section 11A(a)(1)(B) of the Act.

[7] Section 11A(a)(1)(C)(i) of the Act.

or system which the association operates or controls" [8] and that such system "not impose any burden on competition not necessary or appropriate in furtherance of [the Act]." [9]

The Commission believes that automation in the OTC market, as reflected by SOES and other OTC small order execution services, benefit both investors and the OTC market by increasing the speed of order execution and efficiency of OTC market making. Specifically, as noted above, the Commission believes that SOES provides significant order routing, execution, comparison and clearing efficiencies. The Commission encourages the development of SOES and other OTC automated systems and services consonant with the requirements of the Act.

During the temporary SOES approval period, the NASD submitted to the Commission expense and revenue estimates for the operation of SOES as well as a description of how those projections were made.[10] In that submission, the NASD stated that it "intends to review the SOES fee annually to assure that it continues to be fair and reasonable."

In the January Submission the NASD states that the SOES fee was formulated to recover the fully distributed costs of SOES, including both development and operating costs. With respect to projected revenues, the NASD has used actual cleared trade data, excluding internalized trades, to project anticipated SOES trading volume. Revenues were then estimated based upon this projection, taking into account retail trades, trade size, and the assumption that SOES would receive 50% of eligible trades.

The Commission notes that the limited operating history of SOES makes it difficult to predict with certainty whether the instant fee will produce sufficient revenues to recover costs. The Commission believes, however, that the NASD has made a good faith attempt to assess the costs of operating SOES and the revenues necessary to meet those costs. While all NASDAQ securities are eligible to be traded in SOES, pursuant to a phase-in plan, only a few hundred National Market System Securities have been traded in SOES to date. The Commission believes that actual SOES trading volume in these securities generally tracks the NASD's projections after being adjusted for the smaller number of stocks currently being traded in SOES.[11] Therefore, in light of the NASD's good faith effort in assessing SOES costs, the Commission believes that the proposed fees are reasonable.

Because the Commission deems it important for the NASD to review actual system usage for a new competitive service such as SOES to evaluate the appropriateness of the service's fees, the Commission has determined to approve SOES until July 1, 1986. This approval will permit the NASD to conduct a year-end review of the fee and will provide time to evaluate the results of that review and to develop a new rate[s] if necessary.[12] The NASD by letter dated February 8, 1985, has agreed to such a limited term approval.[13]

The Commission does not believe that Instinet's concerns regarding system linkages and the application of the SOES fee to market makers warrant interruption of the initial operation of SOES. The Commission believes that some integration of OTC execution systems would be desirable if it results in increased opportunities for public customers to receive superior prices or greater liquidity for their orders. Therefore, the Commission encourages the NASD to discuss with Instinet, and other interested parties, possible means of linking SOES and other similar systems in a fair and efficient manner. The Commission does not believe, however, that such linkages are a prerequisite to start-up of SOES or that any linkage discussions should interfere with the operation of SOES, which even in its present unlinked state provides significant benefits to the OTC market.

Finally, the Commission disagrees with Instinet that it is inappropriate for the NASD to impose the SOES fee exclusively on market makers without also charging fees to order entry firms. The Commission believes that the NASD should have flexibility in designing SOES rates that are competitive in the marketplace, especially where operators of competing systems are not regulated in the same manner and have had the benefit of considerable flexibility in designing their own rate structure.

The Commission also does not believe that the fees inequitably distinguish between market makers and other NASD members, such as order entry firms. As an initial matter, the Commission notes that SOES is a voluntary system and that market makers will utilize SOES only after determining that the services provided by the system justify the costs.[14] In addition, the Commission has, in a number of contexts, permitted fees on classes of SRO members who receive unique (but not exclusive) benefits from the operation of an SRO facility.[15] SOES provides market makers a more efficient means to access order flow from broker-dealers with which they presently have agreements, as well as the ability to attract new order flow.

Accordingly, while the NASD could have designed its fees in a variety of ways, the Commission finds that the approach adopted provides for an equitable allocation of fees among member firms and SOES users. The Commission also finds that the proposed fees do not impose an unnecessary or inappropriate burden on competition.

In this regard, the Commission notes that Instinet has argued that this fee structure is a "sale of order flow," involving private deals in which market makers, in effect, purchase order flow from retail firms by paying rebates for agency orders routed to market makers for execution.[16] Indeed, while the

[8] Section 15A(b)(5) of the Act.

[9] Section 15A(b)(9) of the Act.

[10] *See* Letter to John Wheeler, Secretary, SEC, from Frank J. Wilson, Executive Vice President and General Counsel, NASD, dated January 25, 1985 ("January Submission").

[11] The Commission notes that, in the present proceeding, the NASD has represented that SOES revenues are intended to meet the fully distributed costs of the system. In reviewing this proposed fee, the Commission takes no position on when, or whether, fully distributed costs (generally the most rigorous cost analysis) are the appropriate price measure.

[12] In its comment letter, Instinet also argued that SOES was similar to the NASD's Computer Assisted Execution System ("CAES") and, therefore, questioned the dissimilarities between each service's fees. As a preliminary matter, the Commission does not believe that all services offered by a self-regulatory organization ("SRO") must be priced similarly, as long as the fees associated with each service meet the requirements of the Act. In addition, aside from the apparent functional dissimilarities of the services (*e.g.*, SOES is for small orders, while CAES is for orders of any size), the NASD's January Submission notes the separate and independent development and operation costs incurred by SOES. Moreover, as separate services, it is likely that SOES and CAES will attract different users and levels of order flow. Accordingly, the Commission believes that the differing fee structures are justified because of the clear distinctions between the two services.

[13] Letter to Michael J. Simon, Assistant Director, Division of Market Regulation, SEC, from Frank J. Wilson, Executive Vice President and General Counsel, NASD, dated February 8, 1985.

[14] In this context, the Commission notes that there are a number of competing small order execution systems available in the OTC market that market makers could utilize as an alternative to SOES.

[15] *See e.g.*, Securities Exchange Act Release No. 19622 (March 22, 1983) (approval of Pacific Stock Exchange, Inc. ("PSE") rule change imposing charges on PSE specialists and option market makers use of the Intermarket Trading System).

[16] The Commission's primary concerns in this area have been the possibility that a market maker may not always provide best execution to orders on which it pays rebates, and failure to disclose to

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Commission has expressed concern in this area, and understands that the NASD is investigating the area, the Commission does not believe that those concerns are relevant here. Specifically, in the present case, the fees are uniform and public; in addition, SOES is structured so that orders are executed only at the best NASDAQ market quotations, thus precluding inferior executions as a result of order flow decisions based on rebates.[17]

### Approval of Rule Change

In light of the above considerations, the Commission finds that the approval of the rule change until July 1, 1986 is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of Sections 11A and 15A and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change referenced above be, and hereby is, approved.[18]

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

**John Wheeler,**

*Secretary.*

[FR Doc. 85-4352 Filed 2-21-85; 8:45 am]

BILLING CODE 8010-01-M

## DEPARTMENT OF TRANSPORTATION

## Research and Special Programs Administration

## Grants and Denials of Applications for Exemptions

**AGENCY:** Materials Transportation Bureau, DOT.

**ACTION:** Notice of Grants and Denials of Applications for Exemptions.

**SUMMARY:** In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR Part 107, Subpart B), notice is hereby given of the exemptions granted in January 1985. The modes of transporation involved are indentified by a number in the "Nature of Exemption Thereof" portion of the table below as follows: 1—Motor Vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo-only aircraft, 5—Passenger-Carrying aircraft. Application numbers prefixed by the Letters EE represent applications for Emergency Exemptions.

RENEWAL AND PARTY TO EXEMPTIONS

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 3095-P | DOT-E 3095 | Dow Chemical Company, Midland, MI | 49 CFR 173.119(a), 173.245(a), 173.248(a), 173.263(a), 173.264, 173.283, 173.289, 178.342-5, 178.343-5. | To become a party to Exemption 3095. (Modes 1, 3.) |
| 3095-X | DOT-E 3095 | Dowell Schlumberger Inc., Tulsa, OK | 49 CFR 173.119(a), 173.245(a), 173.248(a), 173.263(a), 173.264, 173.283, 173.289, 178.342-5, 178.343-5. | To authorize use of a non-DOT specification cargo tank, for shipment of certain hazardous materials. (Modes 1, 3.) |
| 3330-X | DOT-E 3330 | Babcock & Wilcox, Lynchburg, VA | 49 CFR 173.214(b), 173.214(d) | To renew and to authorize a 5 gallon capacity DOT Specification 37A as additional containers. (Modes 1, 2.) |
| 3330-X | DOT-E 3330 | Teledyne Wah Chang Albany Corp., Albany, OR. | 49 CFR 173.214(b), 173.214(d) | To authorize hafnium metal powder as an additional commodity. (Modes 1, 2.) |
| 3498-X | DOT-E 3498 | U.S. Department of Defense, Washington, DC. | 49 CFR 146.02-22, 146.09, 146.29-100, 146.29-43, 176.3, Part 107, Subpart B, Part 176, Subpart B, Part 177, Parts 172, Parts 174, Subpart C, D, F, H, Subpart I, J, L, M, Subpart N, O. | To authorize transport of vehicles loaded with military explosives classed as explosive A, B or C and other hazardous materials essential for military operations. (Modes 1, 2, 3.) |
| 4242-X | DOT-E 4242 | U.S. Department of Defense, Washington, DC. | 49 CFR 173.134, 173.87 | To authorize use of a non-DOT specification aluminum pressure vessel, for transportation of certain pyroforic mixture. (Mode 1.) |
| 4453-P | DOT-E 4453 | A&M Contracting, Grove City, PA | 49 CFR 173.114a(h)(3) | To become a party to Exemption 4453. (Mode 1.) |
| 4726-X | DOT-E 4726 | U.S. Department of Energy, Washington, DC. | 49 CFR 173.245 | To authorize transport of certain liquid metal fluorides, in non-DOT specification monel cylinders, overpacked in a strong wooden box with cushioning material. (Mode 1.) |
| 4803-P | DOT-E 4803 | Southeastern Industrial Cleaning Services, Inc., Ensley, AL. | 49 CFR 173.245, 173.248, 173.249, 173.263, 173.272, 173.289, 178.343-5. | To become a party to Exemption 4803. (Mode 1.) |
| 5022-X | DOT-E 5022 | U.S. Department of Defense, Washington, DC. | 40 CFR 174.101(L), 174.104(d), 174.112(a), 174.86, 177.834(L)(1). | To authorize shipment of certain Class A and Class B explosives in temperature controlled equipment. (Modes 1, 2.) |
| 5022-X | DOT-E 5022 | United Techologies Corp., San Jose, CA. | 49 CFR 174.101(L), 174.104(d), 174.112(a), 174.86, 177.834(L)(1). | To authorize shipment of certain Class B explosives in temperature controlled equipment. (Modes 1, 2.) |
| 5022-X | DOT-E 5022 | Morton Thiokol, Inc., Elkton, MD | 49 CFR 174.101(L), 174.104(d), 174.112(a), 174.86, 177.834(L)(1). | To authorize shipment of certain Class A and Class B explosives in temperature controlled equipment. (Modes 1, 2.) |
| 5263-X | DOT-E 5263 | Dow Corning Corporation, Midland, MI | 49 CFR 173.245(a) | To authorize transport of trifluoromethane sulfonic acid in a non-DOT specification stainless steel container. (Mode 1.) |
| 6267-X | DOT-E 6267 | Bio-Lab, Incorporated, Conyers, GA | 49 CFR 173.154, 173.217(a) | To authorize use of DOT and non-DOT specification double-faced fiberboard boxes, for shipment of certain oxidizing materials. (Modes 1, 2, 3.) |
| 6267-X | DOT-E 6267 | UTICO Corporation, Paterson, NJ | 49 CFR 173.154, 173.217(a) | To authorize use of DOT and non-DOT specification double-faced fiberboard boxes, for shipment of certain oxidizing materials. (Modes 1, 2, 3.) |
| 6267-X | DOT-E 6267 | Coastal Industries, Incorporated, Carlstadt, NJ. | 49 CFR 173.154, 173.217(a) | To authorize use of DOT and non-DOT specification double-faced fiberboard boxes, for shipment of certain oxidizing materials. (Modes 1, 2, 3.) |
| 6267-P | DOT-E 6267 | Imperial Plastics, Evansville, IN | 49 CFR 173.154, 173.217(a) | To become a party to Exemption 6267. (Modes 1, 2, 3.) |

customers in confirmations or otherwise these rebates, which are ultimately passed on to customers. *See* Letter to John E. Pinto, Jr., Senior Vice President, NASD, from Richard G. Ketchum, Director, Division of Market Regulation, SEC, dated October 5, 1984.

[17] An additional concern with the sale of order flow is the potential effect it could have on the OTC market by orienting competition for order flow into rebates rather than quotation competition. The Commission notes that SOES is structured so that in the near future, undesignated SOES orders will be routed to market makers only if they match the inside bid or offer, as the case may be, in NASDAQ. This enhancement of SOES should encourage quotation competition. The Commission is concerned, however, that initial activity in SOES has occurred primarily through designated orders. The Commission requests the NASD to include an analysis of the use of preferenced and unpreferenced orders in SOES in its annual review of the system.

[18] The Commisson, today, also has approved on a permanent basis SR-NASD-84-26, which describes SOES. *See* Securities Exchange Act Release No. 21743 (February 12, 1985).

RENEWAL AND PARTY TO EXEMPTIONS—Continued

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 6296-X | DOT-E 6296 | Uniroyal Chemical, Bethany, CT | 49 CFR 173.377(g) | To authorize additional bag packagings, for transportation of certain Class B poisons in DOT Specification 44D multi-wall paper bags. (Modes 1, 2.) |
| 6325-P | DOT-E 6325 | A&M Contracting, Grove City, PA | 49 CFR 173.154(a) | To become a party to Exemption 6325. (Mode 1.) |
| 6418-P | DOT-E 6418 | Wilbur-Ellis Company, Fresno, CA | 49 CFR 173.357(b) | To become a party to Exemption 6418. (Mode 1.) |
| 6484-X | DOT-E 6484 | ANGUS Chemical Company, Northbrook, IL. | 49 CFR 172.101, 173.149a | To authorize various nitromethane mixtues classed as flammable liquids, as additional commodities. (Mode 1.) |
| 6583-X | DOT-E 6583 | Phillips Petroleum Company, Bartlesville, OK. | 49 CFR 173.249(a)(7) | To authorize shipment of a corrosive material in a DOT Specification 51 portable tank. (Mode 1.) |
| 6629-X | DOT-E 6629 | Fenwal, Inc., Ashland, MA | 49 CFR 173.304(a)(1), 173.305(c), 175.3 | To authorize use of a modified DOT Specification 4B cylinder, for transporation of certain gases or mixture of gases or a nonhazardous material and a gas. (Modes 1, 4, 5.) |
| 6686-X | DOT-E 6686 | Chilton Metal Products Division, Chilton, WI. | 49 CFR 173.304, 178.65 | To authorize use of a modified DOT Specification 3B steel cylinder, for transporation of a certain flammable gas. (Modes 1, 2.) |
| 6762-X | DOT-E 6762 | Continental Products of Texas, Odessa, TX. | 49 CFR 173.286(b)(2), 175.3 | To authorize transport of chemical kits in plastic inside bottles packed in plastic boxes overpacked in fiberboard boxes. (Modes 1, 2, 3, 4.) |
| 6762-P | DOT-E 6762 | Texo Corporation, Cincinnati, OH | 49 CFR 173.286(b)(2), 175.3 | To become a party to Exemptipn 6762. (Modes 1, 2, 3, 4.) |
| 6762-X | DOT-E 6762 | Main Line Distributors, Inc., King of Prussia, PA. | 49 CFR 173.286(b)(2), 175.3 | To authorize transport of chemical kits in plastic inside bottles packed in plastic boxes overpacked in fiberboard boxes. (Modes 1, 2, 3, 4.) |
| 6773-X | DOT-E 6773 | E.I. du Pont de Nemours & Company, Inc., Wilmington, DE. | 49 CFR 173.314(c) | To authorize shipment of a flammable compressed gas, in a DOT Specification 105A600W tank car. (Mode 2.) |
| 6874-X | DOT-E 6874 | Mitsui & Co., (U.S.A.), Inc., New York, NY. | 49 CFR 172.101, 173.370(a)(13) | To authorize transport of sodium and potassium cyanides in non-DOT specification wooden boxes. (Modes 1, 2, 3.) |
| 6874-X | DOT-E 6874 | ICI Americas, Incorporated, Wilmington, DE. | 49 CFR 172.101, 173.370(a)(13) | To authorize transport of sodium and patassium cyanides in non-DOT specification wooden boxes. (Modes 1, 2, 3.) |
| 6984-P | DOT-E 6984 | Thermex Energy Corp., Dallas, TX | 49 CFR 173.103(a), 173.66(g), 177.835(g)(2)(i) | To become a party to Exemption 6984. (Mode 1.) |
| 7052-P | DOT-E 7052 | Motorola, Inc., Schaumburg, IL | 49 CFR 172.101, 175.3 | To become a party to Exemption 7052. (Modes 1, 2, 3, 4.) |
| 7052-P | DOT-E 7052 | Singer Company, American Meter Division, Philadelphia, PA. | 49 CFR 172.101, 175.3 | To become a party to Exemption 7052. (Modes 1, 2, 3, 4.) |
| 7052-P | DOT-E 7052 | General Dynamics, Fort Worth, TX | 49 CFR 172.101, 175.3 | To become a party to Exemption 7052. (Modes 1, 2, 3, 4.) |
| 7052-P | DOT-E 7052 | Halliburton Services, Duncan, OK | 49 CFR 172.101, 175.3 | To become a party to Exemption 7052. (Modes 1, 2, 3, 4.) |
| 7641-X | DOT-E 7641 | American President Lines, Ltd., Oakland, CA. | 49 CFR 176.905(c) | To authorize carriage of motor vehicles aboard cargo vessels with battery cables connected. (Mode 3.) |
| 7708-X | DOT-E 7708 | HTL Industries, Inc., Duarte, CA | 49 CFR 173.302(a), 175.3, 178.44 | To authorize carbon dioxide with 2% by volume helium, nonflammable gas as additional commodity and to include an additional design pressure vessel. (Modes 1, 2, 4, 5.) |
| 7765-X | DOT-E 7765 | Moog, Inc., Tampa, FL | 49 CFR 173.302(a)(4), 175.3 | To authorize manufacture, marking and sale of nonrefillable, non-DOT specification pressure vessels, for transportation of compressed gases. (Modes 1, 2, 4.) |
| 7834-X | DOT-E 7834 | U.S. Department of Defense, Washington, DC. | 49 CFR 173.306(b)(4), 175.3 | To authorize transport of nonliquefied sulfur hexafluoride in certain X-ray machines, overpacked in strong wooden or fiberboard boxes. (Modes 1, 2, 3, 4, 5.) |
| 7835-P | DOT-E 7835 | Sunox, Incorporated, Charlotte, NC | 49 CFR 177.848, Part 107 Appen. B(1) | To become a party to Exemption 7835. (Mode 1.) |
| 7835-P | DOT-E 7835 | Lincoln Big Three, Inc., Baton Rouge, LA. | 49 CFR 177.848, Part 107 Appen. B(1) | To become a party to Exemption 7835. (Mode 1.) |
| 7873-X | DOT-E 7873 | Bromine Compounds, Limited, Beer Sheva, Israel. | 49 CFR 173.353a | To authorize use of non-DOT specification intermodal portable tanks, for transportation of a Class B poison liquid. (Modes 1, 3.) |
| 7969-X | DOT-E 7969 | Crosby & Overton Inc., Long Beach, CA. | 49 CFR 173.119(a), (m), 173.245(a), 173.346(a), 178.340-7, 178.342-5, 178.343-5. | To authorize transport of certain waste hazardous materials in non-DOT specification single compartment cargo tanks similar to DOT Specification 307/312 except for bottom outlet and circumferential reinforcement. (Modes 1.) |
| 8009-X | DOT-E 8009 | Oklahoma Gas Transport, Inc., Oklahoma City, OK. | 49 CFR 172.101, 173.301(d)(2), 173.302(a)(3) | To authorize use of DOT Specification 3AAX cylinders made of 4130X steel, for transportation of a compressed natural gas. (Mode 1.) |
| 8083-X | DOT-E 8083 | Matson Navigation Company, San Francisco, CA. | 49 CFR 172.101 Column 7(c) only | To authorize stowage of carbon bisulfide (or carbon disulfide) and nickel carbonyl aboard vessels also carrying explosive, under conditions approved by the Captain of the Port. (Mode 3.) |
| 8084-X | DOT-E 8084 | E.I. du Pont de Nemours & Company, Inc., Wilmington, DE. | 49 CFR 173.65(a)(5) | To authorize transport of Class A explosives containing more than 5% of moisture in plastic tubes, overpacked in DOT Specification wooden or fiberboard boxes. (Modes 1, 2, 3.) |
| 8084-X | DOT-E 8084 | Ireco Chemicals, Salt Lake City, UT | 49 CFR 173.65(a)(5) | To authorize transport of Class A explosives containing more than 5% of moisture in plastic tubes, overpacked in DOT Specification wooden or fiberboard boxes. (Modes 1, 2, 3.) |
| 8086-X | DOT-E 8086 | U.S. Department of Defense, Washington, DC. | 49 CFR 172.101, 172.102, 173.118(b), 173.119, 173.206, 173.87. | To authorize transport of a cruise missile containing hazardous materials, packed in a wooden box. (Mode 1.) |
| 8119-X | DOT-E 8119 | B-J Hughes Services, Houston, TX | 49 CFR 173.119(a), (m), 173.245(a), 173.263(a), 176.342-5, 178.343-5. | To authorize use of a non-DOT specification cargo tank designed and constructed in full compliance with DOT Specification MC-307 or MC-312 with certain expections, for transportation of certain corrosive and flammable liquids. (Mode 1.) |
| 8129-P | DOT-E 8129 | U.S. Department of Defense, Washington, DC. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | Fred Hutchinson Cancer Research Center, Seattle, WA. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | Radio Research Corporation, Brooklyn, NY. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | Spencer Kellogg, Division of Textron, Inc., Buffalo, NY. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | Syntex (U.S.A.) Inc., Palo Alto, CA | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | James H. Stewart and Associates, Inc., Fort Collins, CO. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | HazMat Environment Group, Inc., Buffalo NY. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | Chemical Processors, Inc., Seattle, WA. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | Resource Recovery Corporation, Seattle, WA. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |

RENEWAL AND PARTY TO EXEMPTIONS—Continued

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 8129-X | DOT-E 8129 | E.I. du Pont de Nemours & Company, Inc., Wilmington, DE | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of certain waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1.) |
| 8129-P | DOT-E 8129 | Environmental Technology Speciality Services, West Chester, OH. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-X | DOT-E 8129 | Monsanto Company, Saint Louis, MO | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of certain waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1.) |
| 8129-P | DOT-E 8129 | General Motors Corporation, Detroit, MI. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | University of Washington, Seattle, WA | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-X | DOT-E 8129 | University of Maryland, College Park, MD. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of certain waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1.) |
| 8129-P | DOT-E 8129 | Weyerhaeuser Company, Tacoma, WA | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-X | DOT-E 8129 | Hopkins Agricultural Chemical Company, Madison, WI. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of certain waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1.) |
| 8129-P | DOT-E 8129 | DDD Environmental Management Corporation, Buffalo, NY. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | Thomas Gray & Associates, Inc., Orange, CA. | 49 CFR 177.834(k), Part 173, Subparts D, E, F,H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-P | DOT-E 8129 | D&J Transportation Specialist, Inc., Liverpool, NY. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To become a party to Exemption 8129. (Mode 1.) |
| 8129-X | DOT-E 8129 | Union Carbide Corporation, Danbury, CT. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of certain waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1.) |
| 8129-X | DOT-E 8129 | Union Carbide Agricultural Products Company, Danbury, CT. | 49 CFR 177.834(k), Part 173, Subparts D, E, F, H, Subparts K, L, M, O. | To authorize shipment of certain waste hazardous materials packed in bottles surrounded by absorbent material overpacked in DOT Specification 37A, 17H, or 6J drums. (Mode 1.) |
| 8141-X | DOT-E 8141 | The Boeing Co., Seattle, WA | 49 CFR 172.101, 173.206, 173.247 | To authorize transport of individual cells and modules consisting of three cells containing lithium metal and thionyl chloride in non-DOT specification wooden boxes. (Modes 1, 3.) |
| 8361-X | DOT-E 8361 | Yellow Spring Instrument Co., Inc., Yellow Spring, OH. | 49 CFR 173.861, 173.862, 175.3 | To authorize the shipment of a temperature measuring device containing small quantities of gallium metal in non-DOT specification packaging. (Modes 1, 2, 4.) |
| 8386-X | DOE-E 8386 | J.J. Mauget Co., Burbank, CA | 49 CFR 172.101, 172.400 | To authorize rail as an additional mode of transportation. (Modes 1, 2.) |
| 8407-X | DOT-E 8407 | Occidental Chemical Corp., Niagara Falls, NY. | 49 CFR 173.245, Part 172, Subpart C | To authorize transport within plant over public highway, various waste residues, classed as corrosives liquids, n.o.s., without shipping papers, in non-DOT specification portable tanks. (Mode 1.) |
| 8445-P | DOT-E 8445 | Northwestern University, Evanston, IL | 49 CFR Part 173, Subpart D, E, F, and H | To become a party to Exemption 8445. (Mode 1.) |
| 8445-X | DOT-E 8445 | Rollins Environmental Services, Inc., Chadds Ford, PA. | 49 CFR Part 173, Subpart D, E, F, and H | To authorize shipment of various hazardous substances and wastes packed in inside plastic, glass, earthenware or metal containers, overpacked in a DOT Specification removable head steel, fiber or polyethylene drum, only for the purposes of disposal, repackaging or reprocessing. (Mode 1.) |
| 8445-P | DOT-E 8445 | SET Liquid Waste Systems, Inc., Wheeling, IL. | 49 CFR Part 173, Subpart D, E, F, and H | To become a party to Exemption 8445. (Mode 1.) |
| 8445-P | DOT-E 8445 | Environmental Technology Speciality Services, West Chester, OH. | 49 CFR Part 173, Subpart D, E, F, and H | To become a party to Exemption 8445. (Mode 1.) |
| 8445-X | DOT-E 8445 | Advanced Environmental Technology Corp., Flanders, NJ. | 49 CFR Part 173, Subpart D, E, F, and H | To authorize shipment of various hazardous substances and wastes packed in inside plastic, glass, earthenware or metal containers, overpacked in a DOT Specification removable head steel, fiber or polyethylene drum, only for the purposes of disposal, repackaging or reprocessing. (Mode 1.) |
| 8445-X | DOT-E 8445 | Environmental Transfer Corporation, Flanders, NJ. | 49 CFR Part 173, Subpart D, E, F, and H | To authorize shipment of various hazardous substances and wastes packed in inside plastic, glass, earthenware or metal containers, overpacked in a DOT Specification removable head steel, fiber or polyethylene drum, only for the purposes of disposal, repackaging or reprocessing. (Mode 1.) |
| 8445-P | DOT-E 8445 | Environmental Response, Inc., Nashville, TN. | 49 CFR Part 173, Subpart D, E, F, and H | To become a party to Exemption 8445. (Mode 1.) |
| 8445-P | DOT-E 8445 | Radiac Research Corporation, Brooklyn, NY. | 49 CFR Part 173, Subpart D, E, F, and H | To become a party to Exemption 8445. (Mode 1.) |
| 8445-P | DOT-E 8445 | Resource Recovery Corporation, Seattle, WA. | 49 CFR Part 173, Subpart D, E, F, and H | To become a party to Exemption 8445. (Mode 1.) |
| 8445-P | DOT-E 8445 | Chemical Processors, Inc., Seattle, WA. | 49 CFR Part 173, Subpart D, E, F, and H | To become a party to Exemption 8445. (Mode 1.) |
| 8453-P | DOT-E 8453 | Viking Explosives & Supply, Inc., Hibbings, MN. | 49 CFR 173.114a | To become a party to Exemption 8453. (Mode 1.) |
| 8472-X | DOT-E 8472 | Ohmart Corporation, Cincinnati, OH | 49 CFR 173.302, 174.5 | To authorize use of non-DOT specification, metal, single trip, inside container, for shipment of a nonflammable gas. (Modes 1, 2, 3, 4, 5.) |
| 8480-X | DOT-E 8480 | The Gillette Company, Boston, MA | 40 CFR 173.24(a)(1), 175.3, Parts 172, 177 | To authorize transport of a flammable gas in a device which allows a slow rate of leakage of the gas. (Modes 1, 2, 3, 4.) |
| 8487-X | DOT-E 8487 | Brunswick Corporation, Lincoln, NE | 49 CFR 173.302(a)(1), 173.304(a)(2), 175.3, 178.44. | To authorize manufacture, marking and sale of non-DOT specification fiber reinforced plastic aluminum lined full composite cylinder's, for shipment of a certain nonflammable compressed gas. (Modes 1, 2, 3, 4, 5.) |
| 8489-X | DOT-E 8489 | Ciba-Geigy Corporation, Ardsley, NY | 49 CFR 173.154, 173.182, 173.217, 173.245b | To authorize shipment of certain oxidizers, a poison B, waste arsenical mixture, and a corrosive material in collapsible polyethylene-lined, woven polypropylene bags having a capacity not exceeding 2200 pounds each. (Modes 1, 2, 3.) |
| 8509-X | DOT-E 8509 | BASF Wyandotte Corporation, Parsippany, NJ. | 49 CFR 173.263(a)(9), 179.201-1 | To authorize use of a safety relief valve in lieu of a safety vent in DOT Specification 111A100W5 tank car tanks, for transportation of hydrochloric acid. (Mode 2.) |

RENEWAL AND PARTY TO EXEMPTIONS—Continued

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 8519-X | DOT-E 8519 | Polish Ocean Lines, Gdynia, Poland | 49 CFR 176.905(L) | To authorize stowage of motor vehicles containing gasoline, in their fuel tanks, classed as a flammable liquid in the same cargo compartment with other hazardous materials on specially equipped roll-on/roll-off cargo vessels. (Mode 3.) |
| 8519-X | DOT-E 8519 | Atlantic Container Line, Limited, Elizabeth, NJ. | 49 CFR 176.905(L) | To authorize stowage of motor vehicles containing gasoline, in their fuel tanks, classed as a flammable liquid in the same cargo compartment with other hazardous materials on specially equipped roll-on/roll-off cargo vessels. (Mode 3.) |
| 8522-X | DOT-E 8522 | Bay Street Packaging, Santa Fe, CA | 49 CFR 177.839(a), 177.839(b), 178.150, Part 173 Subpart F. | To authorize manufacture, marking and sale of non-reusable expanded polystyrene cases similar to DOT Specification 33A, except that it will incorporate 6 cavities to contain not more than six 5-pint bottles, or 6 20-ounce bottles, for shipment of those commodities presently authorized in DOT-33A. (Modes 1, 2, 3.) |
| 8523-X | DOT-E 8523 | Fauvet-Girel, Paris, France | 49 CFR 173.304, 173.315 | To authorize use of non-DOT Specification IMCO Type 5 portable tanks, for transportation of flammable and nonflammable compressed gases. (Modes 1, 2, 3.) |
| 8526-P | DOT-E 8526 | The Cleveland, Columbus & Cincinnati Highway, Inc., Cleveland, OH. | 49 CFR 177.834(L)(2)(i) | To become a party to Exemption 8526. (Mode 1.) |
| 8526-P | DOT-E 8526 | Be-Mac Transportation Company, Inc., St. Louis, MO. | 49 CFR 177.834(L)(2)(i) | To become a party to Exemption 8526. (Mode 1.) |
| 8554-X | DOT-E 8554 | E.I. du Pont de Nemours & Company, Inc., Wilmington, DE. | 49 CFR 173.114a, 173.154, 173.93 | To authorize an additional design cargo tank motor vehicle. (Mode 1.) |
| 8554-P | DOT-E 8554 | A&M Contracting, Grove City, PA | 49 CFR 173.114a, 173.154, 173.93 | To become a party to Exemption 8554. (Mode 1.) |
| 8554-X | DOT-E 8554 | Wampum Hardware Co., New Galilee, PA. | 49 CFR 173.114a, 173.154, 173.93 | To authorize transport of propellant explosives, blasting agents and oxidizers, in a DOT Specification MC-306, MC-307 and MC-312 cargo tank. (Mode 1.) |
| 8554-X | DOT-E 8554 | Austin Power Company, Cleveland, OH. | 49 CFR 173.114a, 173.154, 173.93 | To authorize transport of propellant explosives, blasting agents and oxidizers, in a DOT Specification MC-306, MC-307 and MC-312 cargo tank. (Mode 1.) |
| 8554-X | DOT-E 8554 | E.I. du Pont de Nemours & Wilmington, DE. | 49 CFR 173.114a, 173.154, 173.93 | To authorize transport of propellant explosives, blasting agents and oxidizers, in a DOT Specification MC-306, MC-307 and MC-312 cargo tank. (Mode 1.) |
| 8554-X | DOT-E 8554 | Mesabi Powder Company, Hibbing, MN. | 49 CFR 173.114a, 173.154, 173.93 | To authorize transport of propellant explosives, blasting agents and oxidizers,in a DOT Specification MC-306, MC-307 and MC-312 cargo tank. (Mode 1.) |
| 8556-P | DOT-E 8556 | Union Carbide Corporation, Danbury, CT. | 49 CFR 173.318(a), 176.76(h)(4) | To become a party to Exemption 8556. (Modes 1, 3.) |
| 8572-X | DOT-E 8572 | American Explosives, Inc., Hayden Lake, ID. | 49 CFR 172.101, 172.406, 172.504, 173.114a | To authorized shipment of packages marde "nitro carbo nitrate" and labelled "oxidizer" in lieu of "Blasting Agent". (Mode 1.) |
| 8627-P | DOT-E 8627 | LaSalle Tester & Service, Inc., Jena, LA. | 49 CFR 173.119, 173.245, 178.253 | To become a party to Exemption 8627. (Mode 1.) |
| 8645-P | DOT-E 8645 | Wampum Manufacturing Co., Senecaville, OH. | 49 CFR 173.154(a)(18) | To become a party to Exemption 8645. (Mode 1.) |
| 8645-P | DOT-E 8645 | Wampum Supplies Co., New Galilee, PA. | 49 CFR 173.154(a)(18) | To become a party to Exemption 8645. (Mode 1.) |
| 8645-P | DOT-E 8645 | Wampum Distributing Co., New Galilee, PA. | 49 CFR 173.154(a)(18) | To become a party to Exemption 8645. (Mode 1.) |
| 8645-P | DOT-E 8645 | A&M Contracting, Grove City, PA | 49 CFR 173.154(a)(18) | To become a party to Exemption 8645. (Mode 1.) |
| 8645-P | DOT-E 8645 | Armstrong Explosives Co., Kittanning, PA. | 49 CFR 173.154(a)(18) | To become a party to Exemption 8645. (Mode 1.) |
| 8645-P | DOT-E 8645 | Northern Ohio Explosives, Inc., Forest, OH. | 49 CFR 173.154(a)(18) | To become a party to Exemption 8645. (Mode 1.) |
| 8645-P | DOT-E 8645 | Belmont Mine Supply Co., Inc., Flushing, NY. | 49 CFR 173.154(a)(18) | To become a party to Exemption 8645. (Mode 1.) |
| 8646-X | DOT-E 8646 | Marshall Hyde Incorporated, Port Huron, MI. | 49 CFR 172.101, 173.100, 173.86 | To authorize transport of an explosive pest repellant device in limited quantities, in non-DOT specification inner fiberboard cartons. (Modes 1, 2.) |
| 8748-X | DOT-E 8748 | Battelle, Pacific Northwest Laboratories, Richland, WA. | 49 CFR 172.101, 173.302, 175.3 | To authorize use of non-DOT specification containers, for transportation of a nonflammable gas. (Modes 1, 2, 3, 4, 5.) |
| 8760-X | DOT-E 8760 | Barton Solvents, Inc., Des Moines, IA | 49 CFR 172.326, 172.334(b) | To renew and to authorize other combustible and flammable materials to be identified under UN1993. (Mode 1.) |
| 8845-P | DOT-E 8845 | Allegheny Nuclear Surveys, Inc., Weston, WV. | 49 CFR 173.110(c)(1), 173.80(b), 173.80(c) | To become a party to Exemption 8845. (Modes 1, 3.) |
| 8845-P | DOT-E 8845 | Four Way Logging & Perforating, Inc., Colorado City, TX. | 49 CFR 173.110(c)(1), 173.80(b), 173.80(c) | To become a party to Exemption 8845. (Modes 1, 3.) |
| 8845-P | DOT-E 8845 | Mountaineer Logging & Perforating Corporation, Vienna, WV. | 49 CFR 173.110(c)(1), 173.80(b), 173.80(c) | To become a party to Exemption 8845. (Modes 1, 3.) |
| 8877-P | DOT-E 8877 | American Hoechst Corporation, Somerville, NJ. | 49 CFR 173.119, 173.245 | To become a party to Exemption 8877. (Modes 1, 2, 3.) |
| 8877-X | DOT-E 8877 | SCM Speciality Chemicals, Gainesville, FL. | 49 CFR 173.119, 173.245 | To authorize shipment of certain materials described as flammable liquids, corrosive, n.o.s. (corrosive to skin only) and corrosive liquids, n.o.s., in DOT-12A65 and DOT-12B65 fiberboard boxes with inside glass bottles having a capacity not to exceed one-gallon. (Mode 1, 2, 3.) |
| 8890-X | DOT-E 8890 | Sunbelt Airlines, Camden, AR | 49 CFR 172.101, 172.204(c)(3), 173.27, 175.30(a)(1), 175.320(b), Part 107, Appendix B. | To authorize carriage of Class A, B and C explosives that are not permitted for shipment by air, or are in quantities greater than those prescribed for shipment by air. (Mode 4.) |
| 8898-X | DOT-E 8898 | Petrolane Gas Service, Seattle, WA | 49 CFR 173.315 | To authorize use of a non-DOT specification ASME Code stamped portable tank, for transportation of liquefied compressed gases. (Mode 1, 3.) |
| 8904-X | DOT-E 8904 | Keith Huber, Inc., Gulfport, MS | 49 CFR 173.119(a), 173.119(m), 173.245(a), 173.346(a), 178.340-7, 178.342-5, 178.343-5. | To authorize manufacture, marking and sale of non-DOT specification cargo tanks complying generally with DOT Specification MC-307/312 except for bottom outlet valve variations and certain other features, for transportation of flammable, corrosive or poisonous waste liquids or semi-solids. (Mode 1.) |
| 8906-X | DOT-E 8906 | FMC Corporation, Middleport, NY | 49 CFR 173.365 | To authorize shipment of used, essentially empty containers with residual amounts of carbofuran, packed in a non-DOT specification double wall BC flute corrugated fiberboard box. (Mode 1.) |

## RENEWAL AND PARTY TO EXEMPTIONS—Continued

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 8940-X | DOT-E 8940 | Syntex Chemicals, Inc., Boulder, CO | 49 CFR 173.230 | To authorize shipment of sodium, metal dispersion in organic solvent, in DOT Specification 5, 5C, 6B or 6C closed head metal drums, overpacked in DOT Specification 17H drums. (Mode 1.) |
| 8947-X | DOT-E 8947 | Townsend, Inc., Worcester, MA | 49 CFR 173.221 | To authorize shipment of a small quantity of methyl ethyl ketone peroxide solution, in non-DOT specification polyethylene tube, packed in a DOT Specification 12B fiberboard box. (Mode 1.) |
| 8950-X | DOT-E 8950 | Structural Composites Industries, Inc., Pomona, CA. | 49 CFR 173.302(a)(1), 173.304(a), (d), 175.3 | To authorize manufacture, marking and sale of non-DOT specification fiber reinforced plastic hoop wrapped cylinders, for transportation of certain flammable and non-flammable compressed gases. (Modes 1, 2, 3, 4, 5.) |
| 8952-X | DOT-E 8952 | Trojan Corporation, Salt Lake City, UT | 49 CFR 173.65 | To authorize use of a DOT Specification 21C fiber drum, for transporting desensitized HMX (cyclotetramethylene tetranitramine). (Mode 1.) |
| 8958-X | DOT-E 8958 | Goex, Inc., Moosic, PA | 49 CFR 172.101, 173.60 | To authorize transport of limited quantities of black power, classed as a flammable solid, in DOT Specification 12H fiberboard boxes. (Modes 1, 2.) |
| 8959-X | DOT-E 8959 | Greer Hydraulics, City of Commerce, CA. | 49 CFR 173.302(a)(1), 173.304(a), 173.304(d), 175.3 | To authorize shipment of nitrogen or nitrogen mixtures in steel hydraulic accumulators. (Modes 1, 2, 3, 4.) |
| 9014-X | DOT-E 9014 | Hunter Drums Limited, Burlington, Ont., Canada. | 49 CFR 173.262, 173.266 | To authorize shipment of hydrogen peroxide solutions not to exceed 60% and hydrobromic acid not to exceed 63% as additional commodities. (Modes 1, 2, 3.) |
| 9064-P | DOT-E 9064 | Optical Fibres, Deeside, Wales | 49 CFR 173.245, 173.271 | To become a party to Exemption 9064. (Modes 1, 3.) |
| 9110-P | DOT-E 9110 | Huron Chemicals of America, Jacksonville, FL. | 49 CFR CFR 173.163 | To become a party to Exemption 9110. (Modes 1, 2, 3.) |
| 9110-P | DOT-E 9110 | ERCO Industries Limited, Islington, Ont., Canada. | 49 CFR 173.163 | To become a party to Exemption 9110. (Modes 1, 2, 3.) |
| 9157-P | DOT-E 9157 | RCA, Lancaster, PA | 49 CFR 173.314(c), 179.300-7 | To become a party to Exemption 9157. (Mode 1.) |
| 9169-P | DOT-E 9169 | Keystone Steel & Wire Co., Peoria, IL | 49 CFR 173.154 | To become a party to Exemption 9169. (Modes 1, 3.) |
| 9182-X | DOT-E 9182 | Stoneco, Inc., Dacono, CO | 49 CFR 172.101, 173.53(g), 175.30 | To authorize rail as an additional mode of transportation. (Modes 1, 2, 4.) |
| 9241-X | DOT-E 9241 | Stoneco, Inc., Dacono, CO | 49 CFR 172.101, 175.30 | To authorize rail as an additional mode of transportation. (Modes 1, 2, 3, 4.) |
| 9244-X | DOT-E 9244 | Stoneco, Inc., Dacono, CO | 49 CFR 172.101, 175.30 | To authorize rail as an additional mode of transportation. (Modes 1, 3, 4.) |
| 9248-X | DOT-E 9248 | Kross Inc., San Fernando, CA | 49 CFR 173.1200, 173.154a | To authorize rail as an additional mode of transportation. (Modes 1, 2.) |
| 9266-P | DOT-E 9266 | National Refrigerants, Inc., Radnor, PA | 49 CFR 173.315, 178.245 | To become a party to Exemption 9266. (Modes 1, 2, 3.) |
| 9328-X | DOT-E 9328 | Petersburg Oil Co., Inc., Petersburg, WV | 49 CFR 173.119, 177.814 | To authorize use of non-DOT specification cargo tank, motor vehicles, for transportation of a flammable liquid. (Mode 1.) |

## NEW EXEMPTIONS

| Application No | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| 9235-N | DOT-E 9235 | Bennett Industries, Peotone, IL | 49 CFR 178.116-6 | To authorize manufacture, marking and sale of non-DOT specifications steel drums of 24-gauge thickness and six-gallon capacity, to be used in place of 24 gauge, five-gallon capacity, DOT Specification 17E steel drums, for transportation of various hazardous materials. (Mode 1,2, 3.) |
| 9276-N | DOT-E 9276 | St. Louis Flight System, Inc., Chesterfield, MO. | 49 CFR 172.101, 172.204(C)(3), 173.27, 175.30(a)(1), 175.320(b), Part 107, Appendix B. | To authorize carriage of certain class A, B and C explosives that are not permitted for air shipment or are in quantities greatet than those prescribed for shipment by air. (Mode 4.) |
| 9290-N | DOT-E 9290 | Dow Corning Corporation, Midland, MI | 49 CFR 173.119(m) | To authorize use of of DOT Specification MC-330 and MC-331 cargo tanks, for transportation of flammable liquids which are also corrosive materials. (Mode 1.) |
| 9290-N | DOT-E 9290 | Mauser Packaging Limited, New York, NY. | 49 CFR 178.134 | To authorize manufacture, marking and sale of 15 gallon steel overpacks similar to DOT 3M except for a slight reduction in wall thickness with polyethylene liner meeting DOT 25L except for marking for shipment of those commodities authorized in DOT 37M/25L. (Modes 1, 2, 3.) |
| 9294-N | DOT-E 9294 | Marchem Limited, Widnes, Cheshire, England. | 49 CFR 173.247 | To authorize shipment of benzoyl chloride, classed as a corrosive material, in DOT Specification 6D/25L composite packaging. (Modes 1, 3.) |
| 9295-N | DOT-E 9295 | Applied Environments Corporation, Woodland Hills, CA | 49 CFR 173.302(a) | To authorize manufacture, marking and sale of non-DOT specification toroidal pressure vessel equivalent to a DOT Specification 39 cylinder, for transportation of nonflammable, nonliquified gases. (Modes 1,2, 4.) |
| 9305-N | DOT-E 9305 | ARCO Pipe Line Company, Independence, KS. | 49 CFR 173.119, 173.304, 173.315 | To authorize uses of a non-DOT specification container, for transportation of flammable liquids and gases. (Mode 1.) |
| 9312-N | DOT-E 9312 | The National Aeronautics and Space Administration, Washington, DC. | 49 CFR parts 170-179 | To authorize shipment of Space Shuttle Orbiters which contain small quantities of explosives, flammable liquids and posions, and nonflammable gases in non-DOT specification pressure vessels. (Mode 1.) |
| 9318-N | DOT-E 9318 | Stern Air, Inc, Dallas, TX | 49 CFR 172.101, 172.204(c)(3), 173.27, 175.30(a)(1), 175.320(b), Part 107, Appendix B. | To authorize carriage of certain Class A, B And C explosives that are not permitted for air shipment or are in quantities greater than those prescribed for shipment by air. (Mode 4.) |
| 9331-N | DOT-E 9331 | Rio Linda Chemical Company, Sacramento, CA. | 49 CFR 173.263(a)(10) | To authorize shipment of sodium Chlorite solutions, in DOT Specification MC-306 and MC-307 cargo tanks. (Mode 1.) |
| 9332-N | DOT-E 9332 | Engelhard Corporation, Newark, NJ | 49 CFR 172.101, 173.150, 175.3 | To authorize transport of a solid explosive dissolved in an ammonia solution as a flammable solid, in DOT Specification 34 polyethylene containers or DOT Specification 2E polyethylene bottles, packed in DOT Specification 15A wooden boxes. (Modes 1, 2, 4. |

EMERGENCY EXEMPTIONS

| Application No. | Exemption No. | Applicant | Regulation(s) affected | Nature of exemption thereof |
|---|---|---|---|---|
| EE 7987-X | DOT-E 7987 | Stauffer Chemical Company, Westport, CT. | 49 CFR 173.343, 173.377 | To authorize shipment of a poison B, in non-DOT specification five ply natural kraft multiwall bags. (modes 1, 2.) |
| EE 9369-N | DOT-E 9369 | Schlumberger Well Services, Rosharon, TX. | 49 CFR 172.101, 175.320(a) | To authorize transport of class A explosive with Class C explosives and nonhazardous material on cargo aircraft only. (modes 4.) |
| EE 9376-N | DOT-E 9376 | Pennwalt Corporation, Buffalo, NY | 49 CFR 172.101 Column 6(b), 173.21(b)(2), 173.221(a)(9), 175.30(a)(1). | To authorize transportation of an organic peroxide in quantities exceeding the package limitation for cargo aircraft only. (modes 1, 4.) |
| EE 9378-N | DOT-E 9378 | Monsanto Company, St. Louis, MO | 49 CFR 173.386, 173.387 | To authorize one-time, phased shipment of approximately 4000 small samples of certain etiologic agents contained in tubes and vials, packed in inside fiber drums overpacked in DOT Specification 21C fiber drums or equivalent. (modes 1.) |
| EE 9379-N | DOT-E 9379 | Kaiser International Crop. Savannah, GA. | 49 CFR 173.182(b)(6)(ii), Part 107 App. B(1) | To authorize shipment of ammonium nitrate fertilizer in collapsible polyethylene-lined, woven polypropylene bags having a capacity for approximately 2,000 pounds each. (modes 1, 3.) |

Issued in Washington, DC, on February 12, 1985

**J.R. Grothe,**

*Chief, Exemptions Branch, Office of Hazardous Materials Regulation, Materials Transportation Bureau.*

[FR Doc. 86-4084 Filed 2-21-84; 8:45 am]

BILLING CODE 4910-60-M

## DEPARTMENT OF THE TREASURY

### Office of the Secretary

### Public Information Collection Requirements Submitted to OMB for Review

Dated: February 14, 1985.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB (listed by submitting bureau(s)), for review, and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511. Copies of these submissions may be obtained by calling the Treasury Bureau Clearance Officer listed under each bureau. Comments regarding these information collections should be addressed to the OMB reviewer listed at the end of each bureau's listing and to the Treasury Department Clearance Officer, Room 7221, 1201 Constitution Avenue, NW., Washington, D.C. 20220.

**Internal Revenue Service**

*OMB No:* 1545-0242
*Form No:* IRS Form 6197
*Type of Review:* Revision
*Title:* Fuel Economy Tax

*OMB No:* 1545-0295
*Form No:* IRS Form 5064
*Type of Review:* Reinstatement
*Title:* Label—405 MMR Media Program Label. Notice 210—Preparation Instructions for Magnetic Media Reporting Label
Clearance Officer: Garrick Shear, (202) 566-6254, Room 5571, 1111 Constitution Avenue, NW., Washington, D.C. 20224
OMB Reviewer: Milo Sunderhauf, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

**Bureau of Alcohol, Tobacco and Firearms**

*OMB No:* 1512-0075
*Form No:* ATF F 5150.18
*Type of Review:* Revision
*Title:* User's Report of Denatured Spirits
Clearance Officer: Howard Hood, (202) 566-7077, Bureau of Alcohol, Tobacco and Firearms, Room 2228, Federal Building, 1200 Pennsylvania Avenue, NW., Washington, D.C. 20226
OMB Reviewer: Milo Sunderhauf, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

**U.S. Customs Service**

*OMB No:* 1515-0081
*Form No:* CF 213
*Type of Review:* Extension
*Title:* Importers' Premise Visit, Significant Importation Report
Clearance Officer: Vince Olive, (202) 566-9181, U.S. Customs Service, Room 2130, 1301 Constitution Avenue, NW., Washington, D.C. 20229
OMB Reviewer: Judy McIntosh, (202) 395-6880, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, D.C. 20503.

**Joseph F. Maty,**

*Departmental Reports Management Office.*

[FR Doc. 85-4379 Filed 2-21-85; 8:45 am]

BILLING CODE 4810-25-M

# Sunshine Act Meetings

Federal Register
Vol. 50, No. 36
Friday, February 22, 1985

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).

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| Equal Employment Opportunity Commission | 1, 2 |
| Federal Reserve System | 3, 4 |
| National Credit Union Administration | 5 |
| Tennessee Valley Authority | 6 |

1

**EQUAL EMPLOYMENT OPPORTUNITY COMMISSION**

**DATE AND TIME:** Monday, March 4, 1985, 2:00 p.m. (Eastern Time).

**PLACE:** Clarence M. Mitchell, Jr., Conference Room No. 200-C on the 2nd Floor of the Columbia Plaza Office Building, 2401 "E" Street, NW., Washington, D.C. 20507.

**STATUS:** Closed to the Public.

**MATTER TO BE CONSIDERED:**

*Closed*

Litigation Authorization: General Counsel Recommendations

Note.—Any matter not discussed or concluded may be carried over to a later meeting. (In addition to publishing notices on EEOC Commission meetings in the Federal Register, the Commission also provides a recorded announcement a full week in advance on future Commission sessions. Please telephone (202) 634-6748 at all times for information on these meetings.)

**CONTACT PERSON FOR MORE INFORMATION:** Cynthia C. Matthews, Executive Officer at (202) 634-6748.

Dated: February 20, 1985.

**Cynthia C. Matthews,**

*Executive Officer, Executive Secretariat.*

[FR Doc. 85-4406 Filed 2-20-85; 8:45 am]

**BILLING CODE 6570-06-M**

2

**EQUAL EMPLOYMENT OPPORTUNITY COMMISSION**

**DATE AND TIME:** Tuesday, March 5, 1985, 9:30 a.m. (Eastern Time).

**PLACE:** Clarence M. Mitchell, Jr., Conference Room No. 200-C on the 2nd Floor of the Columbia Plaza Office Building, 2401 "E" Street, NW., Washington, DC 20507.

**STATUS:** Part will be open to the public and part will be closed to the public.

**MATTERS TO BE CONSIDERED:**

1. Announcement of Notation Vote(s)
2. A Report on Commission Operations: A Briefing on the Sunshine Act
3. Proposed Contract for Subscription Services
4. Opinion Letter: Concerning Redution in Compensation Rate for Unused Sick Leave Days Beyond Retirement
5. Opinion Letter: Concerning Voter Registration as a Mandatory Condition of Employment
6. Opinion Letter: Concerning Interpretation of the Pregnancy Discrimination Act
7. Proposed Compliance Manual Section 90, Processing Complaints Transferred or Referred From Federal Fund Granting Agencies
8. Proposed Compliance Manual Section 25, On-Site Investigation

*Closed*

1. Litigation Authorization: General Counsel Recommendations
2. Proposed Commission Decisions: ORA Decisions and Guidance Decisions
3. Discussion of Commissioners' Charges

Note.—Any matter not discussed or concluded may be carried over to a later meeting. (In addition to publishing notices on EEOC Commission meetings in the Federal Register, the Commission also provides a recorded announcement a full week in advance on future Commission sessions. Please telephone (202) 634-6748 at all times for information on these meetings.

**CONTACT PERSON FOR MORE INFORMATION:** Cynthia C. Matthews, Executive Officer at (202) 634-6748.

Dated: February 20, 1985.

**Cynthia C. Matthews,**

*Executive Officer, Executive Secretariat.*

This Notice Was Issued February 20, 1985.

[FR Doc. 85-4497 Filed 2-20-85; 2:51 pm]

**BILLING CODE 6570-06-M**

3

**FEDERAL RESERVE SYSTEM**

**TIME AND DATE:** 10:00 a.m., Wednesday, February 27, 1985.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, D.C. 20551

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:**

1. Proposed policy statement and regulation on capital adequacy for state member banks and bank holding companies. (Published earlier for public comment; Docket No. R-0526)

2. Publication for comment of revisions to Regulation B (Equal Credit Opportunity). (Preliminary notice of rulemaking given; Docket No. R-0473)

3. Proposed interpretations of Regulations D (Reserve Requirements of Depository Institutions), H (Membership of State Banking Institutions in the Federal Reserve System), and Q (Interest on Deposits) regarding the status of shares of certain money market mutual funds and repurchase agreements involving those shares.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: February 19, 1985.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 85-4464 Filed 2-20-85; 11:06 am]

**BILLING CODE 6210-01-M**

4

**FEDERAL RESERVE SYSTEM**

**TIME AND DATE:** Approximately 11:30 a.m., Wednesday, February 27, 1985, following a recess at the conclusion of the open meeting.

**PLACE:** Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, D.C. 20551.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:**

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company application scheduled for the meeting.

Dated: February 19, 1985.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 85-4666 Filed 2-20-85; 11:06 am]

BILLING CODE 6210-01-M

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**5**

**NATIONAL CREDIT UNION ADMINISTRATION**

**TIME AND DATE:** 2:00 p.m., Wednesday, February 27, 1985.

**PLACE:** 1776 G Street, NW., Washington, D.C. 20456, Filene Board Room, 7th Floor.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:**

1. Approval of Minutes of Previous Open Meeting.
2. Review of Central Liquidity Facility Lending Rate.
3. Final Rule: Section 701.12, NCUA Rules and Regulations, Supervisory Committee Audits and Verifications.

**TIME AND DATE:** 12:30 p.m., Wednesday, February 27, 1985.

**PLACE:** 1776 G Street, NW., Washington, D.C. 20456, Filene Board Room, 7th Floor.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:**

1. Approval of Minutes of Previous Closed Meeting.
2. Actions under section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8) and (9)(A)(ii).
3. Special Assistance to Prevent Liquidation under section 208 of the Federal Credit Act. Closed pursuant to exemptions (8) and (9)(A)(ii).
4. Review of Petiton purusant to section 205(d) of the Federal Credit Union Act. Closed pursant to exemptions (6) and (8).
5. Personnel Actions. Closed pursuant to exemptions (2) and (6).

**FOR MORE INFORMATION CONTACT:** Rosemary Brady, Secretary of the Board, telephone (202) 357-1100.

**Rosemary Brady,**

*Secretary of the Board.*

[FR Doc. 85-4508 Filed 2-20-85; 3:38 pm]

BILLING CODE 7535-01-M

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**6**

**TENNESSEE VALLEY AUTHORITY**

(Meeting No. 1345)

**TIME AND DATE:** 10:15 a.m. (EST), Tuesday, February 26, 1985.

**PLACE:** TVA West Tower Auditorium, 400 West Summit Hill Drive, Knoxville, Tennessee.

**STATUS:** Open

**Agenda Items**

Approval of minutes of meeting held on January 16, 1985.

**Discussion Items**

1. Principles of the TVA Floodplain Management Program.

**Action Items**

*Old Business Items:*

*1. Authorization of sale of coal lease—Tract XEKCR-14L (Helton Branch Tract)—Red Bird Coal Reserves—Leslie County, Kentucky.

*2. Cooperative Agreement No. TV-65607A with Duke Power Company for Phase III engineering services for the Atmospheric Fluidized Bed Combustion Demonstration Project.

*New Business Items:*

A—Budget and Financing

A1. Amendment to Fiscal Year 1985 Capital Budget for the Power Program—Engineering and construction of a 161-kV delivery point at the Triune, Tennessee, 161-kV Substation.

A2. Retention of net power proceeds and nonpower proceeds and payments to the U.S. Treasury in March 1985, pursuant to section 26 of the TVA Act.

B—Purchase Awards

B1. Proposal 52-836644—Tenant improvements and building modifications for the Chattanooga Office Complex.

B2. Invitation C2-962824—Requirement for magnetite for use in the heavy-media circuits at Paradise Fossil Plant.

B3. Negotiation 33-969238—Replacement of horizontal reheater elements for Cumberland Fossil Plant units 1 and 2.

C—Power Items

C1. Subagreement No. 36 under the TVA/Department of Energy Memorandum of Understanding No. TV-48296A covering arrangements for measurement of background variance of radon and radon daughter levels in homes in the Tennessee Valley region.

C2. Letter agreement with Southern Illinois Power Cooperative providing for TVA to wheel nonform power and energy on an interruptible basis.

D—Personnel Items

D1. Supplement to personal services contract with General Electric Company, Norcross, Georgia, providing for services in connection with the implementation of the Regulatory Performance Improvement Plan for the Browns Ferry Nuclear Plant.

D2. Personal services contracts with Kenneth L. Penegar, Richard S. Wirtz, Kenneth D. McCasland, Sr., and James C. Winkles in connection with contracts diputes appeals.

E—Real Property Transactions

*E1. Resolution designating approximately 144 acres of Melton Hill Reservoir land located in Anderson County, Tennessee (Carden Farm Industrial Site), as surplus and for sale at public auction for development of an industrial park; and proposed agreement with Town of Clinton, Tennessee—Tract No. XMHR-49.

E2. Grant of permanent easement to the State of Tennessee for the construction, operation, and maintenance of a highway and appurtenances affecting approximately 0.12 acre of Nolichucky River access land in Greene County, Tennessee—Tract No. XTNORA-1E.

F—Unclassified

F1. Changes in designation of certifying officers authorized to approve payments made by TVA.

F2. Revised TVA code relating to procurement of personal property and of services.

*F3. Supplement to interagency agreement with the U.S. Army Corp of Engineers covering arrangements to proceed with the second phase of concrete investigation at Center Hill Dam.

F4. Supplement to Agreement No. TV-64685A with Oak Ridge Operations, U.S. Department of Energy (DOE) covering arrangements for analysis of macrobenthos samples from the Bear Creek and Grassy Creek watersheds near Oak Ridge, Tennessee.

F5. Memorandum of Understanding No. TV-66067A between TVA and National Associations of Towns and Townships covering arrangements for cooperation in developing and disseminating information concerning approaches to the solution of problems in the Nation's small towns and rural areas.

F6. Contract No. TV-66121A between TVA and State of Mississippi Governor's Office of Appalachian Development providing for economic development projects in the Tennessee-Tombigbee Waterway area.

F7. Contract No. TV-66128A between TVA and Johnson County Industrial Commission providing for assistance under TVA's Special Opportunities Counties and Cities program.

F8. Contract No. TV-64538A between TVA and the Agricultural Stabilization and Conservation Service covering arrrangments for cooperation in a project to demonstrate animal waste management systems to improve water quality in the Duck River and its tributaries.

**CONTACT PERSON FOR MORE INFORMATION:** Craven H. Crowell, Jr., Director of Information, or a member of his staff can respond to requests for information about this meeting. Call (615) 632-8000, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 245-0101.

Dated: February 19, 1985.

**W.F. Willis,**

*General Manager.*

[FR Doc. 85-4531 Filed 2-20-85; 4:03 pm]

BILLING CODE 8120-01-M

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*Items approved by individual Board members. This would give formal ratification to the Board's action.

Federal Register

Friday
February 22, 1985

Part II

# Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 71, 170, 171, 180, 201, 310, 312, 314, 330, 430, 431, 433, 510, 511, 514, 570, 571, 601, 812, 1003, and 1010

New Drug and Antibiotic Regulations; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 71, 170, 171, 180, 201, 310, 312, 314, 330, 430, 431, 433, 510, 511, 514, 570, 571, 601, 812, 1003, and 1010**

**[Docket No. 82N-0293]**

## New Drug and Antibiotic Regulations

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is revising its regulations governing the approval for marketing of new drugs and antibiotic drugs for human use. FDA is taking this action to speed up the availability of beneficial drugs to consumers by improving the efficiency of the agency's approval process for new drugs and antibiotic drugs, while improving the already high level of public health protection the drug approval and surveillance processes now provide. The improvements will help applicants prepare and submit higher quality applications and permit FDA to review them more efficiently and with fewer delays. This will benefit both consumers and applicants by permitting earlier availability and marketing of new drugs and antibiotics. This action is one part of a larger effort by FDA to review all facets of the agency's drug approval process.

**DATES:** These final regulations are effective May 23, 1985, except 21 CFR 314.80 *Postmarketing reporting of adverse drug experiences* is effective August 22, 1985. FDA will, however, accept applications until February 24, 1986 that are in the format required under either the current regulations or this final rule. For additional information concerning these effective dates see IV. "Paperwork Reduction Act of 1980" appearing in the preamble of this document.

**FOR FURTHER INFORMATION CONTACT:** Steve H. Unger, Center for Drugs and Biologics (HFN-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.

**SUPPLEMENTARY INFORMATION:**

### I. Introduction

This final rule completes the first phase of efforts by the Department of Health and Human Services (HHS) to revise Federal regulations governing the new drug approval process. This phase of the regulations (called the NDA Rewrite) finalizes new procedures in 21 CFR Part 314 for FDA review of new drug and antibiotic applications for marketing. This action completes the rulemaking process begun on October 19, 1982 (47 FR 46622). The second phase of these regulatory revision efforts (called the IND Rewrite) covers FDA procedures in 21 CFR Part 312 for reviewing investigational new drug applications. This second phase is nearing completion, following the publication of proposed regulations in the **Federal Register** of June 9, 1983 (48 FR 26720). A third phase of improving the drug approval process involves noncodified guidelines on application format and on fulfulling testing requirements. Together with other regulatory and administrative reforms, the IND/NDA Rewrite and related guidelines represent a major effort on the part of FDA to improve the entire process of drug approval regulation. This effort was begun by FDA through concept papers made available for public comment (44 FR 58919, October 12, 1979) and a related public meeting on November 9, 1979. It was accelerated and intensified at the request of the President's Task Force on Regulatory Relief.

The objectives of the NDA Rewrite final rule are to establish an efficient, but thorough, drug approval process in order both: (a) To facilitate the approval of drugs shown to be safe and effective; and (b) to ensure the disapproval of drugs not shown to be safe and effective. These regulations are also intended to improve FDA's surveillance of marketed drugs. Accordingly, the final regulations enable FDA to act as both a public health promoter, by facilitating the approval of important new safe and effective therapies, and as a public health protector, by keeping off or taking off the market drugs not shown to meet safety and efficacy standards.

In preparing the final rule, FDA carefully reviewed approximately 120 comments received from pharmaceutical manufacturers, trade associations, health professionals and professional societies, consumers and consumer organizations, and Congress. In addition, FDA held a series of meetings with agency employees in order to gain their views as part of the internal decisionmaking process. The agency also considered the recommendations of the Congressionally sponsored Commission on the Federal Drug Approval Process. In preparing the final rule, therefore, the agency has considered the views of virtually all persons having an interest in the drug approval process.

Like both the NDA and IND proposals, the NDA final rule has been reviewed by a special task force appointed by the Secretary of Health and Human Services, and chaired by the Commissioner of Food and Drugs, whose specific charge has been to review these regulations in accordance with Executive Order 12291 (46 FR 13193, February 19, 1981), the mandate of the President's Task Force on Regulatory Relief, and the policy objectives outlined above. Many of these issues were also reviewed by a separate FDA task force, which the Commissioner also chaired.

The NDA final rule is designed to complement the proposed IND regulations, especially in terms of fostering a continuous dialogue between FDA and applications throughout the drug development and approval process. For example, one of the major improvements over present practice suggested in the IND proposal was to allow any drug sponsor an opportunity to attend an "end-of-Phase 2" meeting with FDA officials in order to agree on a plan for Phase 3 clinical investigations. As stated in that proposal, FDA believes that such meetings can significantly shorten the period of subsequent NDA review. The IND proposal also encourages "Pre-NDA" meetings between FDA and applicants to discuss format and modes of presentation in the marketing application. These meetings will be especially necessary as applicants learn how to prepare marketing applications under the new format. As described further below, the NDA Rewrite final rule encourages such dialogue to continue throughout the NDA review period as well.

The new NDA regulations will be supplemented by a series of guidelines. These guidelines are intended to provide applicants with guidance on application format and on how to fulfill testing requirements. The format guidelines will address the overall summary and each of the different technical sections of the application. The guidelines on how to fulfill testing requirements will focus on the areas of animal toxicity testing and chemistry and manufacturing controls, as previously announced in the preamble to the IND Rewrite proposal (48 FR 26720, 26721). These guidelines are in addition to the overall 25 clinical guidelines that FDA prepared in the middle and late 1970's concerning the design of adequate and well-controlled studies on different classes of drugs. Finally, FDA plans to issue a guideline regarding the reporting of adverse drug experiences on marketed drugs, a draft of which has already been made available for public comment (48 FR 4049; January 28, 1983). FDA intends to continue to solicit public comment on

draft guidelines before they are published in final form. For example, notices announcing the availability of several draft guidelines concerning how to fulfill chemistry and manufacturing controls requirements have already been published (see the Federal Register of February 1, 1984 (49 FR 4040) and May 7, 1984 (49 FR 19412 and 19413)). FDA hopes to have all these guidelines publicly available, at least in draft form, before the new regulations become effective, although the agency does not view the existence of draft or final guidelines as being a prerequisite for implementing this final rule.

The IND/NDA Rewrites and related guidelines are part of a larger, overall effort to improve the drug development and approval process. For example, FDA will continue to recognize the high priority given to new drug and antibiotic application reviews, to increase the efficiency in the management review of applications, and to strengthen the agency's scientific base. In addition, with the passage of the Orphan Drug Act of 1983, the agency's Office of Orphan Products Development is actively involved in facilitating the development of new drug and other products intended to treat rare diseases.

Highlights of this final rule, the agency's economic analysis, and responses to general comments are contained in the following introductory sections. The remainder of this preamble is devoted to a section-by-section analysis of comments received, responses to them, and contents of the final regulations.

## II. Highlights of the Final Rule

As noted above, the guiding principle in the NDA Rewrite final rule is that the drug approval process should be efficient, but thorough, in order to facilitate the approval of drugs shown to be safe and effective, and ensure the disapproval of drugs not shown to be safe and effective. The regulations are also intended to improve FDA's surveillance of marketed drugs. In response to comments and further internal deliberations, the final rule has modified certain provisions of the proposal in order to meet these objectives better. The major provisions of the final rule are summarized as follows:

1. *Application format.* The final rule incorporates the proposed revisions designed to make the application format more amenable to efficient agency review. Thus, like the proposal, the new format requires an overall summary of the entire application and separate, detailed technical sections that each contain individual summaries and analyses of the specific information needed by the particular reviewing disciplines: clinical, pharmacology, chemistry, statistics, and biopharmaceutics (as well as microbiology for anti-infective drugs). The new format will therefore permit parallel review by each of the five (or six) disciplines. In addition, detailed technical sections that synthesize the important information about the drug will greatly facilitate review by agency officials. The final rule also provides applicants the option of submitting the chemistry section (if it is complete) 90 to 120 days prior to submission of the main application in order to expedite review and permit early resolution of deficiencies.

2. *Safety update reports.* The final rule also incorporates the general requirement contained in the proposal for applicants to submit new safety information learned about a drug while an application is being reviewed by FDA. The final rule modifies the timing and frequency of these reports in order to focus FDA evaluation of them at key points in the review process. Thus, under the final rule, safety update reports will be required 4 months following the initial submission of the application, following receipt of an "approvable" letter, and at other times upon FDA request. These safety update reports will ensure that approval decisions reflect the most up-to-date safety information available.

3. *Case report forms and data tabulations.* The final rule follows the general principle enunciated in the proposal that an efficient agency review of individual patient data should be based primarily on well-organized, concise, data tabulations, and that reliance on the more lengthy case report forms should be reserved for those instances where a more detailed review is necessary. Accordingly, the final rule provides: (i) That case report forms will be routinely required where the patient dropped out or died during a clinical study (because these forms are likely to disclose the most serious safety problems); (ii) that individual patient data tabulations will be required for the remaining patients; and (iii) that additional case report forms will be requested by FDA when needed to conduct a proper review of the application. In response to comments, the final rule clarifies that FDA reviewers, with the concurrence of the division director, will have access to whatever additional case report forms are needed to conduct a proper review. The preamble explains that this may include requests for full case reports from the most critical studies, but that these reports will ordinarily be requested early in the review process so as not to cause undue delay. These data submission requirements should promote a more focused, efficient review of the application without compromising the thoroughness of that review. FDA estimates that this approach will result in a 75 percent reduction, on average, in the number of case report forms now required to be submitted to the agency in order to obtain approval.

4. *Time frames for FDA review.* The final rule incorporates the time frames contained in the proposal pertaining to the agency's review of applications. Accordingly, the final rule gives the agency 180 days from receipt of an application to issue either an "approval" letter, an "approvable" letter, or a "not approvable" letter. This time period may be extended when major amendments are received, although the extension would only be for the extra time needed to review the amendments. The final rule, like the proposal, also defines the procedure and time frame for "filing" an application within the meaning of section 505(c) of the act (21 U.S.C. 355(c)). Codification of these time frames demonstrates the agency's commitment to reviewing applications promptly in accordance with the statutory mandate.

5. *Action letters.* The final rule also incorporates provisions contained in the proposal which clarify the meaning of its three action letters: approval letters, approvable letters, and not approvable letters. Like the proposal, the final rule clarifies that only an approval letter grants permission for marketing of a drug. In addition, the final rule adopts the proposed policy that the agency will issue an approval letter, rather than an approvable letter, when the only deficiencies in the application concern editorial or other minor changes in the labeling, with approval conditioned on the deficiencies being corrected, as requested, before the drug is marketed.

6. *Foreign data.* The final rule incorporates the proposed policy that an application based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved by FDA if: (i) The foreign data are applicable to the U.S. population and U.S. medical practice; (ii) the studies have been performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate

means. These criteria assure the quality of any drug products so approved, while at the same time removing the need to conduct repetitive clinical testing in this country in those instances where adequate data have been generated abroad.

7. *Communication between FDA and applicants.* The final rule greatly expands upon the proposed provision concerning communication between FDA and applicants. The final rule, with greater emphasis than the proposal, encourages dialogue between FDA and applicants about scientific and medical issues that arise during the review process. This includes notifying applicants of easily correctable deficiencies found in an application shortly after those deficiencies are discovered, providing an opportunity for an informal meeting mid-way through the review process and again after FDA's review is completed, and expressly permitting telephone calls and other informal meetings as the need may arise. This provision builds on portions of the IND Rewrite proposal that encouraged such communication during the testing phase of the drug development process.

8. *Dispute resolution.* The final provision on dispute resolution has been significantly revised in order to build upon the general principles noted above with respect to communication between FDA and applicants. For administrative and procedural issues, the final rule establishes an ombudsman whose function will be to investigate what has happened and to facilitate a timely and equitable resolution. For scientific and medical disputes, the final rule provides that applicants should seek resolution through an "end-of-review conference", with appropriate agency staff and management representatives, and at other informal meetings as the need may arise. The final rule also provides for the participation of outside experts at these informal meetings when feasible. This procedure supersedes the appeals process described in the NDA (and IND) Rewrite proposals because that process was seen as being too formal and was not effective during the pilot period.

9. *Supplements.* The final rule, like the proposal, establishes different categories of supplements to approved applications concerning manufacturing and controls changes. The rationale for the categories is that changes that could affect the safety or effectiveness of a final drug product should be preapproved by FDA, but that other changes may be implemented by a firm while notifying FDA either concurrently or in the next annual report. Although some changes have been placed in different categories than originally proposed, the final rule should still result in a 20 percent reduction in the number of manufacturing and controls supplements that require prior approval by the agency. Thus, the final rule will enable drug manufacturers to implement some kinds of manufacturing changes significantly more promptly without compromising drug safety and effectiveness.

10. *Postmarketing surveillance.* The final rule modifies the proposal in several ways in order to focus FDA review more directly on the more serious adverse drug experiences. Under the final rule, 15 working day "alert reports" will be required for all adverse drug experiences that are both serious and unexpected, and for any significant increase in frequency of an adverse drug experience that is both serious and expected (rather than only unexpected fatal and life-threatening experiences, as had been proposed). Other adverse drug experiences, as specified in the final rule, will be required to be reported at quarterly intervals in the first 3 years following approval, and annually thereafter. The quarterly reporting requirement reflects the fact that close surveillance of a new drug's side effects is especially important during the first 3 years of marketing. Although the quarterly/annual reporting of adverse drug experiences is less frequent than the proposed period of 30 working days, FDA believes that such quarterly/annual reporting is consonant with the agency's need to review reports of expected or nonserious adverse drug experiences.

## III. Economic Analysis

The agency has examined the economic consequences of these regulations in accordance with Executive Order 12291 and the Regulatory Flexibility Act. A final regulatory impact analysis has been prepared and placed in file with the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

The regulations are expected to shorten the total elapsed time required to approve the average application, including resubmission, from about 27 months to 21 months—an average savings of 6 months. The average approval time for applications involving important new chemical entities is projected to improve from about 19 months to 17 months—an average savings of 2 months. The faster approval and smaller savings for new chemical entities reflect the special priority already accorded these applications. Faster approvals for applications would benefit both consumers and pharmaceutical manufacturers. Consumers would have earlier access to important new drugs that have the potential to extend life, avoid hospitalization, or provide other significant health benefits. Firms developing new drugs would realize faster return on their research investments, thereby encouraging further investment in subsequent pharmaceutical research. The regulatory impact analysis examines some measures of these various benefits, although none are amenable to simple quantification in monetary terms.

Nonetheless, these benefits are substantial. For example, a 2-month speed-up in the approval of 15 therapeutically significant applications per year would result in about 500,000 additional prescriptions for these important drugs in the first year following FDA approval. The number of persons benefiting from these additional prescriptions would probably exceed 200,000, after adjusting the total for renewal and repeat prescriptions. Some of these individuals should receive very significant medical benefits such as avoidance of surgery, cure or stabilization of a life-threatening disease, or relief of a physical handicap. Many individuals should also save money as compared to alternate treatments.

The accelerated availability of new drugs to consumers will also increase industry revenues. However, the increase will not be as great as gross sales because some of the new drugs will displace less effective or more costly drugs.

Changes in the cost of the new drug application process itself will be minor. Increases include $1.2 million annually for detailed NDA summaries, $0.5 million annually for NDA safety update reports, and $0.4 million annually for increased adverse experience reports for approved NDA's; decreases include $0.4 million for less routine paperwork for NDA's, $1.6 million for reduced supplements for approved NDA's, and $1.6 million for reduced supplements for approved ANDA's. These latter two decreases relate to applications to change postmarketing manufacturing procedures for NDA's or ANDA's in minor ways. The net decrease of $1.5 million is about $1.0 million less than the cost savings estimated in the preliminary analysis, attributable primarily to cost estimates for safety update reports and adverse experience

reports that were not calculated at the proposal stage.

The agency also concludes that these regulations will have a favorable impact on small firms because of cost savings associated with abbreviated applications, the type of application most frequently held by small firms. Due to the elimination of requirements for submitting certain postmarketing supplements, FDA estimates a savings of $540 for each abbreviated application. While this impact is favorable, it will not be a significant savings for any one firm. Therefore, the agency certifies, in accordance with the Regulatory Flexibility Act, that this rule will not have a significant economic impact on a substantial number of small entities.

## IV. Paperwork Reduction Act of 1980

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the reporting and recordkeeping requirements in §§ 314.50, 314.55, 314.70, 314.71, 314.72, 314.80, 314.81, 314.90, 314.110, 314.120, 314.126, 314.200, 314.300, and 314.420 in these regulations will be submitted for approval to the Office of Management and Budget (OMB). Interested persons desiring to submit comments on the collection of information requirements pursuant to the Paperwork Reduction Act and its implementing regulations (5 CFR Part 1320) should direct them by April 15, 1985, to the Office of Information and Regulatory Affairs, OMB, Rm. 3002, New Executive Office Bldg., Washington, DC 20503, Attn: Bruce Artim. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register prior to May 23, 1985.

## V. Comments on Proposed Rule

*General Comments*

1. FDA received approximately 120 comments on the proposed rule. These comments were received from pharmaceutical manufacturers, trade associations, health professionals and professional societies, consumer and consumer organizations, and Congress. A number of the proposed changes were generally supported by these diverse groups, especially those improving the application format, establishing time frames for FDA review of applications, and requiring safety update reports for pending applications. Other items considered especially beneficial by consumers included the requirement for a description of the foreign marketing history of the drug and the proposal concerning postmarketing surveillance. In addition, industry comments found especially beneficial the adoption of a single set of regulations for both antibiotics and nonantibiotic drugs, the reductions in supplements and other reports, and the clarified definitions and procedures for FDA's issuance of action letters.

2. The major concerns raised by consumers and consumer organizations was the fear that two of the proposed changes could possibly result in the marketing of drugs that are not safe or effective, as required by law. The issues of concern in this regard were the proposal to eliminate the routine submission of most case report forms, and the proposal concerning the acceptance of foreign data.

FDA shares the view that any changes made in the new drug regulations should not in any way lower the safety and effectiveness of marketed drugs, and FDA has carefully reviewed each section of the final regulations to ensure that that result does not occur. With respect to case report forms, the final rule ensures that FDA reviewers will have access to any case report forms necessary to conduct a proper review of the drug's safety and effectiveness. With respect to foreign data, FDA carefully reviewed its proposed policy, and explains in this preamble why the agency does not believe that fears about a possible lowering of drug quality are warranted. The agency intends to administer the policy with this concern in mind. Both of these issues are discussed in more detail in the section-by-section analysis.

3. Comments received from the pharmaceutical industry raised three kinds of objections. First, industry comments believed that the proposed regulations were deficient in not addressing several areas that the industry believes are important, such as granting sponsors a right to bring disputed matters to an outside advisory committee, providing an ombudsman to resolve minor procedural disputes, expanding communication between FDA and applicants, and codifying substantive provisions of the standards for safety and effectiveness.

Second, industry comments suggested that, although many of the proposed revisions represented movement in the right direction, FDA should make more dramatic changes in the drug approval process in order to achieve adequate regulatory reform. For example, some industry comments urged replacing both case report forms and detailed tabulations with briefer summaries, placing even greater reliance on foreign data and requiring many fewer supplements to approved applications.

Finally, while agreeing with the concept of strengthened postmarketing surveillance, industry comments generally stated that the specific reporting requirements proposed were excessive and did not provide a corresponding public health benefit. These comments stated that the reporting requirements should be better tailored to the relative importance of the adverse drug experiences involved.

In response to these comments, FDA has added to the final rule major sections on communication between FDA and applicants and on dispute resolution, including establishment of an ombudsman. The final rule also contains a detailed statement on the agency's use of advisory committees, although the agency has not provided, for the reasons stated in that discussion, applicants with rights to advisory committee reviews of issues. With respect to codifying substantive standards for safety and effectiveness, FDA believes that current statutory and regulatory provisions contain the necessary flexibility to administer these provisions to the wide variety of drugs subject to FDA's approval authority. The agency has, moreover, undertaken to provide further guidance with respect to the efficacy standard through the publication of guidelines for over 25 classes of drugs. Finally, in the IND Rewrite proposal, FDA stated its intent to make "end-of-Phase 2" meetings available for all IND's. These meetings provide a mechanism for agency reviewing officials and sponsors, with input from outside experts, to agree on an overall plan for Phase 3 investigations and the objectives and design of particular studies necessary to demonstrate the safety and effectiveness of the drug. (See 48 FR 26732.) FDA believes that this in-depth, case-by-case approach, will greatly facilitate the drug development process by providing sponsors with specific information about safety and effectiveness requirements in a timely manner.

Second, FDA generally disagrees with the industry comments that suggested that specific provisions in the proposal did not go far enough in providing regulatory relief. As described further below, FDA believes that case report forms and tabulations provide information, viewed as necessary, that may not be obtained through summaries alone; that further changes in the foreign data policy are not now appropriate; and that significant further changes in the area of supplements could possibly adversely affect the assurance of FDA regulation of marketed drugs.

Finally, FDA agrees that improvements in postmarketing surveillance should focus high priority reporting requirements on the more important adverse drug experiences. Accordingly, as described further below, the final rule provides for more stringent reporting requirements for adverse drug experiences that are both enexpected and serious, and less stringent requirements for the others.

4. Several comments urged FDA to adopt more specific and detailed regulations that give clear guidance to the regulated industry and to FDA personnel. According to these comments, these regulations should include detailed requirements for FDA actions, broad admonitions about normative conduct, requirements for agency documentation of decisions, and internal review mechanisms. Comments objected to FDA relying upon guidelines, internal manuals, memoranda, and other similar informal mechanisms to handle practices and procedures because they are too imprecise, subject to change, and of questionable authority. However, if FDA does decide to rely heavily on staff manual guides, one comment urged FDA to establish and codify a policy stating that such guides are binding upon the agency.

Many comments addressed further the issue of guidelines. Several comments argued that it was hard to discern the proposal's true impact without reviewing the guidelines FDA intends to use to implement the regulations and, accordingly, that FDA should reopen the administrative record once the guidelines are available. Moreover, these comments believe FDA should limit the use of guidelines to those situations where negotiation and alternative methods are clearly necessary or desirable, such as in clinical trials of different diseases. Several comments also asked FDA to provide notice and comment procedures on draft guidelines and staff and compliance manuals before final ones are prepared. Finally, some comments objected to FDA's reliance on guidelines because such documents often remain internal working documents and, according to these comments, are applied less consistently than the regulations. Finally, one comment urged that the final rule, or another proposal, should address procedural issues in the application review process, such as the designation of a primary review team early in the process, the need for meetings, concurrent review of an application by members of a review team, the finality of each part of the review once it is completed, and the importance of a tracking system to determine the history and current location and status of all submissions to FDA.

FDA believes its proposal provided adequate notice of the rights and responsibilities of both applicants and the agency in the drug approval process. FDA believes the more detailed regulations urged by these comments would add very little to the structure of the new drug approval process provided by FDA's combination of regulations, guidelines, and staff guides, while making the process more inflexible and difficult to change. The agency believes the proposal struck a proper balance between the need for regulatory requirements, the use of guidelines to help persons comply with those requirements, and the use of staff manuals to direct agency employees. FDA recognizes that the prompt issuance of clear guidelines will be most helpful to applicants and, thus, the agency is taking steps to expedite the development of guidelines and to clarify for its staff the role of guidelines in the regulatory process. Because FDA recognizes the significant contribution the industry, the medical community, and other members of the public can make to the development of scientifically sound guidelines, the agency routinely solicits comments on its guidelines either as draft or as final documents. With respect to the guidelines developed to implement this final rule, FDA intends to issue them as draft guidelines and to seek comments on them before they are made final. FDA believes it has provided adequate notice for this rulemaking proceedings and does not intend to reopen the administrative record on the regulations after the guidelines (or draft guidelines) are issued. Finally, FDA believes that administrative steps short of codification, such as staff manual guides, are appropriate for many management issues.

5. Several comments suggested that FDA implement many of its proposed procedural improvements in the new drug approval process immediately following the closing of the comment period (for example, changes in the content and format of an application, time frames for filing and reviewing an application and amendments, provisions on communications between the agency and applicants, and procedures for action letters).

Although FDA implemented several changes at the time it published the proposal (i.e., implementation of the informal appeals process; changes in the procedures for submitting samples; and the policy to notify applicants about deficiencies in chemistry, manufacturing, and controls information within 90 days of the beginning of the review of an application), the agency believes there is insufficient justification to implement other new requirements in advance of traditional effective date periods. FDA also notes that certain changes in the regulation (such as the procedures for action letters) simply codify current practice and so that immediate implementation of the final rule would not have had measurable impact.

6. One comment suggested that FDA impose user fees on industry for services FDA performs, particularly the costs of on-site inspections of domestic and foreign facilities. Another comment suggested that the agency incorporate into a final rule requirements for the evaluation of important new drugs in children before or at the time of approval of the application.

FDA believes these complex issues are sufficiently unrelated to the regulatory improvements in the new drug approval process that are implemented by the final rule that full consideration of them now would unnecessarily delay implementation of the rule. The agency is, however, exploring each of these issues separately and welcomes further discussion of them.

*Effective Date*

7. FDA received several comments recommending various effective dates for the final rule. Several comments suggested an effective date for the final rule of 180 days or 1 year, but also suggested that FDA accept applications up to the effective date in either the old, proposed, or new formats. A medical association suggested that FDA clarify how the regulations will apply to studies already in progress and to studies completed but not submitted before the effective date of the regulations. Finally, one comment urged that FDA not issue a final rule amending its new drug application regulations until after it has published and received comments on its proposal to revise the investigational new drug regulations.

FDA has concluded that these final regulations will become effective May 23, 1985, except § 314.80 *Postmarketing reporting of adverse drug experiences* will become effective August 22, 1985. FDA will, however, accept applications until February 24, 1986, that are in the format required under either the current regulations or this final rule. The separate effective date for the reporting of adverse drug experiences reflects the

time FDA believes applicants may need to adapt to the new regulations. As noted above, with respect to application format, FDA has followed the suggestion to permit applications to be submitted in the format prescribed by either the current regulations or this final rule (but not the proposed rule). This 1-year period also covers the submission of case report forms and data tabulations. FDA believes this 1-year period of optional formatting will facilitate a smooth transition from the old to the new regulations. Within the parameters described above, the effective dates apply to studies in progress or not yet submitted to FDA.

Although FDA will accept for 1 year applications in the format required under the current regulations, the substantive requirements of the regulations will apply to pending and approved applications on and after May 23, 1985 under this final rule. For example, the requirements and procedures for amendments, communication between FDA and applicants, dispute resolution, withdrawal by the applicant, safety update reports, supplements, records and reports, time frames for FDA action, action letters, adequate and well-controlled studies, and withdrawal of approval will apply after 90 days to all applications regardless of the format in which they appear.

Finally, in the Federal Register of June 9, 1983 (48 FR 26720), FDA proposed to revise its regulation governing the investigational use of new drugs. The comment period on the proposal closed August 8, 1983, and the agency is reviewing those comments. FDA does not believe that the IND rulemaking proceeding should further delay these final regulations because the two sets of regulations address different stages of the new drug development and approval process, and can be implemented separately in a satisfactory manner.

8. FDA has added to the final rule a new section that states the agency's intention that the regulations be applied in a manner that facilitates the approval of safe and effective new drugs, ensures that drugs not shown to be safe and effective are not marketed, and provides for an effective system for FDA's surveillance of marketed drugs.

*Definitions (§ 314.3)*

9. Several comments objected to the agency's proposed definition of the term "drug substance," claiming that the definition is overbroad and would wrongly subject the following to FDA regulation as new drugs: foods, vitamins, minerals, amino acids, other nutritional substances, and intermediates used in the synthesis of the drug substances.

FDA does not believe that the proposed definition of "drug substance" has the broad reach attributed to it by the comments. The proposed definition does not subject substances to FDA regulation as new drugs that do not fall within the definition of "new drug" in section 201(p) of the act (21 U.S.C. 321(p)). Moreover, the proposed definition is consistent with the definition of "drug" in section 201(g)(1) of the act and the agency's definition of "active ingredient" in § 210.3(b)(7) (21 CFR 210.3(b)(7)) of FDA's current good manufacturing practice regulations. FDA has, however, revised the definition in the final rule to make clear that it does not apply to intermediates used in the synthesis of the drug substance.

*Application Form (§ 314.50(a))*

10. One comment suggested that the proposed changes in the format for an application, under which a reviewer would receive only an overall summary and a technical section devoted to the reviewer's own discipline, would make it harder for a reviewer to consider relevant data that appear only in another reviewer's technical section.

The new application format should not have the result suggested by this comment. The application summary is intended to provide reviewers with adequate information about subjects outside their own review disciplines. Moreover, reviewers will also have access to other technical sections in the archival copy of the application, which will be maintained as a reference copy in the reviewing division's document room. Thus, reviewers will have access to whatever data they need for their reviews.

11. Several comments suggested that the regulations should make it clearer that the revised new drug and antibiotic application form is intended to serve essentially as a check list of basic information about the new drug and the application.

FDA agrees that the application form should serve only as a capsule listing of the contents of the application and the most basic information about the drug. This purpose will be self-evident from the revised form itself and, for that reason, no changes in this regard have been made in the regulations.

12. One comment objected to the requirement that the application form contain the established name, proprietary name, and code of the drug product. The reason for the objection was that some of the information may not yet exist when the application is filed. Two comments also sought clarification of the term "code" and asked whether it referred to the chemical name, shipping code, or marketing code.

The reason that names and codes used for the drug product must be submitted on the application form is to provide reviewers with easy identification of the product formulations to which the application refers. The term "code" would apply to any designation of a drug that would help identify it. To the extent one of the listed identifiers is not available, it would not need to be provided.

13. One comment suggested that the agency should establish procedures providing for the early submission and review of the chemistry, manufacturing, and controls section and/or the preclinical data section before submission of the clinical data and other sections. According to the comment, these early submissions would expedite ultimate approval by permitting early review and resolution of deficiencies in these technical areas.

FDA has revised the final rule (to be elaborated on by a staff manual guide) to provide for the early submission of chemistry, manufacturing, and controls information, at the option of the applicant. During the IND period, applicants will be permitted to submit information about fully developed chemistry, manufacturing, and controls procedures and specifications 90 to 120 days in advance of the submission of the main application. Chemistry, manufacturing, and controls submissions would not be accepted less than 90 days before the submission of the main application, as they would come too late to improve the speed of the review process significantly. Similarly, such submissions would not be accepted more than 120 days before submission of the main application because they would be premature and would likely not be sufficiently complete or final for review purposes. (Because review of preclinical data is not a common source of delay in the review process, the final rule does not provide for their early submission.)

The final rule expands upon past practice which had been to limit such early submissions only to drugs offering therapeutic advances. The agency notes, however, that in expanding the permissibility of such early submissions to other drugs, FDA's ability to review them early will depend upon available resources. Full applications are viewed as having higher priority, as are early submissions of chemistry, manufacturing, and controls information for drugs offering therapeutic advances.

Nevertheless, this change in the final rule provides a mechanism for speeding the review of at least some applications for which a mechanism does not presently exist.

14. One comment suggested that FDA clarify the status of its paper NDA policy in the final rule.

FDA has revised the final rule to include a description of the "paper NDA." This is an application for a duplicate of a marketed drug product which relies primarily on published literature to provide substantial evidence of effectiveness and adequate scientific evidence of safety for the claimed indications. A complete description of FDA's paper NDA policy appears in the **Federal Register** of May 19, 1981 (46 FR 27396).

*Summary (§ 314.50(c))*

15. Several comments endorsed the requirement for an overall summary, but urged that it should resemble more a brief summary than a lengthy treatise.

FDA agrees in part. As stated in the proposal, the summary is intended to facilitate review of the application. If a more complete summary of any specific section of the application is needed to provide the necessary information for review purposes, it should appear in the appropriate technical section. FDA also will not refuse to file an application or delay its approval if the summary is inadequate, provided the data contained in the technical sections of the application show that the drug is safe and effective. Applicants should recognize, however, that a superficial, poorly written, or incomplete summary will not serve its intended function of facilitating review and could even prolong the review process if it is confusing. The summary, therefore, should include critical details of study design, sufficient numerical data (tabular or graphic) to provide a quantitative understanding of the data, and a forthright discussion of any problem areas. Althought the preamble to the proposal suggested that a typical summary should be 50 to 200 pages long, length will likely vary according to the nature of the drug and the quantity and type of information available. Fifty pages should not be viewed as a minimum requirement, nor 200 pages a maximum; applicants should instead be guided by the circumstances surrounding the particular application at hand.

16. FDA received several comments concerning the proposed requirement that the overall summary contain a fully annotated copy of the draft labeling. One comment asked that FDA require annotations to drug labeling only for claims about safety and effectiveness. Another comment asked for clarification about how omissions from labeling should be annotated. The comment also objected to the requirement that the labeling bear annotations to the information in both the summary and the technical sections of the application, suggesting that such a requirement is redundant. A third comment suggested that the summary should contain only a brief summary of the labeling information about the drug, and that copies of the labeling itself (including labels, packages, and package inserts) should not be required. Finally, one comment found the proposal unclear about whether labeling should be included in the clinical or chemistry sections of the application, and whether reviewers would receive copies of labeling.

Assessment of the adequacy of labeling is a critical part of FDA's review of a new drug application. In determining whether the data and information in an application support the claims made in the product's labeling, it is helpful to know the precise information that the sponsor considers supportive. By providing reviewers with an annotated copy of the proposed labeling for the drug, and by directing the reviewer to both the summarized and detailed data supporting the labeling, the sponsor can assure that critical supporting data are not ignored and that confusion (with its inevitable delay) about the basis for labeling does not arise.

As indicated, FDA believes that annotations referring to both the technical sections and the overall summary will best facilitate review. The inclusion of annotations to the summary will be particularly important to the reviewers who do not receive the technical sections, and to others, such as FDA's managers and advisory committee members, who will not review all of the technical data. These reviewers also may wish to consider certain matters in detail, however, and the references to technical sections will facilitate this. By law, "specimens" of the labeling are required to be submitted, and brief summaries, as suggested by one comment, are not viewed as adequate. The agency's guideline on preparing a summary will clarify more fully the kinds of information that should appear in annotated labeling, and how omissions from the labeling should be annotated.

Finally, an annotated copy of the labeling will appear in the summary, which will be provided to each reviewer. In addition, copies of labels and other labeling pieces will be contained in the archival copy of the application where they will be available to all reviewers, as necessary.

17. One comment supported FDA's proposal to use the application summary to prepare the summary basis of approval (SBA) document that is made publicly available following approval of the application. Another comment suggested that FDA work with the applicant during the preparation of the SBA and allow the applicant to review the SBA before it is released to ensure the protection of proprietary information.

Although FDA believes applicants can play a large role in the development of the SBA through the preparation of the summary, the SBA necessarily reflects FDA's judgment, and not the applicant's, of what data and information in the application support approval of the drug product. FDA believes that an applicant's review of the SBA to identify proprietary information is unnecessary because FDA has traditionally not included such information in the SBA.

18. One comment suggested that applicants should not ordinarily be required to submit a completely revised summary with a resubmitted application, and should be permitted, to the extent possible, to submit only an addendum to the original summary.

FDA agrees that an addendum to a summary is appropriate if minor changes are made to an application. Significant submissions, however, such as providing additional data in response to a "not approvable" letter, would necessitate a revised summary that again reflects a clear and concise description of the information in the application.

19. One comment asked FDA to clarify its requirement for the "marketing history" of a drug by other persons.

This requirement is limited to the marketing of the drug outside of the United States, and it is intended that it will be met with brief information concerning where and when the drug has been marketed, for what indications, and any significant safety or effectiveness problems that developed during such foreign marketing. The agency has revised this provision to require also a list of countries in which applications for marketing are pending. This information will facilitate FDA contacts with foreign drug regulatory officials about the drug.

*Chemistry, Manufacturing, and Controls Section (§ 314.50(d)(1))*

20. FDA received several favorable comments concerning proposed changes in the chemistry section of the

application. For example, one comment was pleased that the proposal generally reflected the format and level of detail of manufacturing and controls data required by the European Economic Community to market a drug product. Another comment agreed with FDA's proposal to eliminate requirements for information available to the agency under its current good manufacturing practice (CGMP) regulations, stating that this change will substantially lessen the burden of preparing an application without compromising safety or effectiveness.

21. FDA received several comments regarding the agency's proposal to permit references in the chemistry technical section to compendial monographs. One comment urged FDA to go even further and not require detailed descriptions of drug substances subject to compendial monographs if the source of the substance is identified and CGMP's are followed in manufacturing it. A comment supported the proposal, believing that it reflects FDA's willingness to rely upon the compendia as authoritative sources of pharmaceutical quality standards. Two other comments suggested that the agency should also permit references to the Food Chemicals Codex, the British Pharmacopeia, and other compendia.

The agency is issuing this provision essentially as proposed, with one clarification. Although FDA believes that references to the official compendia may be relied upon under proper circumstances to provide required information, new developments in drug synthesis and advances in analytical technology may introduce new concerns about the chemistry of drug substances that are not adequately addressed by current compendial monographs. In those cases, FDA may need additional information about a drug substance to ensure that additives or byproducts of the synthetic process are properly controlled. Although a reference to official compendia will often satisfy the requirements, FDA has revised the final rule to state that FDA may require that additional information be submitted to permit the proper review of the application. This is particularly the case for tests for impurities and adulterants that might be present depending upon the source of material and the manner of processing the applicant employs. While compendial monographs are intended to assure the identity, strength, quality, and purity of the drug, they are not intended to include in each monograph a test for every impurity or adulterant. Thus, FDA concludes that additional information about drug substances subject to compendial monographs will sometimes be required.

The regulation limits the compendial sources that may be referenced to "official compendia" because a special relationship exists between FDA and the official compendia (United States Pharmacopeia/National Formulary) under the act, where FDA is authorized to enforce compendial standards (see section 502(g) of the act (21 U.S.C. 352(g)).

22. Several comments addressed the proposed requirements for documentation of raw materials and reagents used in the manufacture of the drug substance. One comment thought the requirements were ambiguous. A second comment criticized the proposal as continuing to require too much information about the method of synthesis, isolation, and purification of a drug substance. This comment suggested that either the regulations or a guideline should make it clear that an applicant need only submit such information that applies after a pivotal intermediate used to produce the drug substance is identified. Another comment asked for clarification of the requirement for the submission of specifications and analytical methods for components of a drug product (regardless of whether they appear in the finished product) and whether it includes raw materials used in the drug substance.

FDA believes that complete information about raw materials, reagents, in-process controls, and methods used in the manufacture of a drug substance are needed (particularly for a new chemical entity) to characterize fully the drug substance. The level of detail required, however, will vary according to the nature of the drug and FDA's familiarity with it. To provide flexibility, the regulation itself is general in nature, and FDA will prepare a guideline on the chemistry technical section to aid applicants in determining the appropriate level of data and information on a drug substance needed in a particular case.

23. One comment suggested that the agency should only require information about components of a drug substance that remain, in some measure, in the drug product or which could have an adverse effect on safety or effectiveness.

FDA disagrees with this comment. Information about components that do not appear in the finished drug substance or drug product is important in determining whether the specifications and analytical methods are appropriate to assure the identity, strength, quality, and purity of the drug substance and the bioavailability of drug products made for it. This information is also important to assure batch-to-batch reproducibility of the drug substance. Although these components do not appear in the finished drug substance or drug product, they may, or changes in them may, significant affect the finished drug product.

24. Several comments suggested that the final rule should explicitly recognize current practice, under which applications may provide for alternative sources of inactive ingredients and alternative manufacturing procedures, including the following: (1) Reasonable alternatives for any material used in the synthesis of the new drug substance, (2) alternative methods or variations of methods of synthesis within reasonable limits which do not affect the characteristics of the substance, and (3) reasonable quantitative variations in the ingredients in the product.

FDA agrees with these comments, and has revised the final rule to provide for identifying such alternatives. Generally, an alternative method or variation should include a description of the circumstances under which the alternative or variation will be used. Comparable specifications and analytical data for the material produced by the alternative methods or variations must also be submitted.

25. Several comments addressed the inclusion of bioavailability-related information in the chemistry section. One comment objected to the addition of bioavailability to the statutory standards of identity, strength, quality, and purity—standards that, according to the comment, adequately cover the physical and chemical parameters affecting bioavailability. The comment also pointed out tht bioavailability is covered under its own technical section. Another comment objected to the requirement to provide specifications and analytical methods to ensure bioavailability because the methodology may not exist. A third comment suggested that references to the bioavailability of drug products made from a drug substance be deleted from the paragraph on the drug substance because it appears in the paragraph on the drug product.

FDA believes that these comments misunderstood the proposed requirements. The final rule, like the proposal, does not require the chemistry section of an application to contain information about the bioavailability of the drug product. That information is contained in the human pharmacokinetics and bioavailability section. What is required in the

chemistry section is that an applicant provide specifications and analytical methods for the drug substance and the drug product that will assure the ultimate bioavailability characteristics of the drug product. For example, if the bioavailability of the drug product depends on the crystalline form of the drug substance used in the drug product, the chemistry technical section must contain the necessary specifications and analytical methods to ensure that the substance has the necessary crystalline form. This requirement for specifications and analytical methods pertains to both the drug substance and drug product, because specifications at either or both stages could be pertinent to bioavailability, but it does not apply to intermediates and raw materials used in the manufacturing of the drug substance. If specifications and methods are unnecessary for assuring bioavailability, they need not be supplied. Although it might be argued that the standard of "quality" adequately covers the physical and chemical parameters affecting bioavailability, there is no good reason not to be explicit about the requirements for information about drug chemistry that, although they pertain to bioavailability, must be evaluated by FDA's chemistry reviewers.

26. One comment suggested that the phrase "specifications related to stability" should be deleted from the requirements for the drug substance because expiration dates on drug substances are not required.

Like the previous comments on specifications relating to bioavailability, FDA believes this comment misunderstood the proposal. Although expiration dates for drug substances are not required, establishment of a specification for stability of the drug substance may in some cases be needed to assure the quality of the drug product. If there is no such specification, it need not be supplied.

27. One comment suggested that references to process controls should not be required because they are adequately regulated under the CGMP regulations. According to this comment, requiring this information in an application and requiring agency approval before changes can be made takes away manufacturers' flexibility for establishing procedures for in-process tests and for determining the significance of testing results.

The agency disagrees with this comment. FDA believes that a review prior to marketing of in-process controls is needed to determine whether appropriate tests and limits are established (for example, for solvents and particle size) which may affect physiological or pharmacological activity.

28. One comment urged that the agency codify its current policy that methods validations will not delay approval of an application.

FDA views itself as bound by its current policy, unless changed, regardless of whether it is included in the regulations. Moreover, the policy is of a type that the agency would more likely cast as a guideline, given its length and complexity, than as a regulation. In addition, the agency memoranda on this subject, which have been made public, adequately describe the policy and, thus, FDA does not believe that codifying the policy is necessary.

*Nonclinical Pharmacology and Toxicology Section (§ 314.50(d)(2))*

29. Several comments objected to FDA's proposal to require a description of studies of nonclinical pharmacological actions of the drug for possible therapeutic indications for which the applicant is not seeking approval. These objections are premised on the belief that the information would be irrelevant to the drug's proposed indications, that the requirement would delay submission of an application while the applicant gathered the information, and that time and effort of reviewers would be wasted, particularly if the information were to lead them to speculate about other potential, new indications.

FDA agrees in part with these comments, but believes the purpose of this section was not well described in the proposal. Information about pharmacological effects other than the primary effect related to the proposed use is not usually critical to evaluating the effectiveness of the drug, but these pharmacologic properties are pertinent to a full understanding of the drug's effects, e.g., they may help explain side effects and drug interactions. Such information also is pertinent to investigational use of the drug, so it should be unnecessary for an applicant to perform new analyses to meet the requirement. The agency has revised the final rule to make this requirement clearer.

30. Several comments addressed the form of submission of data from animal studies. One comment requested clarification as to whether the revised regulations are intended to continue the current practice under which individual animal data are only reported in tabulations, and the "raw data" (laboratory notebook, worksheets, and other documentation relating to individual animals) are not submitted unless FDA has reason to request them in a particular case. Another comment suggested that FDA require summaries instead of tabulated individual data from long-term toxicity and carcinogenicity studies in order to reduce the size of the application.

The nonclinical pharmacology and toxicity section of the application is intended to continue current practices with respect to the submission of individual animal data. Thus, applicants are not required to submit laboratory notebooks, worksheets, and other documentation relating to individual animals (although those materials are subject to record retention requirements under the good laboratory practice (GLP) regulations (21 CFR Part 58)). Although summaries that contain tabulations and graphs are helpful for describing long-term toxicity and carcinogenicity studies, FDA believes that full tabulations of individual animal data are necessary to conduct a proper review of these important safety-oriented studies.

31. Several comments questioned the implication in the proposal that all pharmacological studies are subject to the agency's GLP regulations. These comments noted that those regulations apply only to nonclinical safety studies and not to other animal studies, such as nonclinical pharmacology studies. Other comments suggested that the regulation should require only a description of "significant" deviations from the GLP regulations, or a "statement of differences" for studies that were not in "substantial" compliance with them.

FDA agrees that the proposal might be read to imply that all pharmacological studies are subject to FDA's GLP regulations. The agency has revised the final rule to clarify that an application is only required to contain a statement regarding compliance with GLP's for a "nonclinical laboratory study" as defined in 21 CFR 58.3(d). FDA, however, has not made the other suggested change. Because the GLP regulations describe minimum standards for nonclinical laboratory studies, FDA believes that it is appropriate that the application contains a description of deviations from those requirements. The agency advises that such studies may still be relied upon, depending on the nature of the deviations.

*Human Pharmacokinetics and Bioavailability Section (§ 314.50(d)(3))*

32. One comment urged that this section contain a comparison analysis of human and animal pharmacokinetic data and the rationale for setting the specifications for the drug substance

and drug product based upon the results of bioavailability studies.

FDA does not agree that the final rule should require a comparison of human and animal pharmacokinetic data. Animal pharmacokinetic data are generally most relevant during the investigational phases of drug development, where they permit the establishment of parameters for the safe use of the drug in human subjects. After human pharmacokinetic data are collected, however, they alone are usually adequate for review of an application. An applicant is free, however, to provide a comparison analysis of the animal and human data if the applicant believes it results in a clearer presentation. At the same time, the agency agrees with the suggestion for inclusion of the rationale for specifications and analytical methods for the drug substance and drug product needed to assure the bioavailability, and FDA has revised the final rule to add that requirement. The rationale for establishing specifications and analytical methods, with the data and information supporting the rationale, is needed to determine whether the proposed specifications or methods will assure the bioavailability of the drug substance or drug product.

33. One comment objected to the statement in the preamble that bioavailability data are needed to assure batch-to-batch consistency and to reevaluate product reformulations or changes in manufacturing processes. The comment argued instead that simpler methods, such as in vitro dissolution, are adequate.

The ability of in vitro dissolution data to determine the bioavailability of a batch of a drug product depends, in FDA's view, on whether the data can be correlated with in vivo data. Generally in vivo bioavailability data and in vitro dissolution data are examined and, if possible, in vitro dissolution methods and specifications are set for the product. Subsequent batch-to-batch consistency is assured by testing each batch by the in vitro method and evaluating the results against the in vitro specifications. Thus, bioavailability data are often needed to establish the simpler in vitro tests.

34. One comment urged that the summarizing discussion and analysis be clearly required at the beginning of the pharmacokinetics and bioavailability section because it brings together information not necessarily present in each of the bioavailability and bioequivalence studies. This comment also suggested that this section should require that the analytical and statistical methods used in each study be described in the report of the study, and not grouped together in a separate section as the proposal suggests. Moreover, the comment believed that each study should be evaluated as an entity because that is the way reports of studies are prepared. The comment asserted that breaking reports in this section apart is likely to lead to errors.

FDA believes this comment misunderstood the proposal. The regulation is intended to describe in general terms the kinds of data and information that are required to appear in this section and the applicant is free to present it in the format that provides the clearest presentation, which may include either an opening or closing summary. Because FDA agrees that, in most instances, the analytical and statistical methods used in each study should be described in the study report, the agency has revised the regulation to suggest that use of that format is usually preferable. Again, however, FDA believes the applicant should use a format that provides the clearest presentation and permits the most efficient review.

*Clinical Data Section—General (§ 314.50(d)(5))*

35. One comment objected to the requirement that the results of each human clinical pharmacology study be compared with the animal pharmacology and toxicology data. The comment explained that most toxicology studies use doses higher than those used in human studies and often for longer periods of time, and that animal pharmacology studies may include disease states in animals not present in clinical studies. Thus, according to this comment, applicants should only be required to compare the results of clinical pharmacology studies with the "major findings" of animal pharmacology and toxicology studies. Another comment urged that this requirement be limited to information related to the intended use of the drug under its proposed labeling and to possible side effects to ensure that the applicant and the agency do not become sidetracked on issues related to potential new indications for the drug.

The agency does not agree that it is necessary to limit the comparison between clinical pharmacology data and animal data, as suggested by the comment. The proposal's call for "a brief comparison of the results of human [pharmacology] studies with the animal pharmacology and toxicology data" is intended to require an examination of the clues to potential usefulness or toxicology in humans provided by animal data. With respect to the second comment, virtually all of the pharmacologic properties of a drug are pertinent to the intended use of the drug, even those properties that are not the ones leading to the drug's intended use. The human results should thus be compared to all pertinent animal observations. If no human observations concerning a particular property exist, of course, no comparison can be made.

36. Noting that a controlled clinical study on a drug may not be relevant to the indications proposed in the application, one comment suggested that the final rule should only require a description and analysis of each controlled clinical study pertinent to the proposed indications for the drug and that other controlled studies should be included in the general description of other data or information relevant to an evaluation of the safety and effectiveness of the drug. This comment also suggested that the regulations require only that the applicant describe, and not analyze, data from studies that are not controlled.

FDA has revised the final rule to require description and analyses of controlled clinical studies pertinent to a proposed use of the drug. The agency notes, however, that § 314.50(d)(5)(iv) still calls for "a description and analysis of any other data or information relevant to an evaluation of the safety * * * of the drug product" not a "general description" as implied by the comment, and does require some analysis of controlled studies not pertinent to the proposed uses of the drug. FDA continues to believe that the usefulness of sources of data, such as clinical trials of drug uses other than those proposed, depends on a reasonably detailed description and analysis of the safety of those trials. The agency notes, however, that the proposal did not require analyses of uncontrolled studies, but only a description of them, which accords with the comment's suggestion. Finally, FDA has revised the final rule to include a requirement for a brief description of pertinent studies that have been discontinued or are ongoing.

37. One comment objected to a requirement for safety data from epidemiological studies of related drugs, believing that the requirement is vague and potentially subject to an overbroad application.

The agency does not believe that information about related drugs, such as epidemiologic data, can be ignored in evaluating a new drug. An applicant developing a new member of an already established drug class usually is, and should be, conscious of the experience

with other members of the class. Such information may be relevant to labeling and may help focus the evaluation of the data submitted. FDA does not believe that the requirement will be applied unreasonably.

38. On its own initiative, the agency has made two additional changes in the final rule. First, FDA has added an explicit requirement for the applicant to synthesize, in an integrated summary, the data which it believes provide substantial evidence of effectiveness of the drug for its proposed uses (§ 314.50(d)(5)(v)). FDA believes that this requirement was implicit in the proposed requirements for an overall summary to help the agency prepare the SBA document, but has determined that a specifically focused discussion in the clinical section will significantly facilitate review. Second, the final rule also requires an applicant to explain briefly why a study is not considered adequate and well-controlled. This will enable the agency reviewers to determine what conclusions can be validly drawn from those studies.

*Safety Update Reports (§ 314.50(d)(5)(vi)(b))*

39. FDA received several comments on the proposed "safety update reports," which are designed to advise FDA of new safety information that becomes available while the application is being reviewed by the agency. The proposal would have required such reports at 4-month intervals and upon receipt of an approvable letter. Although most of the comments addressing this issue favored the concept of safety update reports, concerns were raised that the reporting intervals were too frequent and that the data being requested were more than were necessary. Concerns were also raised that, if not properly limited, the requirement for safety update reports could delay the approval process by creating an ongoing need to review more data.

FDA believes that the basis for the proposed safety update reports, which is to ensure that drug approvals are based on the most up-to-date safety information available, is sound. FDA has, however, revised the final rule to ensure that reporting obligations are no greater than are needed, so that the requirement does not unduly delay approvals.

First, FDA has defined more precisely the type of information that needs to be reported. Whereas the proposal simply said "new safety information," the final rule specifies "new safety information * * * that may reasonably be expected to affect the statement of contraindications, warnings, precautions, and adverse reactions contained in the draft labeling." Thus, under the final rule, the only information that must be submitted in a safety update report is safety information that is different from that previously submitted and that may warrant revision in the draft labeling. It should be emphasized that (1) "new" information includes both adverse effects that were never seen before and a material change in the frequency or severity of effects that were recognized previously; and (2) case report forms for patients who die or who leave a study prematurely because of an adverse event are always required (unless the requirement is waived). Thus, for example, new safety information that suggests that an adverse effect occurs at a higher rate than previously thought would be required because it might change a precaution to a warning in the labeling.

Second, FDA has revised the reporting intervals so that safety update reports will be required (1) 4 months after the initial submission; (2) following receipt of an approval letter; and (3) at other times as requested by FDA. The first safety update report is important because it is designed to let reviewers know if any major new data are available that could affect their recommendations regarding approval of the drug. This first report covers a much longer period than 4 months because it also covers the time period between the "data lock point" and submission of the application, during which time the applicant is preparing the application for submission to the agency. The report following an approvable letter is intended to provide the agency with the most current information available immediately before approval. Moreover, it parallels the normal submission of final printed labeling so that FDA reviewers can be assured that the labeling is up-to-date. In addition, FDA may request safety update reports at other times, such as before an advisory committee meeting or before an approval letter where an unusual amount of time may have passed since issuance of the approvable letter. This may also include the situation where the agency intends to issue an approval (instead of an approvable) letter based on draft labeling, and a special request for a final safety update report will prevent undue delay. Thus, by replacing the "every 4 months" requirement with discretionary requests by the agency, the regulations allow applicants to submit interim reports only when the agency believes they are necessary for review and approval of the application.

FDA does not believe this policy will delay the approval process. As noted above, the reports themselves are tied to information pertinent to labeling, and will be in a familiar format, permitting prompt review. Moreover, FDA expects that major changes in safety information will not be common. If an applicant, however, does obtain new safety information that is so significant that it could affect the overall risk/benefit determination of the drug for one or more indications, a further extension of the review process will inevitably be necessary.

The guideline on the clinical section of the application will describe the format of both original safety reports and updates.

*Samples and Labeling (§ 314.50(e))*

40. Several comments suggested that requiring four samples is excessive and that FDA should request only the actual amount needed.

FDA's experience is that four samples are needed to perform necessary testing. One sample is tested by each of two FDA laboratories, for purposes of replication, and the two remaining samples are held as reserve samples for each of those laboratories in the event that additional testing is necessary. In addition, the final rule represents a significant reduction from past practice in the amount of samples applicants must submit to support approval of an application. Samples are no longer required, for example, of the finished dosage forms used in the clinical investigations, nor of the new drug substance used in manufacturing those dosage forms. FDA has revised the final rule to increase from two to three copies of the analytical methods and related descriptive information FDA needs to test the samples. One copy is needed for each of the FDA laboratories assigned to test the samples and a third copy is needed for the agency's headquarters files.

41. One comment urged that samples be required earlier in the review process, specifically either at the time the application is submitted or when the application is filed. This suggestion was aimed at ensuring that necessary testing is completed on time and does not delay approval of the application.

FDA disagrees with this comment. Under the final rule, the FDA reviewer will contact the applicant to request samples and provide laboratory assignments after a preliminary review of the analytical procedures indicates that the procedures are satisfactory. The date of filing is not appropriate because the review necessary to determine

whether an application is complete and can be filed is not as detailed as the review needed to determine whether analytical procedures are satisfactory. The procedure in the final rule will prevent the premature submission of samples and will ensure that methods validation testing is not conducted on outdated samples. The procedure should not, however, delay the review process so long as applicants make every effort to provide the samples when requested. Moreover, as noted above, it is FDA's policy not to delay approval of a drug solely because methods validation has not been completed.

42. Several comments questioned whether, by combining requirements for samples and labeling, the proposal implied that labeling should be submitted only upon request. Another comment asked FDA to clarify what it means by "related descriptive information" and noted that the proposal would not have required submission of results of the applicant's tests on samples.

FDA has revised the final rule to state that copies of the product's label and labeling should be submitted with the application, and not only upon request. The final rule also states that "related descriptive information" includes a list describing each submitted sample; a list of proposed regulatory specifications; a detailed description of the methods of analysis; supporting data for accuracy, specificity, precision, and ruggedness; and complete results of the applicant's tests on each sample.

43. One comment urged that the current exclusion for sterility and pyrogen testing samples, which was not contained in the proposal, be retained.

Although FDA agrees that sterility and pyrogen testing samples are often unnecessary, particularly if the testing procedures are ones generally recognized as valid (for example, procedures established in the official compendia), new testing procedures may be developed (for example, the limulus amebocyte lysate test for pyrogens) that warrant FDA review. Accordingly, the final rule requires their submission, but FDA will consider waiver requests on a case-by-case basis.

44. One comment suggested that the final rule should follow the current practice and require the submission of only one finished market package.

FDA has revised the final rule to eliminate the suggestion that four samples of the finished market package are required. Samples of the finished market package are required to be submitted only if FDA requests them and, although the agency generally requests only one sample, two are sometimes needed. The final rule provides this flexibility.

*Case Report Forms and Tabulations (§ 314.50(f))*

45. FDA received many comments on the proposed submission of individual clinical data using a combination of case report forms and tabulations. A number of the comments misunderstood the meaning of the terms used and their interrelationship. For example, some comments erroneously equated "case report forms" with "raw data," while other comments mistakenly understood "tabulations" to be the same as "summaries." Before addressing the specific comments, therefore, these terms need to be clarified in the context of the current regulations and the NDA Rewrite proposal.

a. *Raw data.* The "raw data" from a clinical study are the clinical investigator's own records of the individual patients. These records include the patient charts, hospital records, x-rays or other laboratory test results, and notes of the attending physician. These raw data, even under current regulations, are not routinely submitted to FDA as part of a new drug application, but instead remain in the files of the clinical investigator or hospital for FDA audit, if necessary.

b. *Case report forms.* These are the documents that the clinical investigator sends to the drug sponsor that list all the data collected on each individual patient. There is 1 case report for every patient in each study, and case reports typically vary from 5 to 50 pages in length. Under current regulations, all case reports must be submitted to FDA as part of a marketing application. Because such applications frequently contain data on from 1,000 to 3,000 patients, case reports consume a great many volumes in a typical application.

c. *Tabulations.* These are tabular listings of the individual patient data, as taken from the case report forms. The tabulations are prepared by the drug sponsor, usually using an automated data processing system. By using tabulations, the results from a study of a given medical parameter (e.g., blood pressures for an anti-hypertensive drug) can be presented on one or two pages. These tabulations contain the very same numbers as the case report forms on which they are based, and the data are clearly identified by individual patient. Thus, tabulations are ordinarily a more concise and efficient representation of the data contained on the case report forms.

d. *Summaries.* These are usually narrative documents, often interwoven with summary tables and graphic presentations of data, that present the results of a study, using the analyses deemed appropriate. Summaries are the most common means of communication in science, and most scientific journal articles are summaries in this sense, as are the descriptions and analysis called for in the clinical section of the application. Summaries, however, are by their nature interpretive documents that select certain data as being important. Thus, summaries reflect a point of view about what the data mean, and the point of view and data selections are always shaped by the judgment of the writer.

e. *Current requirements.* Current regulations require the routine submission of all case report forms. Use of tabulations is voluntary with the applicant. Recognizing the inherent difficulty of relying on the case report forms themselves to find individual data elements, it is extremely common for applicants to submit tabulations voluntarily in some form to make the review of the data more efficient. Applicants use such tabulations in their own analyses, subjecting them to a variety of statistical procedures to develop analyses and summary tables presented for each study report.

f. *The proposal.* Based on the agency's positive experience with tabulations, FDA proposed to substitute tabulations for case report forms as the primary focus of the data review. Under the proposal, some case report forms would still be required routinely (i.e., for patients who died during or who dropped out of a clinical study due to an adverse event) because these cases are the ones most likely to reveal significant safety problems and demand individual case-by-case review. Also under the proposal, FDA would have access to additional case reports whenever a legitimate need existed. Thus, the intent of the proposal was to focus the agency's review on a more concise and efficient mode of data presentation, while still providing the agency with complete individual patient data. The proposal also contained a requirement for summaries, but only to complement and integrate the individual patient data contained in the case reports and tabulations.

46. FDA received a considerable number of comments on this provision, concerning primarily the concept of how data should be submitted (i.e., summaries versus tabulations versus case report forms). Comments on both these subjects covered a wide spectrum. Several comments argued that all case report forms should be routinely required, on the ground that FDA needed this "raw data" to conduct a full

scientific review. In contrast, other comments suggested that even the review of tabulations would be more time consuming than necessary, and that FDA should instead rely on summaries alone.

FDA believes that the proposal to require data submission through a combination of summaries, tabulations, and case report forms allows a scientific review that is both thorough and efficient. FDA believes that, for many purposes, tabulations can provide adequate information for review because these tabulations will be required to contain the same individual patient data listed on the case report forms. As described above, even case report forms are not actually "raw data" (but instead constitute individual patient data as transposed by the clinical investigator from the doctor's charts), so concerns raised about the agency no longer requiring "raw data" are misplaced.

FDA also disagrees with the suggestion that it rely on summaries alone, without a routine submission of individual patient data (either as case report forms or tabulations). As noted above, summaries are, by their very nature, interpretive documents. Although summaries are extremely useful in reviewing applications, FDA believes they need to be complemented by the underlying data (either in tabulations or case report forms) for the agency to be able to conduct a thoroughly independent and objective review.

In response to these comments, however, FDA has reevaluated the proper mix of tabulations and case report forms that should be required. Although FDA believes that tabulations will be extremely useful in promoting a more efficient review process, the agency also recognizes that there are some inherent limitations on the use of tabulations and that, in certain instances, direct reference to case reports will be necessary. Theses may include, for example, instances where important narrative or other information on the case report form is not amenable to tabular presentation, or where case reports are desired to spot check the accuracy of the tabulations.

Accordingly, in order for the agency to conduct a scientific review that is both thorough and timely, a complete set of case report forms will ordinarily be needed for the most critical studies. In order to choose these appropriately, and at a time when they can be provided without causing delay, FDA reviewers will designate, approximately 30 days after receipt of an application, the critical studies for which case reports will be requested. These studies will ordinarily also be the ones utilized by the Division of Scientific Investigations in conducting its on-site data audits, and that division will make use of the same case reports, whenever possible, in order to eliminate the need for duplicate submissions.

FDA believes this policy is consistent with its overall goal of improving the efficiency of the drug review process. By relying more heavily on summaries and tabulations, FDA's initial review will be focused onto a more concise form of data presentation. This initial review, however, may trigger the need to review certain patient histories in more detail, especially those from the most critical studies, and case reports provide the basis for that more detailed review. Requests for full case reports from certain critical studies does not necessarily imply the need for a case-by-case review of every patient; instead, such requests are intended to ensure that FDA reviewers can make reference to, when needed, case report forms for those patients requiring further review. By making such requests approximately 30 days into the review process, delay is unlikely to occur.

Even with this modification, FDA estimates that there will be an average reduction of about 75 percent in the number of case reports that are routinely requested, when compared to the current requirement of full submission. As reviewers become more comfortable with tabulations, and applicants become more skillful in making them usable, it is possible that requests for case reports will decrease. The regulation itself is general in nature so as to accommodate both the present expectation and any future changes.

47. Several comments that opposed the substitution of tabulations for most case report forms were concerned that this change could enhance the possibility that FDA would receive inaccurate data.

FDA does not believe that this change will decrease the accuracy of the data received or undermine the agency's ability to assure data accuracy. First, FDA's Division of Scientific Investigations routinely conducts a data audit on two or more critical studies in each marketing application. Such data audits compare the data on case report forms to the raw data retained by the clinical investigators. The policy of conducting these audits will continue. In addition, as noted above, medical reviewers may need to spot check the accuracy of tabulations for the most critical studies by comparing them to the data in the case report forms, and FDA can request the submission of case reports for that purpose.

48. FDA received a number of comments on the proposed standard that additional case reports could be obtained whenever a "legitimate need" existed to conduct an adequate review of the application. Comments generally believed that this provision was vague. Many interpreted it as an attempt to discourage requests for additional case report forms. Several comments, on the other hand, were concerned that the provision would lead to excessive requests and urged that the final rule contain explicit criteria for justifying request, and that requests should be made in writing with a supporting rationale.

FDA had modified this provision in the final rule to reflect the agency's central concern—namely, to permit the agency access to case report forms when it believes that they are needed to conduct a proper review of the application. The agency did not intend the phrase "legitimate need" to imply a barrier, and the final rule has been modified to contain more neutral language. FDA recognizes the concern expressed by several comments that some reviewers may be prone to request more case reports than the applicant believes are necessary. Although there will inveitably be differences among reviewers, FDA believes that assuring the reasonableness of requests for case report forms is the responsibility of FDA management. To strike what FDA believes is the appropriate balance between these competing interests, the final rule provides that all requests for additional case reports (other than those required to be routinely submitted) must be approved by the director of the division responsible for reviewing the application. Any applicant that feels it is being asked for an excessive number of case reports may raise the matter directly with the releveant division director or with the ombudsman.

FDA notes that the need for additional case reports will likely vary according to the type of drug under review. For example, case reports appear to contribute significantly less to the efficacy review of an anti-hypertensive drug because blood pressures can quite adequately be complied in a tabulation, patient dropouts are usually few, and most patients entered into a trial are analyzed. Conversely, FDA believes that case reports may be critical to the review of controlled studies for an antibiotic drug. This is because the efficacy determination for an antibiotic turns largely on which patients were included and which were excluded from

the study analysis, and the reasons for inclusion or exclusion often involve close judgments that cannot readily be shown in a tabulation. FDA will advise applicants, either in guidelines or in "pre-NDA" conferences, of particular case report needs for particular drug classes.

49. Several comments addressed the time aspect involved in FDA requesting additional case report forms or tabulations. One comment was concerned that the proposal might actually delay the review process, because reviewers would have to wait for the submission of additional case report forms. Another comment suggested that the 30 days for the submission of case report forms, as provided in the proposal, may not be adequate. A third comment suggested that, if additional case reports or tabulations are submitted more than 30 days following an FDA request, any extension to the review period should be limited to the number of days the submission was late.

FDA does not believe that this requirement will cause delay in the review process. Case report forms are still required to be maintained by drug sponsors, and the time needed to respond to requests should be relatively short. Moreover, applicants, who themselves seek an expeditious review, have an incentive to respond to such requests quickly. Finally, as noted above, the agency's policy of identifying needed case report forms early in the review process should also help reduce delay. When applicants do take more than 30 days to respond, the agency considers it reasonable to extend the review period in accordance with § 314.60. The length of such extension will involve not only the time taken to respond, but also other factors, such as the stage of the review process and the reasons for the request. For example, case reports requested to investigate data discrepancies may require a longer extension than requests for case reports to provide information not contained in the tabulations.

50. Several comments urged that FDA require the routine submission of case report forms for deaths and dropouts only for patients who receive the investigational drug, and that case reports for patients on placebo or a reference drug not be included. In addition, one comment asked whether the term "adverse event" in this section of the proposal would include a patient who dropped out of the study because of a "lack of expected pharmacological effect."

FDA believes that case report forms for deaths and dropouts are particularly useful for determining safety problems with a drug. In determining whether these events were drug-related, FDA's evaluation necessarily includes comparing safety problems for patients who took the test drug with patients in the control group who also died or dropped out of the study. Thus, the agency believes that this provision of the final rule should not distinguish between patients in a study on the basis of whether they actually received the investigational drug, and the final rule has been so revised. The term adverse event in this context (as distinguished from its use in § 314.80 concerning postmarketing surveillance) does not include "lack of expected pharmacologic effect."

51. Several comments addressed the level of detail required in the tabulations. A number of comments objected to requiring "every datum" obtained on each patient so that FDA reviewers can reanalyze the data already analyzed by the applicant. These comments preferred tabulating data on categories of patients, which is the standard procedure used in submitting papers to scientific journals. Another comment took the opposite view and suggested that the tabulations include full listings of individual patient data. One comment simply asked that FDA clarify the level of detail needed.

As a general rule, FDA believes that individual patient information that is important enough to be recorded on a case report form would be pertinent to the agency's review of the drug's safety and effectiveness. As noted earlier, the tabulations are intended to present essentially the same information as the case reports, except in a more efficient form.

Nevertheless, the agency recognizes that not all individual patient information will be needed for the agency to conduct a proper review of the application. The regulation, for example, exempts from submission tabulated data on effectiveness derived from uncontrolled Phase 2 and Phase 3 studies. This is because the agency's effectiveness review relies upon adequate and controlled studies, as required by law.

The regulation further provides that the applicant may delete additional tabulations which the agency agrees, in advance, are not pertinent to a review of the drug's safety or effectiveness. Upon request, FDA will discuss with the applicant in a "pre-NDA" conference those tabulations that may be appropriate for such deletion. The regulation also provides that, barring unforeseen circumstances, tabulations agreed to be deleted at such a conference will not be requested during FDA's review.

*Other Information (§ 314.50(g))*

52. One comment suggested that applicants be permitted to submit English language abstracts that appear in original publications in foreign languages and that they be required to submit an English translation of the full publication only upon request.

The agency believes that it is not unreasonable to ask an applicant who relies upon an original literature publication in a foreign language to submit both the foreign publication and an English translation of it. Otherwise, FDA would not be able to review the full presentation. This is not a new requirement.

*Format of an Original Application (§ 314.50(h))*

53. Several comments addressed the provision whereby applicants could submit the archival copy of the application on microfiche. Comments generally suggested that limiting submissions to microfiche is too restrictive and that FDA should permit microfilm and other data storage forms. One comment suggested that roll microfilm is more economical and easier to make hard copies from than microfiche. Some comments stated that most applicants already submit copies of raw data on indexed microfilm to Canadian drug approval authorities, and that the same form should be acceptable in this country. One comment also suggested that case report forms should be permitted on microfiche or roll microfilm.

FDA has revised the final rule to provide that applicants may submit the relevant portion of an application on microfiche or, if FDA agrees, on another suitable microform system. This change would permit the use of new microform technologies while ensuring that the submission would be in a form usable by FDA. Although other currently available systems (such as indexed roll microfilm) have some advantages over other microform systems, they also have significant disadvantages when used under the circumstances of an FDA application review because of the difficulty in locating specific information even in well-indexed systems. Decisions on using alternative microform systems will be made on a case-by-case basis, as will decisions on whether a microform system may be used for case reports and tabulations.

*Abbreviated Applications (§ 314.55)*

Note.—On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417). A primary purpose of this law is to greatly expand the universe of drugs for which FDA will accept abbreviated applications. Pursuant to section 105(b) of the new law, on November 26, 1984, FDA began accepting such applications. Section 105(a) of the new legislation provides FDA with 1 year from the date of enactment to promulgate new implementing regulations. Section 105(b) further provides that, until such time as FDA has new implementing regulations in place, the currently existing regulations will be effective, absent a conflict with the new statute. Because the provisions in this final rule governing abbreviated applications merely restate, in slightly different form, the current regulations on this subject, FDA considers these provisions of the final rule to have the same effect under section 105 of the new law as do the current regulations governing abbreviated new drug applications.

54. One comment asked how the standard of "very closely related" in proposed § 314.56(c) for determining whether an abbreviated application is suitable differs from the standard of "identical, related, and similar drug products" in § 310.6 (21 CFR 310.6) for applying FDA's efficacy conclusions in the Drug Efficacy Study Implementation (DESI) project.

In the **Federal Register** on January 21, 1983 (48 FR 2751), FDA amended its new drug regulations to clarify its policy on when abbreviated new drug applications are suitable and will be accepted. That rule states that, when FDA finds that an abbreviated application is suitable for a drug product, the finding will apply only to drug products "identical" to the product that was the subject of the finding. At the same time, FDA established a petition procedure under which prospective applicants may ask FDA to determine whether an abbreviated application is suitable for similar or related products. Such decisions on suitability will be made on a case-by-case basis, and abbreviated applications will be accepted only if the safety and efficacy data on the first product are applicable to the product that is the subject of the petition. FDA has revised § 314.55 to conform to the text of that final rule.

In the preamble to the January 21, 1983 final rule, FDA addressed the relationship of this provision to the DESI policy contained in § 310.6. As stated in that preamble, a DESI finding of effectiveness for one drug product does not automatically apply to all similar or related products. Rather, "There will be * * * areas where the judgments of experts must determine the applicability of efficacy findings. The determination will be based on the chemical structure of the drug, recommended use, route of administration, its pharmacological properties and any other information available on the action or properties of the drug." (48 FR 2751 at 2753.) It is through the petition procedure described in § 314.55 that this determination will be made.

*Application Development File*

55. FDA has removed from the final regulations the proposed provision on the application development file (proposed § 314.57). The provision would have established a mechanism for prospective applicants of abbreviated applications to obtain agency comments on their formulation data, dissolution data, bioequivalence protocols, and pilot studies before conducting bioequivalence tests. FDA has determined that a codified procedure is unnecessary because less formal procedures for providing guidance to potential applicants exist. For example, FDA provides applicant with guidance on developing bioavailability studies through guidelines, meetings between applicants and agency staff, and general correspondence. Moreover, many applicants now rely upon contract laboratories to conduct bioavailability studies, and these laboratories are generally familiar with the requirements for performing acceptable bioequivalence studies. The agency also believes that providing general prospective guidance on bioavailability studies, as opposed to application-specific review, will consume significantly less agency resources while providing adequate guidance to potential applicant.

*Amendments to an Unapproved Application (§ 314.60)*

56. Several comments asked that FDA inform an applicant if the agency considers a submission to be a major amendment and the approximate amount of time the division needs to review it. Some of these comments urged FDA to reply within 30 days after the agency receives the amendment. Other comments urged that the final rule clarify that the maximum extension will be 180 days. One comment suggested that, if an amendment is made in response to an agency request, FDA should inform the applicant within 30 days of whether the response was adequate.

As stated in the proposal, the director of the reviewing division will inform an applicant that submits a major amendment if an extension is needed. The agency has clarified the final rule to state explicitly that the division director will also inform the applicant of the amount of time the division needs to review the amendment. The agency will strive to make such notifications as timely as possible. FDA has added a statement to the final rule to clarify that the maximum extension of the review period will be 180 days. Finally, FDA may notify the applicant of particular deficiencies found in the amendment and request further clarification or, depending upon the deficiency, may respond to it in an action letter. In this respect, agency comments on an amendment will be handled in the same way as on any other part of the application.

*Supplements and Other Changes to an Approved Application (§ 314.70)*

57. FDA views the requirements under which applicants can make manufacturing and controls changes in their approved applications as an area in which it can significantly reduce regulatory burdens on the drug industry without compromising public health protection. Currently, nearly all changes in the conditions originally approved in the application are subject to prior FDA approval in a supplemental application, with the few exceptions listed in the regulations. In the same manner suggested by the proposal, the final rule changes this scheme significantly by reducing the number of changes that require supplements and listing those changes (instead of the exceptions) in the regulations. Thus, the final rule retains the three proposed regulatory categories: (1) prior approval, for those changes in marketed drugs which could affect FDA's previous conclusions about the safety and effectiveness of the drug; (2) changes requiring supplements concurrent with the change but on which FDA prior approval is not necessary; and (3) annual reports for changes that do not fall into one of those two categories. The final rule, like the proposal, specifically lists the kinds of changes falling into the first two categories. The final rule also lists examples of changes that can be described in the annual report, but the list is not intended to be exhaustive because the annual report is the residual category.

In the proposed rule, FDA identified several areas where it believed applicants could make changes in their approved applications under less restrictive conditions than currently required. Since then, FDA has conducted an exhaustive examination of its current practices with respect to

supplements and has determined that, although significant improvements can be made in this area, for the reasons stated below, not all of the proposed changes have been implemented. As a result, FDA has realigned the specific types of changes among the three categories and is returning several kinds of changes to the prior approval category that, under the proposal, could have been reported to FDA following implementation. At the same time, however, FDA will permit annual reporting of some changes that, under the proposal, would have required prior approval. Under the final rule, FDA estimates that there will be a reduction in approximately 20 percent of manufacturing and controls supplements that now require prior approval, all in areas not likely to affect the safety or effectiveness of the finished drug product. Although FDA proposed to permit the following changes without prior approval, the agency is retaining in the final rule the current prior approval requirements for changing a contract laboratory or labeler, establishing new procedures for reprocessing a batch of a drug product that fails to meet specifications, changing the synthesis of a drug substance, and changing the facility or establishment for manufacturing the drug substance in certain instances. FDA has concluded that prior approval of these changes is needed because they can significantly affect existing agency safety and effectiveness conclusions about a product.

First, FDA has concluded that it should preapprove the ability of a contract laboratory or labeler to comply with CGMP regulations, for such compliance relates directly to the ability of the laboratory or labeler to produce a drug of acceptable quality and/or properly labeled. Second, with respect to the prior approval requirement for reprocessing a batch that fails to meet specifications, many critical factors affect the acceptability of reprocessed batches; for example, the reason for the original batch failure, the storage conditions of the original batch, the tests performed on the reprocessed batch, and the stability of the reprocessed batch. Prior approval of reprocessing procedures will best ensure that rejected batches are not blended with accepted batches, that stability data are used to support recovery or reprocessing operations, and that original control tests are adequate to monitor the reprocessed batch.

Third, prior approval to change the synthesis of the drug substance is needed to assure the safety and effectiveness of the finished product, as is the use of a new facility to manufacture it in certain instances. A change in the synthesis and the many changes in equipment and procedures that occur with a change in manufacturing facilities may significantly affect the finished product. For example, such a change may affect the particle size, crystalline form, stability, or dosage form dissolution of the drug and, thus, affect the bioavailability of the finished product. The method of synthesis of a drug substance is also linked to specifications needed to monitor its strength and purity. Prior approval will ensure that applicants who make a change in synthesis reexamine the adequacy of specifications in light of that change. A product from a different route of synthesis may yield a different purity profile and may require in vivo testing because the limits for specific impurities are normally developed with reference to their toxicity and pharmacological properties. Finally, impurities may also affect the stability of the finished product. In sum, given the significance these changes may have on product safety and integrity, FDA belives it necessary to maintain premarket approval with respect to them.

With respect to changing the facility or establishment that manufactures the drug substance, prior approval will be required where: (1) the manufacturing process in the new facility or establishment differs materially from that in the former facility or establishment, or (2) the new facility or establishment has not received a satisfactory current good manufacturing practice (CGMP) inspection within the previous 2 years covering that manufacturing process. However, the final rule also provides that an applicant may change the facility or establishment that manufactures the drug substance, without obtaining prior FDA approval, if: (1) The manufacturing process in the new facility or establishment does not differ materially from that in the former facility or establishment, and (2) the new facility or establishment has received a satisfactory CGMP inspection within the previous 2 years covering that manufacturing process. If those two criteria are met, the applicant may implement the change concurrent with submission to FDA of a supplement. In that instance, the supplement is to be plainly marked, "Special Supplement—Changes Being Effected."

FDA has also identified certain changes, in addition to those proposed, that may be reported to FDA on an annual basis rather than in a supplement. These include certain changes in the container and closure system for the drug product, and the addition or deletion of alternate analytical methods. These changes are described more fully below in response to comments on the proposal.

Finally, FDA has revised the final rule to provide a mechanism for applicants to obtain expedited review of supplements where special considerations exist. FDA generally reviews supplements subject to prior approval in the order in which they are received, taking into account other review priorities such as investigational new drug applications and applications for important new drugs. A longstanding and understandable concern of applicants is the cost of waiting for FDA to review and approve these supplements, particularly when extraordinary circumstances require a change in the conditions of approval; for example, when an unexpected event forces an applicant to use a different facility to continue manufacturing a product, or a technological breakthrough would greatly reduce costs. The agency has informally recognized the need to expedite such supplements, but believes that the regulations should specifically recognize this practice. Secondly, the agency has revised the final rule to permit applicants to request expedited review of a supplement for a change that requires prior approval. The agency emphasizes that expedited review is available only under extraordinary circumstances, for either public health or economic reasons, and is subject to the agency's discretion and available resources.

This section, like most of the final rule, will become effective May 23, 1985. If an applicant has submitted to FDA supplements for manufacturing and controls changes that do not require a supplement under the final rule, and those supplements have not yet been reviewed by FDA, the applicant should notify FDA in writing that it is withdrawing those supplements. Upon such notification to FDA, the applicant may proceed to implement those changes as permitted by the final rule.

58. Several consumer comments urged FDA to require prior approval of supplements for every change in an approved application to ensure the safety of the change.

FDA does not agree that prior approval of supplements for all changes in approved applications is necessary. For example, the deletion of an ingredient intended only to affect the color of the drug product is unlikely to

affect safety or effectiveness. This is the type of change that, under the final rule, can be implemented by the applicant and submitted to FDA as part of the annual report. FDA believes its combination of prior approval requirements, requirements for supplements not requiring prior approval, and annual reporting requirements focus FDA's resources and attention on those issues that must be monitored closely and properly tailor the time of the reporting to the nature of the change.

59. Several industry comments stated that FDA's proposed reductions in its supplemental application requirements represent a major improvement over current practices. FDA received several comments, however, suggesting that, even with the proposed changes, the regulation of supplements would still be too restrictive. For example, several comments noted that the categories of changes are stated generally and might apply to many changes for which prior approval of a supplement should not be required. Another comment observed that, although the preamble suggested it would be unnecessary to explain batch control numbers in an original application, changes in the batch numbering system would be required in an annual report. Finally, one comment suggested that the agency should permit a single supplement to cover all similar and related products; for example, a packaging change that may affect as many as 100 products should require only a single supplement.

FDA does not agree that the categories of changes are stated too generally. It must be remembered that applicants are to inform FDA about only those changes that affect the information previously submitted in the application. Thus, the application itself is a guide to the kinds of information for which, if changed, the applicant must submit a supplement. Moreover, as described more fully in the proposal, FDA will no longer require an original application to contain information about manufacturing practices that FDA monitors under its current good manufacturing practice (CGMP) regulations, a regulatory change that will also eliminate the need to submit supplements that would require prior approval under current regulations. Because batch control numbers fall under the CGMP regulations, an explanation of batch control numbers is not required in either the original application or the annual report.

Finally, the agency does not agree that a single supplement would be adequate to cover a change affecting similar and related products. Eliminating multiple supplements in favor of a single supplement would not affect the review time and speed of approval because FDA now combines those supplements and performs a single review if the applicant adequately notes the relationship of multiple submissions. Moreover, except for the submission of a supplemental application form for each application, the applicant may now make a single submission of the technical data and information necessary for the agency to review the change. Individual application forms are needed, however, because they are the mechanism by which the change is noted in each application. When approved, the supplement is placed in the application and becomes a part of the permanent record. The submission of a single supplement to cover multiple applications would impose an added burden on FDA to document the changes and is more likely than the current system to result in a failure to include documentation of the change in each application.

60. One comment asked whether changes in the manufacturing site of the drug substance require prior approval. Another comment objected that use of a facility for packaging a drug product should not require prior approval if the container and closure system and quality control procedures are unchanged, and the facility has undergone a recent CGMP inspection. Moreover, according to this comment, changes in the manufacturing site or the manufacturer of a drug product should not require prior approval if the method of manufacture and specifications of the ingredients are the same as those identified in the application and the drug product meets all specifications in the application.

FDA is obligated to see that approved new drugs are manufactured under circumstances that ensure that the marketed drug does not differ from the drug approved by FDA and, thus, that the agency's conclusions about safety and effectiveness apply to it. To accomplish these objectives, the agency must continually monitor the applicant's manufacturing and control operations, including packaging operations, to determine the applicant's ability to produce a product of acceptable quality. This includes prior approval of facilities for the manufacture of the drug substance and drug product and for packaging the product. Compliance with product specifications is important, but it cannot supplant the review process. The use of a new facility to manufacture a drug substance or drug product, or to package the product, invariably involves changes in procedures that may affect the agency's conclusions about the safety and effectiveness of the product. FDA encourages manufacturers to advise it early about plans to begin manufacturing or packaging operations in a new facility. When that is done, the agency and the applicant can work together to ensure that the requirement for prior approval of the supplemental application does not delay an applicant's use of the facility. Moreover, as described in paragraph 57 above and § 314.70(c)(3) of the final rule, prior FDA approval is not required when the applicant uses a new facility or establishment to manufacture a drug substance if certain criteria are met. Finally, FDA believes that the comment's confidence in the use of specifications to ensure product quality is too great. Quality is built into a product through the method of manufacture and in-process controls; end product testing is not viewed by FDA as a substitute for adequate control of the manufacturing process.

61. One comment noted that FDA's list of changes that would require prior approval of a supplement includes changes that can now be made at the time a supplement is submitted, and that FDA should continue to permit immediate implementation of all changes for which that practice now exists. Comments urged FDA to retain the provision in the current regulations that permits a change to be made when a supplement is submitted if the change gives increased assurance that the drug will have the characteristics of identity, strength, quality, and purity which it purports or is represented to possess. One comment suggested that FDA go one step further and permit a change without prior approval if the change provides the same level of assurance that the drug will possess its represented characteristics.

FDA did not intend either to require prior approval of any change for which prior approval is not now required or to change current practice with respect to those changes already listed in the regulations (21 CFR 314.8(d)) as giving increased assurance that the drug will possess its represented characteristics. FDA has revised the final rule to retain the provision. The particular changes contained in the section can be made without prior approval because, by assuring to a greater degree that the drug will possess its represented characteristics, the change provides a public health benefit. A change that provides only the same level of assurance, however, does not provide

such a benefit and, thus, the agency finds no basis for making the additional modification suggested by the comment.

62. One comment suggested that the proposal is more restrictive than current requirements in proposing that the "method of manufacture of the drug product, including changing or relaxing an in process control" must be approved by FDA before the change is made. Another comment objected to the phrase "the method of manufacture" because it is too broad and could apply to any change in the procedure for the manufacture of a drug product. One comment suggested that this requirement be revised to apply to changes that "make a significant change to the method of manufacture of the drug product, including changing or relaxing an in process control; for this section a significant change in method of manufacture should be defined as a change resulting in altered product specifications or altered in process controls."

As discussed above, a change in the method of manufacture should be made in the context of the original method of manufacture described in the application and approved by the agency. Moreover, the final rule omits the current requirements under which changes in manufacturing practices covered by FDA's CGMP regulations must be described in a supplement. This change already eliminates the need to seek prior approval for the kinds of changes in the method of manufacture that FDA believes are not significant.

63. One comment suggested that the requirement for prior approval of a new regulatory analytical method is inconsistent with the preamble statement that changes in analytical methods for the drug substance may be made and reported in the next annual report unless there is also a change in synthesis. An applicant suggested that a change in an analytical method should be allowed without prior approval when results are comparable to the approved method. Another comment urged FDA to permit the substitution of a less discriminating analytical method with a more stringent method without prior approval to reward innovation, reduce costs, and introduce benefit from technological advances. Several comments suggested that the agency should permit without prior approval a change in the container and closure system if the applicant demonstrates stability equivalence with the approved container and closure system under an approved stability protocol or where there is no significant alteration in the material of the components.

FDA notes that the comment is correct about the inconsistency in references to changes in analytical methods for drug substances. The preamble statement was incorrect; a change in a regulatory analytical method for a drug substance requires prior FDA approval because it is the method FDA relies upon to determine whether the product meets legal requirements. An applicant may, however, tighten the limits on a specification, or add a new specification without prior FDA approval, if the change is described in the next annual report. FDA is also persuaded that prior approval is unnecessary when adding or deleting an alternate analytical method because FDA will continue to rely upon the regulatory methods, and changes in alternate analytical methods will let applicants take advantage of technological changes. This change will eliminate a large number of supplements, particularly with respect to abbreviated applications.

FDA has also closely examined its supplement requirements with respect to containers and closures. FDA agrees with the comment that an applicant should be permitted to change the container and closures within a particular container and closure system, put the change into effect, and notify FDA about the change in the annual report, if the applicant first determines that the approved and proposed container systems have equivalent stability profiles under an accepted protocol (that is, a protocol appearing in the official compendia or one that has received approval in the application, or a supplement to it). The agency is, however, returning to the prior approval category changes in the container size for nonsolid dosage forms because of the potential adverse effects a change in container size may have for liquids and other nonsolid dosage forms. For example, use of a larger container size for a multi-dose parenteral drug may result in an increase in the number of punctures of the vial stopper and, thus, may adversely affect the product's integrity in use over time.

64. Because CGMP regulations require manufacturers to have validated processes, ongoing stability testing programs, detailed written processes, and quality assurance units, comments urged FDA to permit applicants to make changes in packaging components, excipients, dyes, flavors, fragrances, preservatives, and other changes without prior approval if they do not result in changes in product specifications or performance, or product safety and efficacy. Some comments urged that the agency go even further in reducing the burden of supplements by permitting any change in manufacturing or controls without prior approval if it is properly validated using procedures already accepted by FDA.

FDA believes that these comments confuse the different objectives of the CGMP regulations and the drug approval process. The CGMP regulations establish primarily minimum standards for assuring that the drug is not contaminated during manufacture, and that the drug has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess. Somewhat differently, the new drug approval process and the supplemental application requirements are intended to ensure that the drug is safe, that its benefits outweigh its risks, and that it is effective. Thus, premarket review is still needed to determine whether a change in packaging components, excipients, dyes, flavors, fragrances, and preservatives will affect the safety and effectiveness of the drug. Indeed, because a color may affect a product's stability, FDA concludes that prior approval of the addition of a color is also needed to assure the safety and effectiveness of the product. With these concerns in mind the agency has revised the final rule to require (as it does now) prior approval of a supplement to add a color.

65. One comment suggested that, under the proposal, prior approval of a supplement would be required to delete claims or indications which may now be made upon submission of a supplemental application and without prior approval. The comment urged FDA to permit applicants to delete, without prior approval, any indication for use or claim for effectiveness considered by the applicant to be unsupportable as a result of the applicant's reconsideration of the data or considered by the applicant to present an unacceptable safety to efficacy ratio.

FDA agrees with the comment and has revised the final rule to continue the current practice of permitting the applicant to remove from labeling false, misleading, or unsupported indications for use or claims for effectiveness at the time a supplement describing the change is submitted.

66. FDA received several comments concerning FDA notification of certain changes in the annual report. The United States Pharmacopeial Convention (USPC) supported FDA's proposal to permit changes in an approved application without requiring a supplement if the changes are made to

comply with a change in the compendia. Another comment suggested that the changes that may be described in the next annual report that were listed in the preamble to the proposal should be included in the regulation. One comment suggested that any attempt to list both those changes requiring supplements and those changes not requiring supplements would inevitably leave out some kinds of changes. Several comments suggested that the regulation should clearly identify the container size changes that may be made without a supplement if the applicant informs the agency in the next annual report. Finally, one comment asked that the final rule reflect the preamble statement that applicants would not be required to report changes in information not required in an original application; for example, information about manufacturing practices subject to CGMP regulations.

FDA appreciates the support of the USPC and notes that this change in the agency's supplemental application requirements is based upon close cooperation between FDA and the USPC in the development of compendial standards, including cooperation in the review of data and information supporting changes in standards. FDA has revised the final rule to add to the list of changes that may be described in the annual report. The list includes the following: Any change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied that does not involve a change in the dosage strength or dosage form; an editorial or similar minor change in labeling; the deletion of an ingredient intended only to affect the color of the drug product; an extension of the expiration date based upon full shelf-life data obtained from a protocol approved in the application; a change within the container and closure system for the drug product (for example, a change from one high density polyethylene to another), except a change in size for nonsolid dosage forms, based upon a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium; the addition or deletion of an alternate analytical method; a change in the size of a container for a solid dosage form, without a change in the container and closure system. FDA emphasizes, however, that the list is not intended to be exhaustive. All changes not falling under one of the two categories requiring supplements are to be described by the applicant in the next annual report to the application. Moreover, any change falling under one of the "supplement" categories that is made simply to comply with an official compendium is also to be described by the applicant in the next annual report. Although FDA believes it is impractical, if not impossible, to describe in the regulations every possible change that could occur in any application, the final rule lists the most significant and common changes that may be made and that are to be described in the annual report. Finally, FDA believes that a list of subjects, like changes under the CGMP regulations for which prior approval has been but is no longer required, would be of only historical interest and could be confusing.

67. One comment suggested that the agency permit applicants to add and update biopharmaceutic information in drug labeling in the annual report and without a supplement.

Drug labeling serves as the standard under which FDA determines whether a product is safe and effective. Substantive changes in labeling, which include changes in biopharmaceutic information, are more likely than other changes to affect the agency's previous conclusions about the safety and effectiveness of the drug. Thus, they are appropriately approved by FDA in advance, unless they relate to important safety information, like a new contraindication or warning, that should be immediately conveyed to the user.

68. One comment suggested that FDA create a fourth kind of supplement under which an applicant could implement a change 60 days after notifying the agency unless the agency advises otherwise within that time. Another comment suggested 30 days. These supplements might include changes in labeling or revisions to manufacturing or control procedures.

FDA has not adopted this suggestion because of the impact it would have on FDA's priorities. Were such a system instituted, FDA would be forced to rearrange its priorities to ensure that it acted within the required time frame, often with the effect of deferring action on other older and perhaps more important submissions that cannot be implemented without FDA approval. FDA recognizes applicants' concerns about obtaining timely review of supplements, and the agency is addressing this problem by eliminating unnecessary supplements which should, in turn, reduce any backlog. FDA now works closely with applicants who have a special need for timely review of a supplement and, as described above, FDA is establishing a procedure for applicants to request expedited review of certain supplements.

*Procedures for Submission of a Supplement to an Approved Application (§ 314.71)*

69. Noting that a supplemental application can sometimes be as significant as an original application, such as a supplement for a new indication, several comments found beneficial the application to supplements of all procedures and FDA actions on applications under proposed §§ 314.100 through 314.170. The comments urged, however, that the agency clearly state that § 314.60 on amendments to unapproved applications, § 314.65 on voluntary withdrawal, and § 314.103 on dispute resolution also apply to supplements.

FDA has revised the final rule to clarify that all procedures applicable to an original application also apply to supplements.

70. One comment suggested that the final rule should specify what actions FDA will take in the event that the agency refuses to approve a supplement for a change that the applicant placed into effect at the time the supplement was submitted. The comment stated that FDA should provide a reasonable time for the applicant to correct the problem, including time to exhaust supplies of the drug or labeling affected by the change, unless a significant safety concern exists.

If FDA refuses to approve a supplement for a change that the applicant has already placed into effect, the agency must consider all the factors surrounding its refusal to approve the supplement, including the applicant's reasons for making the change and the alternatives available to the applicant to resolve the problem. Applicants should be aware that they institute such changes subject to agency approval and that, if circumstances warrant, may be required to discontinue the change immediately. Nonetheless, if circumstances permit, FDA agrees that applicants should be able to correct a problem at minimal expense and without unnecessary waste. Because circumstances can vary greatly, however, FDA is not persuaded that a general statement in the regulations would be appropriate.

*Postmarketing Reporting of Adverse Drug Experiences (§ 314.80)*

71. *Overview.* a. *Comments received.* FDA received a considerable number of comments concerning the proposed reporting of adverse drug experiences of marketed drugs, especially the time

frames for such reporting. The current regulations base the reporting times on whether the adverse drug experience is expected or unexpected. All "unexpected" adverse drug experiences are required to be reported within 15 working days, and all "expected" adverse drug experiences are required to be reported in the next periodic report (quarterly in the first year following approval, semiannually in the second year, and annually thereafter). The proposal (with one exception) would have created a standard time frame of 30 working days for reporting almost all kinds of adverse reactions—serious, nonserious, expected, and unexpected. The one exception was a proposed 15-day alert report for fatal and life-threatening adverse drug experiences not mentioned in the product's approved labeling.

The primary criticism of the proposal made by the comments was that, except for the limited 15-day report, the proposal failed to distinguish the more important adverse drug experiences from the less significant ones. Without such focus, the comments argued, the public health would not be best served because both the agency and the pharmaceutical companies would be spending a disproportionate amount of time processing trivial, known reactions—time that could be better spent evaluating and following up on serious adverse drug experiences that are more likely to affect the public health. Comments also complained that, unlike current regulations, the proposal did not make the reporting requirements less frequent for known and nonserious experiences once the drug had been on the market for a period of time.

Given all of these factors, FDA has reevaluated the objectives of the adverse drug reporting system and the regulatory requirements most appropriate to implement them. Based on this review, the agency has modified the final rule in a number of ways designed to increase the system's efficiency and thereby improve public health protection. The details of these modifications are stated below, following a description of the objectives of the reporting system.

b. *Objectives of the reporting system.* Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the much larger patient population and longer period of use associated with the marketing of a drug provides, for the first time, the opportunity to collect information on rare, latent, and long-term effects, some of which may be serious. Accordingly, the primary objective of the adverse drug experience reporting system is to signal potential serious safety problems with marketed drugs, especially newly marketed drugs. As described below, a signal may be received in a variety of ways. Receipt of the initial signal triggers considerable followup work and analysis before any conclusion about necessary action can be reached (e.g., a "Dear Doctor" letter, revised labeling, or, in rare cases, market withdrawal). Thus, the agency believes that the goal of any regulations in this area should be to direct attention to those reports most likely to contain information on potentially serious safety problems.

c. *The final rule.* The final rule has been modified in the following ways so that the reporting requirements are tailored to signal potentially serious, new information.

(1) *Requirement for 15-day Alert reports.* Under the final rule, all adverse drug experiences that are both "serious and unexpected," and any "significant increase in frequency" of an adverse drug experience that is both "serious and expected," will be required to be reported to FDA as soon as possible, but in any case within 15 working days. These are the adverse drug experiences most likely to reveal serious safety problems that were not revealed during the clinical trials and which, therefore, are likely to necessitate a labeling change or other action to protect the public health. FDA believes that the broadening of the 15-day reporting requirement from that in the proposal, which would have required that only unexpected fatal and life-threatening experiences be reported, will increase public health protection. Throughout the final rule, references to "15-day Alert reports" (unless specified otherwise) refer to reports of "serious and unexpected" adverse drug experiences as well as reports of a "significant increase in frequency" of a serious, expected adverse drug experience.

The final rule defines both "serious" and "unexpected" in order to clarify the 15-day reporting requirement. Both of these definitions have been adopted from a draft guideline that has been made available for public comment (see 48 FR 4049; January 28, 1983).

For purposes of the final rule, the term "serious" means an adverse drug experience that is life threatening, is permanently disabling, requires in patient hospitalization, or requires prescription drug therapy. In addition, an adverse drug experience that results in death, congenital anomaly, cancer, or overdose is always to be considered serious.

The term "unexpected" means an adverse drug experience that is not listed in the current labeling for the drug and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling listed only cerebral vascular accidents. This definition of "unexpected" is based on an evaluation of individual case reports of an adverse drug experience.

The regulation also defines "increased frequency," which is defined to mean an "absolute increase in the number of reports of an adverse drug experience received during a specified time period compared to the number of similar adverse drug experience reports received during an equivalent time period in the past." In contrast to the definition of "unexpected," the definition of "increased frequency" is necessarily based on an analysis of a series of previous adverse drug experience reports, rather than a single report.

The 15-day reporting requirement will apply to any "significant" increase in frequency of a serious, expected adverse drug experience. In order to meet this requirement, applicants are required to review periodically the frequency of reports of "serious" adverse drug experiences that are "expected." The regulation requires applicants to conduct this periodic review at least as often as the periodic reporting cycle, and FDA will provide written notice to applicants when the agency believes that circumstances warrant more frequent periodic review (e.g., approval of a major new indication or where previous reports signal possible safety problems with the drug). FDA will describe in a guideline the factors which would make an increased frequency "significant" so as to trigger the 15-day reporting requirement, including an increased "rate of occurrence" of the adverse drug experience based on some measure of use of the drug (such as total prescriptions). Given this periodic review and analysis, the final rule requires applicants to report to FDA any significant increase in frequency of a serious, expected adverse drug experience as soon as possible but in any case within 15-working days of

determining that a significant increase in frequency exists. Of course, if an applicant receives a large number of reports within a short period of time, so that a significant increase in frequency is readily apparent, a 15-day Alert report would be required at that juncture.

(2) *Format for 15-day Alert reports.* The final rule specifies the format for submission of 15-day Alert reports. This format differs, depending upon whether the report is based on a single "serios and unexpected" adverse drug experience or on a "significant increase in frequency" of a serious, expected adverse drug experience (i.e., a series of events). The final rule requires reports of "serious and unexpected" adverse drug experiences to be submitted on Form FDA–1639 because that form is designed to contain information on individual adverse drug experiences. In contrast, the final rule requires applicants to submit reports of significant increases in frequency in narrative form (including the time period on which the increased frequency is based, the method of analysis, and the interpretation of results) rather than using Form FDA–1639. This is because Form FDA–1639 is not well suited for reporting a group of adverse drug experiences. As stated below, however, the requirement for periodic reports requires that a Form FDA–1639 for each "serious and expected" (as well as "nonserious") adverse drug experience be included in each periodic report. Finally, in order to facilitate expedited processing by the agency, the final rule requires prominent identification of all 15-day Alert reports. .

(3) *Requirement for periodic reports.* For all other adverse drug experiences, the final rule requires periodic reporting at quarterly intervals for the first 3 years following approval, and at annual intervals thereafter. This requirement reflects the agency's experience that the most important safety problems with a new drug are usually discovered during the first 3 years of marketing. Although this periodic reporting requirement is less frequent than the 30-day time frame that was proposed, FDA believes that the quarterly/annual time frame reflects better than did the proposal the relative importance and relative urgency of the information being reported (i.e., known and nonserious adverse drug experiences). Moreover, the final rule is more stringent in this respect than the current regulations, under which quarterly reporting is required for only 1 year before less frequent reporting is permitted.

The final rule also provides that FDA may extend quarterly reporting requirements beyond 3 years (when warranted by adverse drug experience received to date), may reestablish the quarterly reporting requirements at a later point in time (such as following approval of a major supplement), or may require the applicant to submit reports at other specified intervals. Thus, the regulation provides for increased surveillance of drugs when the circumstances so warrant.

The final rule states that quarterly reports are due within 30 days of the close of the quarter (the first quarter beginning on the date of approval of the application) and that annual reports are due within 60 days of the anniversary date of approval of the application. The time frame for submission of annual reports conforms to other annual reporting requirements under § 314.81.

(4) *Format for periodic reports.* The final rule specifies the content of periodic reports. These reports are designed to perform two functions: (a) Report to FDA the adverse drug experiences not previously reported under the 15-day requirement; and (b) present an overview of all the safety-related information learned during that quarter or year. In order to serve this second function, each periodic report is required to contain a narrative summary and analysis of the information contained in the report and an analysis of the 15-day alert reports submitted during the reporting interval; an index of all adverse drug experiences reported for the first time in the periodic report; and a history of actions taken, if any, since the last report because of adverse drug experiences (e.g., labeling changes or studies initiated). FDA believes that this safety profile overview will improve the agency's ability to spot drug safety trends.

(5) *Followup reports.* Several comments addressed the issue of followup reports. These comments urged FDA to require followup reports to be submitted 30 days after the date of receipt of followup information, not 30 days after the date of the original report (as had been proposed). One comment proposed 60 working days for submission of complete followup information on 15-day reports. Another comment asked for clarification about appropriate action if followup information cannot be obtained.

Because FDA has substituted quarterly and annual reports for the proposed 30-day reports, the agency expects that followups will be needed principally for the 15-day alert reports for "serious and unexpected" adverse drug experiences. With respect to these, the final rule requires applicants to investigate them promptly. Along the lines suggested by a comment, FDA has revised the final rule to tie the timing for submission of followup reports to the receipt of new information, rather than to the original report. Thirty working days, however, as suggested by the comment, is too long a period, given the possible importance of the information. The final rule, therefore, requires the submission of these followup reports within 15 working days of the receipt of new information or as requested by FDA. If the applicant seeks, but cannot obtain, additional information about an experience, a followup report may be required that briefly describes the steps taken to obtain the information and the reason the new information is unobtainable. Any followup information for adverse drug experiences submitted as part of a periodic report may be submitted with the next periodic report.

Finally, like the proposal, the final rule requires that records of adverse drug experiences be retained by applicants for a 10-year period. The record retention requirement has been moved from the "annual reports" section to the "adverse drug experience" section so that all requirements concerning adverse drug experiences can be found in one place in the regulations.

d. *Other options considered.* FDA decided on the time frames described above only after consideration of a wide range of options. For example, several comments urged that fatal and life-threatening adverse drug experiences be reported sooner than 15 working days, such as "immediately," within 24 hours, or within 1 week. One comment argued that FDA should require applicants to submit early reports of all fatal and life-threatening adverse drug experiences, instead of only those that are unexpected. At the other end of the spectrum, several comments urged that reporting intervals should not only become less frequent the longer the drug is on the market, but that at some point in time (e.g., 10 years after approval) reporting of known reactions should be eliminated entirely.

In response to these comments, the agency notes that the final rule does provide for reporting of "serious and unexpected" adverse drug experiences "as soon as possible," with 15 working days being the maximum. FDA strongly encourages the promptest possible reporting of these adverse drug experiences. The agency believes, however, that reducing the time for submitting these reports would serve only to increase considerably the

number of incomplete reports received by the agency. A large volume of such reports would make it more difficult for FDA to decide on a course of action, and would tend to clog up the system with useless information. FDA's experience is that 15 working days is sufficient time for applicants to gather enough information to submit a meaningful report, even though some followup may still be required. Moreover, the agency believes that adverse drug experiences already described in a drug's approved labeling need not be reported within 15 days even if those experiences were fatal or life-threatening. The importance of information about such experiences would be limited primarily to the question of whether they occur more frequently than assumed. As discussed above, however, any significant increase in frequency of a serious, expected adverse drug experience is also subject to the 15-day reporting requirement.

With respect to the last comment, FDA has staggered the reporting intervals for known and nonserious adverse drug experiences depending on the length of marketing experience. However, FDA does not believe it would be prudent to eliminate annual reporting across-the-board, even after several years of marketing experience, because of the possibility that long-term or other rare or latent effects might be detected.

72. *Definition of adverse drug experience.* Several comments objected to the scope of the proposed definition of an adverse drug experience, which built certain examples into the definition itself. One comment suggested that the current, more general definition should be retained. Another comment, finding the proposed definition open-ended, urged that the final definition be specifically limited to the listed examples. A third comment suggested that the agency delete information about drug overdose, drug abuse, and drug withdrawal because such information could more efficiently be obtained from the Drug Abuse Warning Network (DAWN) system, sponsored by the National Institute on Drug Abuse. Finally, one comment suggested that the definition should be evaluated to include drug misuse, which would provide useful information for treating emergencies.

FDA disagrees with these comments. FDA believes that the proposed definition of an adverse drug experience, which is retained in the final rule, improves upon the current definition because the specific examples provide clearer notice to applicants of what is required. FDA also believes that the definition should be left open-ended because public health protection requires the reporting of all adverse drug experiences, even those that do not fit into one of the more common categories. With respect to use of the DAWN system, although FDA uses drug abuse information generated by that system, its inherent limitations limit its usefulness such that it should be viewed as complementary to the adverse drug reporting system, with each contributing to an assessment of the abuse liability of drugs. Finally, the agency does not agree that "drug misuse" should be added to the definition because drug misuse often does not result in an adverse event.

73. Several comments objected to including in the definition of an adverse drug experience any failure of a drug product to produce its expected pharmacological action. Because drug products are not expected to be effective in all patients, these comments urged that only significant or unusual failures be reported, a required by current regulations.

FDA agrees that the final rule should be revised so that, as with the current regulation, only a "significant" failure of a drug to produce its expected pharmacological action would be reportable. While most instances of drug failure would be understood by physicians to represent the usual variances of biological responses, some failures of action are more important, reflecting, for example, a drug interaction or an unresponsive patient subpopulation. Such failures may also indicate manufacturing problems or batch failures. It is these types of failure that are likely to appear in the literature or as reports to the applicant, and the final rule requires that they be submitted to FDA.

74. *Tabulation of adverse drug experiences.* Several comments contended that a tabulation in the annual report of adverse drug experience reports already reported on Form FDA–1639 is an unnecessary duplication of the other reporting requirements, and would add greatly to the work of applicants without any obvious benefit. One comment suggested that an applicant's tabulation of adverse drug experiences would be less complete and, thus, less useful than FDA's own data base, from which a tabulation could be made.

FDA has revised this section to require that the applicant provide only an index of all adverse drug experiences submitted for the first time in the periodic report. This index is to consist of a line listing of the applicant's patient identification number and adverse reaction term(s). The index is intended to order the potentially large volume of information being submitted and to provide FDA reviewers with ready access to particular reports when necessary.

75. *Published literature.* Several comments objected to the proposed requirement to transfer information from the published literature onto a Form FDA–1639 and urged, instead, that FDA retain its current rule of simply accepting the published articles themselves. These comments argued that such transfer is an unnecessary clerical exercise that would require major expenditures of time, effort, and money. One comment suggested that even an abstract of the article should be sufficient.

The efficient handling of adverse drug experience reports requires that they be made in a form that is convenient for the agency to process. FDA is currently receiving almost 40,000 adverse drug experience reports annually. To analyze those reports efficiently, the agency has developed a reporting form that reflects FDA's experience in monitoring drug safety in a centralized reporting program. Each item of information on a fully completed Form FDA–1639 (Drug Experience Report) fulfills one of the following four purposes: (1) Recordkeeing information, (2) information necessary to monitor compliance, (3) information relating to the seriousness of the report and the event or reaction, and (4) information relating to the sequential relationship between the drug and the event or reaction. Moreover, as constructed, Form FDA–1639 is also intended to facilitate data entry into FDA's computer base. Given the large number of reports submitted to the agency, and the agency's small staff for reviewing and processing them, FDA's system will work only if applicants transfer reports from the scientific literature to Form FDA–1639's. FDA believes, however, that preparation by the applicant of 1639 forms for literature reports represents a minimal burden because, as described below, the regulations limit the kinds of literature reports that need to be submitted, and because the applicant will necessarily have to review any given literature report to determine if it meets the criteria for reporting. Morever, if the applicant believes that the preparation of a 1639 form represents an undue hardship in any particular instance, the regulations provide that the applicant may arrange with the Division of Drug and Biological Product Experience for an acceptable alternative reporting format.

76. Several comments questioned the need for submitting adverse drug experience reports based on the scientific literature. For example, one comment argued that literature reports often do not contain the information needed to complete FDA's form and, therefore, that this requirement will provide FDA with little useful information. One company estimated that, under the proposed requirement, it would have to copy and submit to FDA almost three 5-drawer filing cabinets of literature articles each year, and that this would amount to over 100 filing cabinets industrywide. According to this comment, the number of additional employees needed by the industry and FDA to copy, submit, and review these articles would also be excessive. Other comments suggested that FDA limit the scope of the published reports falling under this section to, for instance, reports in the published literature "primarily concerned" with the occurrence of adverse drug experiences, or only those relating to fatal or life-threatening experiences. Finally, one comment asked whether the requirement applied to individual experiences reported in letters to a journal.

FDA agrees with those comments that urged FDA, in order to keep the amount of information manageable, to limit the scope of required reports from the scientific literature. FDA has revised the final rule in two ways. First, the final rule limits literature reporting to "serious and unexpected" adverse drug experiences and any "significant increase in frequency" of a serious, expected adverse drug experience (i.e., those subject to the 15-day reporting requirement). By focusing the literature review and reporting on the most important adverse drug experiences, this requirement achieves the objectives of a signaling system while maintaining a reasonable reporting burden on applicants. Reporting of the vast numbers of individual cases of known or nonserious adverse drug experiences recorded in the literature would not materially advance public health protection.

Second, the final rule limits the kind of literature reports subject to the 15-day requirement in the following ways. With respect to reporting "serious and unexpected" adverse drug experiences, the final rule limits literature reporting to adverse drug experiences appearing in scientific and medical journals as "case reports" or as the result of a formal clinical trial. Case reports are reports of experiences in individual patients, including those appearing in letters to the editor and in studies of adverse effects, but do not include literature reports of adverse drug experiences in clinical trials that do not tie experiences to individual patients. The limitation should help provide FDA with complete, rather than partial and less useful, information about events reported. In addition, limiting the requirement to reports in scientific and medical journals ensures that reports come from scientifically credible sources. As noted above, a Form FDA-1639 is required for each case report, even when a journal may contain less than all items of information needed to complete the form. With respect to reporting a "significant increase in frequency," the final rule limits literature reporting to scientific and medical journals containing reports of either formal clinical trials, or epidemiologic studies or analysis of experience in a monitored series of patients. Once again, this limitation is intended to focus attention on those types of literature reports most likely to yield useful information.

77. Several comments said that the proposal is unclear about when FDA considers an applicant to have knowledge of an experience in a published report. Unsure about when FDA will impute to an applicant knowledge of a published report known by one of the applicant's employees, one comment recommended that applicants be required to report only experiences that employees discover in the normal course of business through a literature review program, or that employees discover on their own time (e.g., while reading a scientific journal at home) and bring to their supervisor's attention at work. However, according to this comment, the regulation should not require that applicants establish literature review programs.

As was clear in both the proposal and the final rule, adverse drug experiences an applicant discovers through an organized literature review program must be reported. Although the final regulations do not require applicants to establish literature review programs, an applicant is obligated to report those experiences that come to its attention in the normal course of business. Whether an employee's knowledge of a report in a scientific journal would be imputed to the applicant will depend upon the factors surrounding the employee's knowledge of the report. As a general rule, however, FDA will consider companies responsible for information known to employees, and companies should adopt procedures that require employees to bring important information to the attention of superiors.

78. Several comments suggested that the regulations should permit a single initial Form FDA-1639 for an adverse drug experience in multiple patients from nonliterature sources because the number of patients is often exaggerated. According to these comments, individual forms could be required for followups of documented patients.

FDA believes that permitting the use of a single initial report for multiple patients with individual forms for followup, while it might reduce by a small number of the forms required, has the potential for creating confusion about the number of experiences reported. It is necessary for FDA, if it is to utilize the data properly, that information on the number of adverse events be received in an unambiguous manner so as to reflect clearly the extent of a problem. The submission of multiple events on a single reporting form is inconsistent with the agency objective. Moreover, a practice of grouping reports on one form would make it harder for FDA to determine whether an experience was covered by an initial report and thus was reported in a timely way, and whether appropriate followup was conducted in each case.

79. *Identification of patients.* Several comments objected to the provision under which FDA would have access to individual patient information. For example, comments suggested that the review of patient records by FDA raises questions about their continued confidentiality. Several comments urged that submission of patient records should require a determination in writing by the Director of the Center for Drugs and Biologics that there is good cause to believe that the reports in the application do not represent actual cases or actual results obtained, or that FDA should provide examples of situations where good cause to review actual reports would exist. Some comments suggested that the proposal did not provide the same types of protection for patient confidentiality accorded by State statutes. These comments suggested that FDA should describe the safeguards the agency will employ to protect and ensure patient privacy.

FDA believes that these comments misunderstood the proposal as it relates to FDA access to patient records. FDA disagrees with the suggestion that its safeguards for information that identifies patients are inadequate. As noted in the proposal, FDA urges applicants not to include names and

addresses of individual patients in adverse drug experience reports, although applicants should inlcude some other identifier, such as initials or code numbers. Initials and codes are useful for eliminating duplicate reports of an adverse drug experience. As noted in the regulations, names of patients, health care practitioners, hospitals, and any geographic identifier are not releasable to the public under FDA's public information regulations in Part 20 (21 CFR Part 20). Moreover, FDA's Division of Drug and Biological Product Experience routinely deletes information that could identify patients, health care professionals, and hospitals before copies of adverse drug experience reports are provided to the public, or even to other components within FDA itself. Thus, FDA believes that the final rule adequately protects confidential information about patients.

80. Several comments also believed that the proposal implied that applicants should maintain in their records the names and addresses of patients. One comment stated that its practice is to retain only identifying information that permits it to find the name and address of a patient, using records maintained by the investigator. Another comment noted that an applicant may be unable to obtain the patient's name, as some hospitals will not release patient identification. The comment suggested that the phrase "upon written request by FDA the applicant shall submit individual patient identification information from designated reports" should be changed to "the applicant shall maintain sufficient patient identification information to permit FDA, by using that information alone or along with records maintained by the investigator of a study, to identify the name and address of individual patients."

FDA agrees with this comment and has revised the final rule to provide that an applicant need only retain identifying information that permits FDA to find the name and address of a patient using records maintained by the applicant or maintained by the investigator in a study.

81. *Postmarketing clinical trials.* Several comments urged that adverse drug experiences from clinical investigations conducted on marketed drugs under an investigational new drug application (IND) should be exempt from the reporting requirements because study blinding will make it impossible to identify whether the adverse drug experience was associated with either the test drug or the control drug. Accordingly, this comment suggested that adverse drug experiences from these studies should be reported to FDA in the final study report. One comment noted that in double-blind studies it is not known whether an experience is associated with a placebo, a control drug, or the study drug, and the code should only be broken for fatal or life-threatening reactions. One comment urged that the regulations clearly specify whether adverse experiences occurring with an approved drug product used in a clinical study under an IND should be reported to the application or the IND. Another comment objected to the use of Form FDA–1639 for reporting experiences from clinical investigations conducted under an IND. According to this comment, those experiences are best reported in the final clinical report, which should be submitted after the study is completed.

FDA agrees with the general thrust of these comments and has revised the final rule to provide that only "serious and unexpected" experiences or a "significant increase in frequency" of a serious, expected experience (i.e., those subject to the 15-day reporting requirement) must be reported when they occur in clinical trials conducted using marketed drugs. As noted above, the 15-day reports are the most important part of the adverse drug experience reporting system, and it is important to keep these reports current. FDA does not interpret this requirement as requiring clinical investigators to break the blinding code, but this requirement does apply to serious, unexpected adverse drug experiences when the code is normally broken anyway (such as when the patient dies or drops out of the study).

82. Several comments also objected to FDA prohibiting the reporting of adverse drug experiences from Phases I and II studies on Form FDA–1639.

The prohibition objected to has been deleted from the final rule. FDA agrees that reporting of "serious and unexpected" adverse drug experiences from clinical trials on marketed drugs required under this section should be submitted on a Form FDA–1639. As noted above, the review of adverse drug experiences by FDA's Division of Drug and Biological Product Experience is geared to this form, and its use also facilitates entry of the information into the computer base for marketed drugs. This interpretation does not apply to 15–day reports of significant increases in frequency which, for reasons described above, are to be reported in narrative form. It should be noted, however, that the final rule does not apply to reporting requirements under the IND regulations (Part 312), where a more detailed type of reporting may be required because much less is known about the safety of unmarketed drugs and, therefore, more extensive information on individual incidents is needed.

83. *Postmarketing surveillance/epidemiological studies.* One comment objected to the submission of adverse drug experience information from postmarketing surveillance/epidemiological studies on Form FDA–1639 in the same fashion as information from spontaneous reports because these studies would generate a large number of reactions that would overwhelm the spontaneous reporting system. The comment suggested that only unexpected adverse drug experiences from those studies be submitted under the schedule for spontaneous reporting, with other experiences summarized and submitted later.

FDA has revised the final rule in response to this comment. First, FDA recognizes that reports occurring in a structured study must be evaluated separately from spontaneous reports. Thus, the agency asks that reports of adverse drug experiences clearly note when an experience occurred in a postmarketing study. The agency will file these study reports separately from spontaneous reports. Second, as with postmarketing clinical trials, the 15–day reporting requirement will apply to these studies only where there is no blinding or when the blinding code is otherwise broken, and these reports are required to be submitted on Form FDA–1639. However, other adverse drug experiences from these studies will be subject to periodic reporting and will be required to be reported following the completion of the study (a study is considered completed 1 year after it is concluded); applicants are encouraged to submit these adverse drug experiences in a format different from Form–1639, if agreed to in advance by the Division of Drug and Biological Product Experience.

84. *Recordkeeping.* Several consumers objected to requiring recordkeeping of adverse drug experience reports for only 10 years, arguing that such data may be useful later if a drug is found to have serious adverse effects that do not show up for many years; for example, if the drug is found to be carcinogenic. In contrast, another comment argued that the requirement that adverse drug experience records be maintained for 10 years is excessive, suggesting instead that complete records be retained for 5 years and a summary of adverse drug experiences be retained for an additional 5 years.

FDA has not found it necessary to rely upon applicant records that are more than 10 years old for evaluating current adverse effects, including delayed effects like carcinogenicity. Thus, the agency cannot now justify a record retention requirement of more than 10 years. In addition, FDA would prefer to be able to obtain full rather than summary records when and if needed. The agency is not persuaded that retaining complete records for 5 years and then reducing them to a summary is less burdensome than simply retaining the records for 10 years. Therefore, the final rule will remain as proposed.

85. *Miscellaneous issues.* On its own initiative, FDA has made several additional modifications to the final rule relating to adverse drug experiences. First, the agency has limited the reporting of adverse experiences from foreign marketing to those considered to be "serious and unexpected" as well as those representing a "significant increase in frequency" of a serious, expected adverse drug experience (i.e., those subject to the 15-day reporting requirement), consistent with other efforts to target FDA resources on the most important adverse experiences.

Second, the final rule, like the current regulations, requires any person (in addition to the applicant) whose name appears on the label of an approved drug product (i.e., a manufacturer, packer, or distributor) to comply with the 15-day reporting provisions on adverse drug experiences. Although FDA proposed to delete this requirement for nonapplicants as part of a broader effort to reduce recordkeeping and reporting requirements generally, FDA believes that the 15-day reporting of adverse drug experiences is sufficiently important, and that it is sufficiently likely that any person whose name is on the approved label will be a recipient of adverse drug experience complaints, that this reporting requirement should be retained. In order to avoid unnecessary duplication of reporting, however, a nonapplicant's obligation under this section may be met by forwarding the adverse drug experience information it receives to the applicant within 3 working days, and by retaining a record of that transmittal.

Third, the agency has continued the current rule of requiring two copies of adverse drug experience reports, rather than the proposal's requirement of only one copy, to expedite review of the reports by the Division of Drug and Biological Product Experience and the Office of Drug Research and Review or the Office of Biologics Research and Review, which both evaluate adverse drug experiences. Because of the large volume of reports received, copying by FDA will unnecessarily delay the review of this important information. The agency believes that spreading this burden among all applicants is both reasonable and efficient. Applicants should send both copies of these reports in the same envelope or package directly to the Division of Drug and Biological Product Experience, and the agency will route the second copy to the Office of Drug Research and Review or the Office of Biologics Research and Review. The final regulation also contains a provision for waiver of the requirement for a second copy (for example, in the quarterly/annual report, the reviewing division may want only the tabular listing of non-15-day reports, rather than full Form FDA-1639's).

Fourth, the final rule contains a caution against the submission of multiple reports for the same adverse drug experience. Thus, an applicant should not include in reports under this section any adverse drug experiences that occurred in clinical trials if they were previously submitted as part of the approved application. If a report applies to a drug for which an applicant holds more than one approved application, the applicant should submit the report to the application that was first approved. If a report refers to more than one drug marketed by an applicant, the applicant should submit the report to the application for the drug listed first in the report.

Finally, FDA has added a provision stating that an adverse drug experience report submitted in accordance with these regulations does not necessarily reflect a conclusion by either the applicant or FDA that the report conatitutes an admission that the drug caused or contributed to an adverse effect. This "disclaimer" provision parallels a similar provision recently added to the Medical Device Reporting (MDR) regulation (49 FR 48272; December 12, 1984) in response to comments raised concerning products liability consequences of reporting possible adverse effects. FDA advises, however, as it did in the December 12, 1984 notice, that although FDA does not intend for such a report to be viewed as an admission of liability, whether a court will treat a submission to FDA as an admission will depend on factors outside of the agency's control, such as the contents of the report itself.

FDA believes this disclaimer incorporates long-standing agency policy in the drugs area. Both the previous and the new drug regulations require reporting of adverse events, whether or not considered to be caused by the drug in question. FDA is adding the disclaimer provision for purposes of articulating consistency with the new MDR regulation. For the reasons stated in the December 12, 1984 notice, this provision does not require notice and comment rulemaking and will be made effective along with the other adverse drug experience reporting provisions of this final rule.

86. Several comments suggested that FDA combine the adverse drug experience and annual reporting requirements into a single section of the regulation, because the separate sections in the proposal were confusing and duplicative.

FDA believes that separate sections describing the "adverse drug experience reporting" requirements and the "annual reporting" requirements are helpful because both FDA and some applicants have separate organizational components devoted to each of these areas. For example, in FDA, the adverse drug experience reports are evaluated first by the Division of Drug and Biological Product Experience, whereas the annual reports are reviewed by the Office of Drug Research and Review or the Office of Biologics Research and Review.

Nevertheless, FDA agrees that the proposal did not adequately segregate the requirements applicable to adverse drug experience reports from those relating to the more general records and reports, and, therefore, the agency has made the following changes in the final rule: First, the section relating to the "postmarketing reporting of adverse drug experiences" will include all the regulatory requirements relating to this topic, including the provisions relating to the retention of records and the annual tabulation, both of which were located in the "records and reports" section of the proposal. Second, the reporting requirements for adverse drug experiences have been deleted from the "other postmarketing reports" section (called "records and reports" in the proposal) because they are also found in the section in the final rule on adverse drug experience reporting (the proposal had listed them in both sections).

87. One comment suggested that the agency monitor more closely applicants' compliance with reporting requirements and suggested that the proposal was unclear about who is responsible for submitting reports of adverse drug experiences. The comment also asked how the information is made publicly available.

FDA urges health care professionals to submit adverse drug experience

reports to FDA on Form FDA-1639. Many professionals submit reports to manufacturers, however, and many manufacturers routinely review the literature on their products. It is the reports obtained by the manufacturer with which these regulations are concerned. The regulations clearly place the responsibility for submitting those reports to FDA on the manufacturer. With respect to public disclosure, § 20.111(c)(3) of FDA's public information regulations governs how this information is made publicly available.

88. One comment stated that FDA's regulatory impact analysis on the proposal did not adequately discuss the impact of the changes in the adverse drug experience reporting system.

This comment was made in conjunction with an objection to the proposed requirement that all adverse drug experiences be submitted within 30 working days, a change which the comment believed was excessive and did not provided a corresponding public health benefit. Because FDA has modified that aspect of the proposal, the corresponding economic concern with respect to the proposed 30-day provision is moot. However, the final regulatory impact analysis does address the economic aspects of the major changes between the current regulations and the final rule.

89. Two comments suggested that over-the-counter drugs that are subject to approved applications and that are not intended for systemic absorption, like antimicrobial mouthwashes or soaps and antidandruff shampoos, should be exempt from frequent reporting of consumer complaints, like rashes or minor skin irritations, particularly if the manufacturer provides a toll free telephone number on labels.

FDA believes that the changes in the final rule—to require only "serious and unexpected" adverse drug experiences to be reported quickly—meets the concerns of the comments.

*Other Postmarketing Reports (§ 314.81)*

90. *NDA—Field alert report (§ 314.81(b)(1)).* Two comments objected to the proposal specifying that certain reports, required under current regulations to be submitted "immediately," be submitted within 3 working days. These reports covered: (i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; and (ii) information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specifications established for it in the application. Two other comments, mistakenly believing that the agency intended to require immediate reporting of a broader category of information than currently required, urged that the current language of the requirement be retained because the comments found it preferable to and clearer than the proposed revision. Other comments suggested that FDA allow reports by telephone with written followup information.

Although the agency has retained the proposed wording regarding the kinds of information that are required to be reported under this section, FDA intends the final rule to require the same kinds of reports submitted under the current regulation. The major change from current practice is to require the report within 3 working days. FDA has also revised the final rule to state that this reporting requirement applies only to distributed drug products and that the report should be made to the FDA district office that is responsible for the facility that is the subject of the report. To help the district offices recognize these submissions quickly, these reports have been designated "NDA—Field alert reports" in the final rule. Because these reports can lead to preventing potential safety hazards from products already in distribution, the agency emphasizes that the reports are required for both confirmed and unconfirmed problems. Telephone reports will be permitted, with prompt written followup.

91. *Annual report (§ 314.81(b)(2)).* Several comments stated that the proposal to require an annual report within 30 days of the anniversary date of approval is unnecessarily burdensome, particularly if adverse drug experiences are reported earlier. One comment suggested a due date of 60 days after the anniversary date, and another comment suggested 6 months. Finally, one comment suggested that annual reports should be eliminated after 3 years of marketing because little new information is obtained after that time.

FDA is persuaded that 30 days may be inadequate for an applicant to compile and prepare an annual report. An annual report under the final rule will differ from current annual reports in that it will contain, in addition to what is currently reported, both a summary of new information about the drug and a description of actions the applicant has taken or proposes to take as a result of that information. Thus, to ensure that the summary is clear, concise, and thoughtful, FDA has revised the final rule to require the submission of an annual report 60 days after the anniversary date of the application.

FDA does not agree, however, that annual reports should be eliminated after 3 years. Animal and clinical data may become available long after a drug is first marketed, and the annual reporting requirement is the most effective means for an applicant to provide it to FDA. Moreover, the annual report is necessary for applicants to inform the agency about changes in the application that are not covered by supplements. Thus, FDA relies upon the annual reporting requirement to monitor continuously the safety and quality of approved drugs while they are marketed.

92. *Summary (§ 314.81(b)(2)(i)).* One comment objected to the requirement for an annual report summary containing a description of the actions an applicant intends to take as a result of new information because, according to this comment, action by an applicant should not wait until the applicant prepares its annual report.

FDA believes that this comment misunderstood the proposal. The final regulations, like the proposal, do not require that an applicant delay action until an annual report is made: instead, the summary is simply required to contain a description of actions the applicant has taken and actions the applicant proposes to take.

93. *Distribution data (§ 314.81(b)(2)(ii)).* One comment objected to what was perceived as a requirement for a single report of units distributed for domestic and foreign use. According to this comment, the requirement would make it difficult for FDA to estimate the incidence of a drug's adverse effects because applicants usually will have much less information about adverse experiences in foreign countries.

FDA has revised the final rule to state clearly that quantities of a drug product distributed for domestic use and quantities distributed for foreign use should be stated separately.

93a. *Chemistry, manufacturing, and controls changes (§ 314.81(b)(2)(iv)).* The final rule retains the current requirement for annual reporting of experiences, investigations, studies, or tests involving chemical or physical properties of the drug that may affect the drug's safety or effectiveness. This provision was inadvertently omitted from the proposal.

94. *Nonclinical laboratory studies (§ 314.81(b)(2)(v)).* Several comments urged that requirements for reporting nonclinical laboratory studies be limited to active ingredients. One comment

asked FDA to require applicants to submit routinely published literature about commonly used drug ingredients, such as acetaminophen, codeine, and atropine, rather than to submit them in annual reports on specific drug products. According to this comment, submission of data on the ingredients rather than on individual products would better enable FDA to monitor the drug products adequately. Another comment urged that summaries of published reports be permitted because the reports themselves often contain lengthy reviews of previous literature. Finally, noting that there is no reason to supply FDA with required information it already has, one comment suggested that FDA limit required submissions to "new" toxicological findings in animal and in vitro studies.

The final rule retains the proposed requirement for reporting nonclinical laboratory studies of inactive ingredients, because both active and inactive ingredients can cause safety problems. FDA has also retained the requirement for submitting study results for inclusion in specific applications rather than making a general submission to the agency. This is because each report an ingredient must be separately evaluated with respect to the drug products that contain it. With respect to published literature, the final rule has been revised to require only summaries of published studies, although the applicant will be required to submit a copy of the published study upon request. FDA has retained in the final rule the requirement for full copies of unpublished nonclinical studies. Finally, the final rule, like the proposal, does limit submissions to "new" toxicological findings in animal and in vitro studies.

95. *Clinical data (§ 314.81(b)(2)(vi)).* One comment objected to the required submission of articles from the scientific literature, rather than simply a bibliography, because the articles are readily available to the agency. Two comments suggested that an applicant should only be required to submit published or unpublished reports that present new and different information that has not been previously submitted, instead of requiring applicants to submit all available reports. One comment suggested a revision of the phrase "review articles, papers, and abstracts in which the drug is used as a research tool," to clarify that papers (as well as abstracts) in which the drugs is used as a research tool should not be reported.

Although FDA has access to the scientific literature, it would impose a significant burden on the agency if its reviewers were required to obtain reprints of literature references. It is properly the responsibility of the applicant to assure that the application is kept current. Since the applicant is expected to monitor the literature for developments relating to its products, it is not, in FDA's opinion, unduly burdensome to require the applicant to copy relevant articles and send them to FDA.

As suggested by two comments, applicants are not required to resubmit information previously submitted. However, the final rule retains the requirement for the submission of information from any new clinical trials (i.e., not previously submitted). Even if such trials do not contain dramatically different information, they often provide new information about, or insights into, the safety or effectiveness of the drug product. Finally, FDA agrees that reports of papers (as well as abstracts) in which the drug is used as a research tool need not be reported, and the agency has revised the final rule to so provide.

96. *Status reports (§ 314.81(b)(2)(vii)).* One comment contended that status reports for postmarketing studies are unnecessary because FDA will be receiving adverse drug experience data on a timely basis.

FDA believes that this comment misunderstood the proposal. All that is required is a "statement of the current status of any postmarketing studies." This is simply a requirement to advise the agency about which postmarketing studies, if any, are ongoing, and what the status of such studies is, such as how close a study is to completion. Detailed reporting of adverse drug experiences is not required under this section.

*Time Frames for Reviewing Applications (§ 314.100)*

97. Several comments objected to establishing limits to the application review time and urged that FDA should emphasize the thoroughness and carefulness of its review instead of merely the speed with which approval decisions are made. One comment suggested that it is unlikely that faster approval could be accomplished without compromising the reliability of FDA's safety and effectiveness decisions. These comments were concerned that the 180-day deadline for reviewing applications may place too much pressure on reviewers and thus reduce the quality of the review. Other comments considered the time frames unrealistic, particularly in view of the proposed changes to increase the number of communications and meetings with applicants. Another comment suggested that the agency's time frames for action on applications may create unreasonable expectations, given the restrictions on the agency's personnel and budget resources.

This final rule, like the proposal, is intended to establish efficient procedures, including time frames for review, under which the approval process operates, without reducing the high level of public health protection the approval process now provides. The 180-day review period reflects the statutory requirements that apply to the approval process. FDA believes that improvements in the regulations (such as those relating to the format and content of applications), together with managerial improvements, provide a reasonable basis for concluding that the time frames in the final rule can usually be met.

98. One comment suggested that the agency's two 180-day time limits for reviewing and filing applications (which overlap by 60 days) are confusing. The proposal was unclear, according to this comment, about whether an action letter will issue within 180 days of FDA's receipt or within 180 days of FDA's filing of the application. Another comment urged FDA to adopt a single time frame under which the agency would file the application 30 days from the date of its receipt, thus starting the 180-day clock. Finally, one comment suggested that FDA establish a special deadline for action by the Directors of the Office of Drug Research and Review and the Office of Biologics Research and Review on division recommendations on applications.

Although the agency recognizes that there is a potential for confusion, it believes that its separate time frames for reviewing and filing applications are necessary and are not unduly complicated. The agency suggests that reviewers and applicants should focus on the provision for issuance of an action letter (either an approval, approvable, or not approvable letter) within 180 days of FDA's initial receipt of the application. This is the "review clock" (i.e., the period in which the application will be reviewed) and it is not affected by the date of filing. Thus, moving the deadline for filing from 60 days to 30 days would not have the effect anticipated by the comment: The 180-day review period would be already running when either filing date (30 to 60 days) was reached.

The second 180-day period, or "filing clock," plays an important role in only that small number of cases where the applicant chooses to enter the formal evidentiary hearing process following

the agency's refusal to approve its application. The reason for the "filing clock" is legal: section 505 of the act requires FDA, within 180 days of "filing," either to approve the application or to issue a notice of opportunity for hearing. The preparation of a notice of opportunity for hearing is far more time consuming than the preparation of a not approvable letter. Therefore, by placing the date of "filing" 60 days into the review cycle, the agency gives itself 60 days at the end of the normal review cycle (i.e., issuance of an action letter) to prepare a notice of opportunity for hearing if one is necessary. (As noted below, this 60 days includes 10 days for the applicant to respond to the action letter, so FDA's time is really 50 days.)

What this means, therefore, is that applicant should rely on the 180-day "review clock" as the measure of review time regarding their applications. As described above, this provision calls for the completion of FDA's review and issuance of an action letter within 180 days of initial receipt of the application. The filing notice after 60 days serves as a status report to the applicant that the application has been found to be sufficiently complete for review purposes, and does not affect the period in which applicants are notified of the approvability of their applications. Except in those rare cases that may culminate in a formal evidentiary hearing, the 180-day "filing clock" has no practical significance.

FDA has retained the proposed provision that the "clocks" may be extended by mutual agreement or by the submission of a major amendment. Any extension applies equally to both the "review clock" and "filing clock." This change is consistent with comments, discussed elsewhere in this preamble, that advocated increased use of advisory committees. These comments recognized that bringing a matter before an advisory committee could raise a need to extend the review period.

*Filing an Application (§ 314.101)*

99. FDA received several comments on the proposed provisions concerning filing an application and procedures to be followed when the agency refuses to file an application. Several comments suggested that the regulations should provide for FDA to file the application within the 60-day period instead of on the 60th day after receipt. Several comments objected, as being insufficient, the 10 days provided in the proposal for an applicant to decide whether to request an informal conference on the agency's refusal to file its application. One comment suggested that the agency allow 30 days for a response, with extensions for good cause. Another comment asked whether an applicant needs to resubmit an application that it files over protest and suggested that references to "automatic filing" are inconsistent with the requirement that the applicant initiate a conference to file an application over protest.

FDA does not believe a change in the final rule to provide for filing an application in less than 60 days would have any practical effect. As noted above, an earlier filing date would not affect the deadline for issuance of an action letter, which remains 180 days after initial receipt of the application. Moreover, because FDA's time to prepare a notice of opportunity for a hearing (following a not approvable letter, when requested by the applicant) is to be the same as the time for filing the application, an earlier filing would limit the time, which is already short, for the agency to prepare the requisite notice of opportunity for hearing.

In response to comments, FDA has revised the procedures for filing over protest. Under the final rule, when FDA refuses to file an application, the applicant will have 30 days to decide whether to request an informal conference with agency officials (rather than 10 days, as provided in the proposal). The final rule also priovides that such an informal conference must be held before an application may be filed over protest. However, these changes also necessitate modifications of the "review clock" with respect to applications filed over protest, because an informal conference requested on the 30th day following a refusal to file would leave FDA only 90 days (30 days plus the 60 days before filing) in which both to hold the informal conference and complete the review of the application. Under the final rule, an application which the agency refuses to file will be considered received, for purposes of commencing the 180-day review period, on the date the informal conference is requested. This change is needed to ensure that FDA will have enough time to review any application that is subsequently filed over protest. Moreover, dating receipt from the date the applicant requests an informal conference will result in conferences being held promptly because the review period will already have commenced.

In response to one comment, the agency has modified the final rule to provide that an applicant need not resubmit a copy of the application when it is filed over protest.

FDA agrees with the last comment and has removed the reference to automatic filing of an application. Nevertheless, FDA believes that it is clear from the final rule that FDA will file a complete application in 60 days, and that even an incomplete application can be filed over protest (at a somewhat later point) if the applicant insists.

100. One comment suggested that the provision under which FDA can refuse to file an application that is incomplete should include the following phrase "other than case reports and other information not expressly required under this part." According to the comment, this change would clarify that the provisions in the regulations for the routine submission of less than all case report forms does not conflict with section 505(b)(1) of the act (21 U.S.C. 355(b)(1)), which requires "full reports of investigations."

FDA believes that the additional wording suggested by the comment is unnecessary. The comment erroneously assumes that only submission of all case report forms satisfies the full reports requirements of the statute. As discussed above, however, case report forms are simply one way in which data from a clinical study can be presented. The final rule requires applicants to submit a combination of summaries, analyses, tabulations, and case report forms, with additional case reports available upon request. These materials satisfy the "full reports" requirements of the act, regardless of whether all case reports are submitted.

101. One comment asked for clarification of the provision under which FDA will refuse to file an application if the drug product that is the subject of the submission is already covered by an approved application. The comment suggested that this should prohibit only an applicant who holds an approved application from filing another application for the same product. The comment stated that the provision should not apply to another applicant filing an application for the drug product.

This provision will permit FDA to refuse to review spurious applications. For example, FDA publishes an "Approved Drug Products List" that identifies applicants who hold approved applications, but this list does not identify distributors. Because some State regulatory officials rely upon the list as an index to legal marketers of drugs, distributors may seek applications for products they already distribute in their own names. FDA's review of such an application would require a commitment of resources, but

would not affect the marketing status of the drug under Federal law. Distributors that encounter problems with State procurement or other systems keyed to NDA status should resolve those problems by means that do not involve inappropriate and wasteful use of the NDA process.

*Communications Between FDA and Applicants (§ 314.102)*

102. Several comments agreed with the policies stated in the preamble to the proposal that open communication between FDA and applicants should be fostered and that FDA should promptly communicate with applicants about deficiencies or the need for additional data. These comments, however, urged that these policies be codified in the regulations in order to institutionalize them more formally.

FDA agrees with these comments and, to reflect its commitment to increasing and improving communication between the agency and applicants, has revised the final rule in the following ways.reviewing an application, FDA shall communicate with applicants about scientific, medical, and procedural issues that arise during the review process. Such communication may take the form of telephone conversations, letters, or meetings, whichever is most appropriate to discuss the particular issue at hand. The final rule also requires communications to be appropriately documented, in accordance with § 10.65.

b. The final rule directs FDA reviewers to make every reasonable effort to communicate promptly to applicants easily correctable deficiencies found in an application when those deficiencies are discovered, particularly deficiencies concerning chemistry, manufacturing, and controls issues. The final rule also provides that FDA will inform applicants promptly of its need for more data or information in the application or for technical changes in the application needed to facilitate the agency's review. This policy is designed to permit applicants to correct such readily identified deficiencies relatively early in the review process and to submit an amendment before the review period has elapsed. However, under the final rule, such early communication would not ordinarily apply to major scientific issues, which require consideration of the entire pending application by agency managers as well as the reviewing staff. Instead, these major scientific issues will ordinarily be addressed in an action letter.

c. The final rule contains a new provision for applicants to have an opportunity for an "end-of-review conference" with agency officials. This meeting would be held at the conclusion of FDA's review of an application, as designated by the issuance of an approvable or not approvable letter. The purpose of this type of meeting is to discuss what further steps need to be taken by the applicant before the application can be approved. This meeting will be available on all applications, with priority given to all applications for new chemical entities and major new indications for marketed drugs.

d. The final rule states that FDA will make every effort to grant requests for other meetings that involve important issues and that can be scheduled at mutually convenient times. This policy is designed to facilitate the free exchange of information between FDA and applicants. However, the final rule discourages "drop-in" visits (except for urgent matters, such as to discuss an important new safety issue) in order to minimize disruption of reviewers' work time.

FDA has revised its staff manual guide on communication between FDA and applicants to conform to the provisions of the final rule.

This expanded provision in the final rule embodies FDA's belief that there should be a continuing dialogue between FDA and applicants throughout the IND/NDA process. In the **Federal Register** of June 9, 1983 (48 FR 26720), FDA proposed revisions to the investigational new drug regulations (IND Rewrite). That proposal encourages all applicants to participate in "end-of-Phase 2" meetings in order to reach an agreement on the overall plan for Phase 3 clinical investigations and the objectives and designs of particular studies. That proposal further encourages applicants to participate in "pre-NDA" meetings in order to ensure that marketing applications present data in a manner suitable for efficient agency review. Moreover, this final rule, as did the proposal, provides for FDA to notify an applicant 60 days after receipt of the application about whether it is acceptable for filing, thus providing early feedback on the application. Finally, the final rule gives applicants a right to an informal meeting approximately 90 days into the review cycle on applications for all new chemical entities and major new indications for marketed drugs. FDA believes that these changes, when seen as a whole, will foster open and timely discussions between reviewers and applicants.

103. FDA also received several comments on the 90-day conference. These comments suggested that FDA extend 90-day conferences to include not only new chemical entities and major new indications, but also all other NDA's and major supplements, such as new dosage forms. In addition, believing the meeting would be held 90 days after filing, which would be 150 days after receipt of the application, one comment suggested that FDA should be prepared to make an intial determination of approvability at the meeting.

FDA has limited the right to a 90-day conference to new chemical entities and major new indications because these are the most complex applications and because the resources needed to extend this right to all drugs are not now available. The agency believes that the provisions described above for presubmission meetings, notice of filing, and early notice of easily correctible deficiencies will in most cases provide adequate feedback to applicants on less complex applications and supplements. However, as noted above, the agency will entertain requests by applicants for other meetings, and so a 90-day meeting could be requested on applications other than those provided in the final rule.

The agency has revised the final rule to clarify that the 90-day meeting will be held approximately 90 days after the agency receives the application (rather than 90 days after filing) and thus 90 days before the agency would be expected to provide an action letter on it. Because the meeting will be held only midway through the review process, FDA will rarely be able to give its views on the ultimate approvability of the application.

*Dispute Resolution (§ 314.103)*

104. FDA received a number of comments on the issue of dispute resolution. The proposal outlined a new appeals process which the agency implemented at the time of the proposal through a staff manual guide. Several comments suggested that the appeals process is too complex too address minor administrative and procedural disputes which could be resolved more easily and more promptly by an ombudsman. Several comments also felt that the appeals process is inadequate to resolve major scientific and medical policy disputes which, according to these comments, should be referred (as a matter of right) to one of the agency's standing advisory committees.

FDA is committed to resolving disputes with applicants in a prompt, amicable, and equitable way, and it was towards this end that the appeals process referred to above was implemented. In light of these

comments, however, together with the agency's newly articulated policy on communication with applicants, FDA has reevaluated the entire issue of dispute resolution and has revised this provision in the final rule in the following ways.

First, FDA agrees with the comments that an ombudsman should be designated to resolve administrative and procedural disputes, and the final rule has been so revised. The role of the ombudsman is to investigate what the facts are and to facilitate a timely and equitable resolution of the issue. Appropriate issues to raise with the ombudsman include resolving difficulties in scheduling meetings, obtaining timely replies to inquiries, and obtaining timely completion of pending reviews. Further details on this procedure are available in a staff manual guide that is publicly available.

Second, upon reevaluation, FDA believes that the recently implemented appeals process is too complex to meet the needs of the NDA review period, and that the same goals can be achieved through alternative means. This conclusion is based in part on the fact that the appeals process was rarely used during its first year, possibly due to the inhibiting effects of the detailed procedure. The appeals process was conceived in response to industry complaints that "stalemates" were often reached with individual reviewers whereby applications could be delayed indefinitely without the involvement of upper lever FDA managers. In addition, applicants appear to perceive FDA as being unreceptive to attempts by applicants to resolve problems informally during the application review process. The new appeals process was designed to meet these concerns by legitimizing access to the system and by requiring automatic review by higher level agency managers. However, FDA believes that other specific provisions of the final rule meet these concerns, and thereby obviate the need for a formal appeals process.

For example, the time frame imposed for review of applications ensures that issues are raised in a timely fashion with upper level managers, including both division directors and the Directors of the Office of Drug Research and Review and the Office of Biologics Research and Review. Moreover, the "ninety-day conference" and "end-of-review conference," described above, provide a timely mechanism for applicants to meet with appropriate agency officials to discuss and resolve, if possible, important issues. For other scientific or medical disputes that arise during the NDA review process, the final rule provides that applicants should first discuss the matter directly with the responsible reviewing officials. If the issue is still unresolved, applicants may request an informal meeting with the appropriate reviewers and supervisors. Ordinarily, such meetings would be held first with the Division Director, then with the Office Director, and finally with the Center Director if the matter is still unresolved. As noted in the provision on communication between FDA and applicants FDA will make every effort to grant requests for meetings that involve important issues and that can be scheduled at mutually convenient times.

FDA recognizes the advantages of utilizing the advice of outside scientific experts in the dispute resolution process, where practical and feasible to do so. The final rule therefore provides that, in requesting a meeting with the agency to resolve a scientific or medical dispute, applicants may suggest that FDA seek the advice of outside experts, in which case FDA may, in its discretion, invite to the meeting one or more of its advisory committee members or other agency consultants, as designated by the agency. The applicant is also free to bring its own consultants. The final rule also provides that, for major scientific and medical policy issues not resolved by informal meetings, FDA may refer the matter to one of its standing advisory committees for its consideration and recommendations. Although this section does not provide the "right" to advisory committee review requested by some comments, FDA does intend to integrate outside experts more fully into the drug approval process. FDA believes that providing applicants a right to advisory committee review for any disputed issue is impractical from the standpoint of the potential number of controversial issues and the relatively infrequent number of advisory committee meetings. Moreover, utilization of outside advisory committees is committed to the discretion of the agency, and not properly delegated to members of the public. Nonetheless, by involving individual advisory committee members or consultants in the dispute resolution process on a more informal basis, FDA believes that the goal of interacting with the scientific community can be achieved without the delays, resources, and scheduling problems associated with full advisory committee involvements. The role of outside experts in the drug approval process is discussed more fully in the next section of this preamble.

In sum, the dispute resolution procedures in the final rule center on utilizing the most appropriate mechanisms—be it the ombudsman, informal meetings with outside input, or referral to full advisory committees—to suit the needs of the particular matter under discussion. Thus, the final rule presents a more comprehensive approach to dispute resolution than did the proposal, and FDA believes these procedures will be useful in addressing the full range of issues that arise during the NDA review process.

In the **Federal Register** of October 19, 1982 (47 FR 46622, 46634), FDA announced that the appeals process would be implemented 30 days after publication, as detailed in a Staff Manual Guide (CDB 4820.5). That Staff Manual Guide extended the applicability of the new appeals process to the IND phase as well. However, in light of the factors discussed above, FDA is reevaluating the utility of that process in the IND phase also. The agency will announce the results of this reevaluation in the IND Rewrite final rule. In the interim, Staff Manual Guide CDB 4820.5 is suspended, pending that reevaluation, and sponsors should utilize the procedures set forth in § 314.103 of this final rule for disputes regarding IND's as well.

*Role of Outside Experts*

105. FDA received several comments relating to the role of outside experts in the new drug approval process. Several comments expressed disappointment that the proposal did not formally establish a role for outside experts in the routine review of applications. These comments, believing that involving outside experts would add to the credibility and quality of the decisionmaking process, urged that applicants be given a "right" to advisory committee review of any marketing application.

FDA agrees that the utilization of outside experts adds to the quality and credibility of the decisionmaking process, and FDA intends to improve utilization of experts from the scientific community during the new drug approval process. For example, FDA has centralized oversight of its human prescription drug advisory committees by establishing a separate office for this purpose within the Office of the Center Director of the Center for Drugs and Biologics. The agency has also begun, on a more regular basis, to include individual advisory committee members in meetings with applicants to discuss scientific issues. The advisory committee issue was not addressed in

the proposal because current regulations were seen as providing the necessary flexibility to accomplish these goals. However, in order to respond to comments, this preamble sets forth FDA's policy in this area.

FDA solicits advice from outside experts who serve as either members of advisory committees or as individual consultants. Fifteen standing public advisory committees provide FDA with advice on human prescription drugs. The committees correspond to the drug review groups in the six new drug evaluation divisions, and operate under charters subject to renewal (or cancellation) every 2 years, as required by the Federal Advisory Committee Act.

These advisory committees are also subject to FDA regulations (21 CFR 14.160–14.174), which provide for the committees to advise the Commissioner "generally" on the safety and effectiveness and regulatory control of human prescription drugs, and "specifically" on any particular matter before the agency, including whether the available information is adequate to support a determination that a particular drug meets the statutory standards for proof of safety and effectiveness necessary for marketing approval. High priority items include drugs subject to active IND's and pending NDA's that offer potential therapeutic advances, that pose significant safety hazards, that present narrow benefit/risk considerations, that have novel delivery systems or formulations, that are the subject of a major scientific or public controversy, or that are the subject of special regulatory requirements, such as a limitation on clinical trials, a patient followup requirement, postmarketing studies, or boxed warnings. In addition, applicants can ask to have any relevant matter brought before a full committee.

Advisory committees are used to bring outside experts into the new drug evaluation process in order to: (1) Supplement FDA's in-house expertise; and (2) help agency staff maintain familiarity with current state-of-the-art technology by fostering a close working relationship between FDA scientists and outside experts actively involved in the field. Advisory committee meetings also serve an important function by providing a public forum for discussion of issues.

Advisory committees review, at FDA request, certain critical studies or critical elements of studies on drug products under consideration and labeling issues. They respond to specific questions posed by the agency to identify the adequate and well-controlled studies which demonstrate effectiveness, the seriousness of certain adverse effects, and whether additional studies or data are necessary before a decision can be reached.

FDA also seeks outside advice on clinical research issues. For example, FDA developed approximately 25 clinical guidelines with the help of its advisory committees and others, including the American Academy of Pediatrics' Committee on Drugs and consultants to the Pharmaceutical Manufacturers Association. The guidelines contain generally accepted principles for reaching valid conclusions about the safety and effectiveness of drugs, and they contain views of recognized experts about appropriate methods for studying specific classes of drugs.

Individual advisory committee members have also become involved in the IND process by attending the "end-of-Phase 2" conference, where they aid in the planning of Phase 3 studies. This involvement is explicitly recognized in the IND Rewrite proposal (48 FR 26732).

In addition to advisory committee members, FDA also employs representatives from the scientific community as special consultants or expert reviewers. These persons are called upon for advice on technical matters on an ad hoc basis, or are asked to undertake special review assignments in areas where the agency staff may lack particular expertise or available resources. These consultants may also be present at advisory committee meetings.

In summary, FDA believes that the primary goal of the advisory committee (and outside consultant) system should be to help the agency make sound decisions based upon the reasoned application of good science, and the IND/NDA Rewrites reflect this goal. As noted earlier, the IND proposal provides for the inclusion of outside experts in "end-of-Phase 2" conferences during which the design of the major Phase 3 studies is planned. In addition, as described in the preceding section of this preamble, this final rule envisions the participation of outside experts in informal meetings to resolve scientific and medical disputes, and provides for the referral by FDA, if necessary, of major disputes to a full advisory committee.

The principal and perhaps only issue on which the agency disagrees with the comments is whether applicants should be permitted to utilize advisory committees on demand to review applications or resolve scientific disputes. FDA believes that only the agency is in a position to decide the relative importance of which issues advisory committees should consider. Whether to refer a particular marketing application or scientific dispute to an advisory committee is partly a resource issue given the limitations on time and scheduling that restrict the use of advisory committees, and partly a matter of judgment, based on whether FDA decides that the committee is needed to supplement the agency's internal expertise in evaluating the type of data under review. FDA believes strongly, however, that areas of legitimate scientific debate greatly benefit from the broader views that can be provided by an outside advisory committee, and that committee participation significantly enhances the scientific credibility of any decisions reached. Accordingly, FDA intends to make full use of its advisory committees to ensure that this result is achieved. As noted above, it is agency policy to include, as a priority for advisory committee review, marketing applications where the approval decision is a "close call," from either a safety or efficacy standpoint. This policy, together with an applicant's ability to request advisory committee review under § 14.172, should provide applicants adequate access to advisory committees while still allowing the agency to set reasonable priorities.

106. A number of comments addrressed the subject of conflict of interest. Several comments believed that current conflict-of-interest barriers prevent FDA from using many qualified outside experts and recommended that (1) FDA issue clear guidelines to resolve conflict-of-interest problems; (2) the Commissioner waive conflict of interest rules more often where a closer examination of the facts would show that the expert will be able to serve in an unbiased manner; and (3) FDA solicit a less restrictive interpretation of Federal conflict-of-interest statutes and regulations from the Department of Justice. Other comments expressed concern about FDA'a outside experts and asked for assurance that such advisors will be free of conflicts of interest.

FDA's procedures for employing outside experts appear in staff manual guides and in materials provided to outside experts who are employed to advise the agency. These procedures are designed to ensure that advisors' private interests do not conflict with their public responsibilities. Thus, FDA's guidelines with respect to conflict-of-interest issues are quite clear and widely disseminated. Where highly qualified persons are not free from nongovernmental or private financial interests that present a conflict or potential conflict, FDA may appoint

those individuals to serve on a particular committee but exclude them from participation in certain specific matters in which a real or potential conflict of interest exists. In addition, the Commissioner may waive FDA's conflict-of-interest rules in those instances where FDA is persuaded that an outside expert can, despite a conflict of interest, make an impartial and essential contribution to FDA's mission and strict application of the rules would frustrate the best interests of the public. Because of the high level of interest on this issue, however, FDA is reviewing its conflict-of-interest rules to ensure that a proper balance is struck between obtaining advice from those experts most knowledgeable in the field and ensuring that such advice is free from potential bias.

*Approval of an Application (§ 314.105)*

107. FDA received several comments concerning the proposed policy, stated in the preamble, that the agency would approve an application based on draft labeling if the only deficiencies found in the labeling were editorial or otherwise minor in nature. Two comments suggested that FDA codify this policy in the final rule. Another comment suggested that FDA should not approve an application on the basis of draft labeling, because of the importance of labeling during the introduction of a product into the market and the possibility that final printed labeling would not conform exactly to the approved draft labeling. One comment asked how the agency intends to determine whether appropriate changes have been made in final printed labeling after the agency has approved an application on the condition that deficiencies in draft labeling are corrected before marketing.

FDA has concluded that it should approve an application before submission of final labeling if the agency determines that only editorial or similar minor deficiencies exist in the draft labeling, and the final rule has been so revised. This change in practice should expedite drug approvals without compromising the safety or efficacy of drugs. As described elsewhere in this preamble, when FDA anticipates approving an application based on draft labeling, the agency will request a final safety update report under § 314.50(d)(5)(vii)(*b*) to ensure that the approval is based on the most up-to-date safety information available. When an application is approved under this provision, the approval letter will detail the specific changes required in the labeling and state that approval of the application is conditioned upon incorporating those changes exactly as directed. The approval letter will also require applicants to submit to FDA a copy of the final printed labeling prior to marketing. Although applicants will not have to wait for prior approval of the final printed labeling, this procedure will enable FDA to ensure that the final labeling conforms to the conditions of the approval.

108. One comment urged that FDA revise the final rule to state that approval of an application not be dependent upon the availability of the summary basis of approval.

FDA disagrees with this comment. An SBA is prepared for all original applications and supplemental applications for a new use or a substantially different dosage. The SBA is prepared by the supervisory medical officer (group leader) within the reviewing division and becomes part of the final approval recommendation forwarded to the Division Director and the Director of the Office of Research and Review or the Office of Biologics Research and Review. Because FDA supervisors may rely, in part, upon the SBA in determining whether to approve a drug, the agency believes that the SBA needs to be prepared before an application is approved. FDA notes, however, that approval of the application may be based on a draft SBA and precede completion of the final version of that document.

109. One comment, who agreed that FDA must exercise flexibility when applying approval standards to different kinds of drugs, argued that FDA must be even handed when applying the standards within a class of drugs.

FDA agrees generally that applications for similar drugs should be handled in the same manner. Nevertheless, applications for new members of an established class of drugs should take into account experience gained with that class, as FDA will take such information into account in making approval decisions. This may involve, for example, more detailed safety data if marketing experience with the class has revealed special safety concerns.

*Foreign Data (§ 314.106)*

110. FDA received a number of comments on the proposed provision setting forth conditions for approving an application based solely on foreign data. In the past, FDA's policy has been, with rare exceptions, to require some U.S. data (in the form of adequate and well-controlled studies) before approving a new drug for marketing. Nevertheless, while requiring the inclusion of U.S. data in applications, FDA has also relied increasingly upon foreign data in its approval decisions, consistent with the increasing quality and quantity of research performed in other countries. Based upon this experience with foreign data, the agency, like the medical community in general, has come to recognize the very high quality of drug testing that has emerged from a number of foreign research institutions.

The proposal built on this experience and sought to balance the ability to place increased reliance on foreign data with appropriate safeguard designed to ensure the quality of those data. The proposal removed the "presumption" in current policy that U.S. data would be required and replaced this with the principle that FDA's foremost consideration would be the quality of the data submitted, regardless of the country of origin. Thus, the proposal presupposed that some foreign studies are of comparable quality to U.S. data such that repeating the studies in this country would be neither scientifically necessary nor in the public interest.

At the same time, however, the proposal recognized that foreign data do present three unique problems not associated with domestic data. These involve (1) medical, genetic, and cultural differences between countries; (2) lack of FDA's familiarity with many foreign clinical investigators and facilities; and (3) FDA's inability to conduct on-site verification of many foreign studies. To meet these concerns, the proposal specified that three criteria must be met before the agency could approve a new drug based solely on foreign data. These three criteria were (1) that the foreign data were applicable to the U.S. population and U.S. medical practice; (2) that the studies had been performed by clinical investigators of recognized competence; and (3) that the data could be considered valid without the need for an on-site inspection by FDA or, if FDA considered such an inspection to be necessary, that FDA would be able to validate the data through on-site inspection or other appropriate means.

Thus, the proposal was cast so as to convey both a more open attitude on the part of FDA to consider the merits of foreign data in their own right, but also to safeguard the public health by imposing rigorous criteria that must be met before approval based on those data could be granted. In this way, the proposal sought to focus attention on the scientific merit of the data rather than on unnecessarily rigid rules regarding domestic data requirements.

111. The major concern raised by comments was the possibility that FDA's proposed policy could result in

lower quality drugs being approved based on foreign studies. For example, one comment suggested that foreign studies may not meet U.S. standards because foreign research is less concerned with peer review and institutional review boards, features less vigorous controls and lower reporting of adverse drug experiences, and, unlike studies in this country, is not publicly reviewed in the current U.S. medical literature. Several comments believed that the policy should be drafted more narrowly so as to apply only to major medical breakthroughs. Opponents of the foreign data policy also cited the recommendation of the Commission on the Federal Drug Approval Process that suggested that some U.S. clincial experience be required before approving a new drug in this country.

FDA has reviewed these comments in detail, but has concluded that the arguments raised do not warrant any change in the proposed regulation. The essence of the comments was a concern that the three safeguards would be insufficient to ensure the quality of drugs approved solely on the basis of foreign data. FDA does not believe that this concern is valid. The criteria contained in the regulation are rigorous, and the agency intends to apply them with the utmost regard for the public health. The rationale for these criteria is discussed at length in the preamble to the proposed regulation (47 FR 46643–46644; October 19, 1982). The agency believes that if the foreign data are applicable to the U.S. population and U.S. medical practice, if the studies are performed by recognized, competent investigators, and if there are no concerns over the validity of the data, then there is no justifiable public health reason not to approve the drug on the basis of the data. In this regard, the agency notes that comments did not suggest inclusion of additional safeguards that, in their minds, would ensure the quality of a drug based solely on foreign data.

As noted in the preamble to the proposed regulations, the agency does agree with comments that the nature of the drug should be taken into account in applying this policy, and that drugs representing major medical breakthroughs would be among those at the upper end of the spectrum. Other drugs falling into this category would be those for diseases that are uncommon in the United States (e.g., tropical diseases and orphan drugs), and drugs on which decisionmaking is less difficult from a risk-benefit point of view (e.g., topical products). However, the agency does not believe that the policy should be applied exclusively to these types of drugs; rather, any drug meeting the criteria should be included.

Finally, FDA does not agree with the recommendation of the Commission on the Federal Drug Approval Process that at least some U.S. experience with a drug be required before it is approved for marketing in this country. Under the Commission's recommendation, such U.S. experience could be in the form of uncontrolled trials where clinicians administer the drug to patients in settings closely resembling normal clinical practice. The agency believes that the Commission's emphasis on uncontrolled trials in this context is misplaced. First, as described above, FDA believes that the three criteria in the regulation adequately ensure the safety and effectiveness of new drugs prior to marketing and that, in those situations, uncontrolled trials would not add significantly to the body of data supporting approval. Second, when the regulation's criteria are not met, FDA does not believe that the mere inclusion of U.S. experience in the form of an uncontrolled trial would be sufficient to meet the test for marketing approval. (See 47 FR 46644.)

112. Several comments supported FDA's proposal to accept foreign data as the sole basis for approval of an application because it recognizes the international nature of clinical research and brings FDA into line with other countries that accept data based exclusively on scientific merit. Some comments, however, suggested that because FDA has inadequate resources and funding to monitor the validity of foreign research and to make on-site inspections, FDA should require more extensive documentation of foreign studies than of domestic studies, including the submission of all case report forms from each foreign study.

FDA agrees that foreign studies forming the sole basis for approval may require more extensive documentation than domestic studies, but the agency believes that the regulations are already flexible enough to accommodate this need. As discussed elsewhere in this preamble, the provisions for submission of summaries, analyses, data tabulations, and certain case report forms should be adequate for FDA's initial review of foreign clinical studies, and FDA will have additional access to data and information, including case report forms, if these are needed. In addition, as noted above, FDA may request full case reports from the most critical studies, and this would include foreign studies as well.

113. Several comments argued generally that the proposed policy was too restrictive. The only specific comments on this point concerned FDA's intention to consider the international reputation, publication experience, participation in meetings, and other factors relating to the competence of foreign investigators. One comment found these tests to be inappropriate, arguing that they are not applied to domestic investigators. Another comment that agreed with the standards urged that FDA establish a mechanism for collecting biographical information to assess the competence of foreign investigators so that individual applicants did not have to.

As noted above, FDA believes that the regulation's three criteria, including the requirement for the clinical investigators to be of recognized competence, are necessary to safeguard the safety and effectiveness of any drugs so approved. Although the review of clinical investigators' competence is highlighted in the foreign data policy, that review is not unique to foreign studies. FDA reviews the qualifications of all clinical investigators, but such a review is more easily conducted with respect to domestic investigators because FDA is generally familiar with them and their institutions. Indeed, FDA has refused to rely on data compiled by domestic investigators who are found to be unreliable. A review of the competence of foreign investigators is therefore also necessary, and FDA believes it appropriate to require the applicant to submit the necessary documentation. FDA believes that this approach will be more practical and efficient than relying on an FDA-compiled biographical library of foreign clinical investigators, which may be incomplete, out-of-date, or otherwise insufficient.

114. Two comments objected to the foreign data policy because it may encourage applicants to conduct more testing abroad. According to these comments, such "export of testing" would have adverse consequences for the United States both economically and scientifically.

Although FDA recognizes there is some merit in the concerns raised by these comments, the agency does not believe it justifiable to impose domestic testing requirements solely for trade restriction purposes, particularly when such requirements might produce an adverse effect on the public health through the delay of approval of new drugs. Moreover, FDA believes that there are two factors mitigating against the concerns raised by these comments.

First, in the IND Rewrite, the agency has proposed to give sponsors greater freedom to conduct the early phases of clinical research, in part due to complaints that U.S. regulatory requirements are too strict and are causing U.S. companies to conduct more and more research abroad. Thus, the purported incentive for moving research abroad is being addressed. Second, as discussed in the preamble to the NDA Rewrite proposal, the agency believes that even with the new foreign data policy, most applications will continue to contain some U.S. data. This is due, in part, to the high quality of U.S. clinical investigators as well as to the view that having some domestic physicians familiar with a new drug once it is approved enhances its prospects in the marketplace.

115.–116. One comment asked that FDA hold a presubmission meeting at which an applicant can present to FDA its proposal to rely upon foreign data. Another comment suggested that the agency's appeals process should be available to applicants if FDA refuses to accept foreign data, and that FDA should raise issues regarding the quality or acceptability of foreign data before the relevant standing advisory committee.

The final regulation, like the proposal, specifically encourages applicants to meet with the agency to discuss their plans to submit applications that rely solely upon foreign data. It should be understood, however, that the adequacy of the data cannot always be assessed prior to a detailed review, and the review can occur only after the application is submitted. The dispute resolution procedures described in the final rule would be applicable to foreign data issues, and this would include referral of those issues, at FDA's option, to an advisory committee.

117. Several comments argued that FDA should be required to accept foreign data unless the agency can demonstrate that the data should not be accepted for some valid scientific or medical reason. These comments also urged that the final rule require FDA to explain in writing its refusal to accept foreign data to ensure that duplicative domestic studies would not be required except for good reason.

FDA disagrees with these comments to the extent that they suggest that the burden of proof should be on the agency to show why foreign data are inadequate. Rather, the final rule, like the proposal, places the burden on the applicant to demonstrate to the agency's satisfaction that the foreign data are sufficient, by themselves, for approval. The agency emphasizes that there are no hidden criteria for evaluating the acceptability of foreign data. FDA will approve an application that relies upon foreign data unless one of the grounds identified in the statute or regulations for refusing to approve an application applies. If the agency concludes that the application is not approvable, it will give the applicant the basis for the conclusion in a deficiency letter or a not approvable letter and, if the applicant wishes, in a notice of opportunity for hearing. Thus, a mechanism already exists under which FDA will explain to the applicant, in writing, its reasons for refusing to approve an application based solely on foreign data.

*Approvable and Not Approvable Letters (§§ 314.110 and 314.120)*

118. One comment understood an approvable letter to mean that, except for matters specifically identified in it, the information already submitted in the application is acceptable and will not be further reviewed, and, except for safety update reports, no more information will be required before approval. Another comment suggested that an applicant's unconditional agreement to comply with conditions in an approvable letter should be sufficient for the agency to approve the application immediately, and that no extension of the review period or additional submission should be needed.

FDA agrees that an approvable letter means that FDA, at the time the letter issues, intends to approve the application if the applicant submits the requested data or information. Nevertheless, the issuance of an approvable letter does not preclude FDA from reexamining any part of the application in light of the applicant's response to the letter, or any other data or information before the agency bearing on the application. Although applicants have long argued that FDA should not re-review parts of an application that it has once determined are acceptable (and FDA agrees that in most cases another review is unwarranted), the agency considers all parts of an application to market a new drug to be interrelated, so that a change in one part may affect other parts of the application. Thus, FDA will continue to consider the impact of new submissions on other sections of the application. With respect to the second comment, except in the situation where the only changes to be made are editorial or affect minor aspects of the draft labeling, FDA believes that responses to approvable letters must be reviewed by FDA prior to final approval of the application because the information submitted could affect the safety or effectiveness of the drug.

119. Several comments argued that 10 days is inadequate time for an applicant to respond to an approvable or not approvable letter and that an applicant should have at least 30 days from the date of receipt of the letter, with an opportunity for extensions of time for good cause. According to these comments, in many cases the applicant must gather a number of experts in several disciplines together to consider FDA's letter, recommend a course of action to management, and obtain a management decision on it.

FDA does not believe that the 10-day period for a response to an approvable or not approvable letter will necessarily be insufficient for applicants to determine whether they will seek to amend an application, or request that the agency issue a notice of opportunity for hearing. In some cases, applicants may have enough information regarding the status of their applications prior to receipt of the action letter to know whether anticipated deficiencies are amenable to remedial action by the firm, or whether they are so great as to require pursuit of an administrative hearing. More importantly, however, the primary purpose in revising this section of the regulations was to provide for agency action within the 180-day time frame specified by the act. In meeting its obligations to reach a decision within the statutory period, the agency has undertaken to observe strict time limits in the review of new drug applications. As meeting the statutory period will necessitate industry responses to agency action, reasonably strict time limits are appropriately applied to industry as well.

Nonetheless, the agency recognizes that in many cases applicants may find 10 days inadequate to respond to an approvable or not approvable letter. For example, the applicant may wish to delay such a decision until after it has had an opportunity to meet with FDA officials in an "end-of-review conference," as provided in § 314.102(d). Thus, FDA has amended the regulations to permit applicants to respond by agreeing to an extension of the approval time, as provided under section 505(c) of the act. Moreover, the regulation makes clear that FDA will honor any reasonable request for such an extension. The 10-day provision, therefore, should not create any undue hardship on applicants. This resolution of the issue presented by the comments accommodates both the comments' concern and the agency's need to adhere to the 180-day period provided for by

statute. The agency considered shortening the time necessary to prepare a notice of opportunity for hearing to accommodate a longer period for an applicant's response to an action letter, but has determined that it is impracticable to shorten the period in which a notice of opportunity for hearing can be prepared to less than 50 days.

120. Several comments objected to the automatic 45-day extension of the review period when an applicant decides to file an amendment in response to an approvable letter. Two comments suggested a provision permitting extensions of "up to" 45 days, while two other comments suggested that 30 days is appropriate. Another comment suggested that the agency should advise the applicant in writing about what the time will be, but that it should be no more than 45 days.

FDA selected 45 days as the maximum time for FDA action on the applicant's response to an approvable letter because it believes it will generally take that long to review the applicant's response, prepare an approval letter recommendation, and issue the approval. If that process is completed sooner, the approval letter will issue in less than 45 days. The agency believes, however, that a significant number of applications would fail to meet the 30-day time period suggested by the comments and, thus, the agency has not adopted it. In addition, FDA believes that the requested change would distract reviews from evaluating the submission by requiring them to decide on a feasible extension shorter than 45 days, and thus would be more likely to disrupt the review process than to benefit applicants.

*Refusal To Approve an Application (§ 314.125)*

121. Noting that the first six reasons for refusing to approve an application rephrase the statutory grounds in section 505(d) of the act, one comment argued that the agency failed to assert a legal basis for the remaining eight reasons and that, accordingly, those eight reasons should be deleted.

FDA does not agree. The agency views each of the grounds stated to be within the scope of section 505(d) of the act. Each of the grounds asserted, both those stated explicitly in section 505(d) of the act and those not, reflect FDA's authority to prohibit marketing of drug products that do not comply with regulatory standards that marketed drugs be safe, effective, and properly labeled. FDA would view as unreasonable a requirement that, for a ground not specifically listed in section 505(d) of the act but included in § 314.125, it must approve such a product and immediately take action against it under some other section of the act. Rather, FDA views it as a reasonable exercise of its rulemaking authority to include within the reasons for refusing to approve an application under section 505(d) of the act reasons consistent with the agency's authority to establish marketing requirements for, or withdraw approval of, new drugs. Moreover, FDA believes that the list of additional grounds in the regulations will give applicants more specific notice of the kinds of grounds on which the agency will refuse to approve applications.

122. One comment objected to FDA removing the characteristics of an adequate and well-controlled study from this part of the current regulation, fearing that it suggested a predisposition of FDA not to involve qualified experts in the evaluation of clinical investigations to determine whether substantial evidence of effectiveness exists.

FDA disagrees and concludes that changing the location in the regulation of the provision in question will have no substantive effect on the agency's refusal to approve an application for a lack of substantial evidence of effectiveness, nor will it affect the role of experts in the review process. The regulation retains almost verbatim the grounds cited in the act for refusal to approve an application because of a lack of substantial evidence of effectiveness. The discussion of the characteristics of adequate and well-controlled studies, although placed in a separate section and somewhat revised in language, is still comprehensive in nature and can be cited by the agency in any decision not to approve an application.

123. One comment urged FDA to exempt minor deviations in proposed labeling when determining whether it complies with the requirements for labels and labeling in 21 CFR Part 201. Other comments objected to the suggestion that bioavailability or bioequivalence data are intended to show that a drug is safe or effective, while one comment asked FDA to retain the wording from the current rule under which approval may be refused if the data in the application do not meet the requirements in 21 CFR Part 320. One comment stated that it is unnecessary to include the provision for refusal to approve an application if a deficiency noted in a refusal-to-file letter had not been corrected. Finally, one comment objected to FDA's assertion that it can refuse to approve an application if the applicant does not permit an FDA investigator to inspect the facilities, controls, and any records relevant to the application. The comment contended that that provision goes well beyond FDA's inspectional authority in section 704(a) of the act (21 U.S.C. 374(a)).

Although FDA has reaffirmed its policy to approve an application if editorial or similar minor changes in draft labeling will be made in the final printed labeling, FDA cannot sanction deviations from the standards in Part 201 that would cause the drug to be misbranded. The agency agrees that the current wording under which FDA may refuse to approve an application if bioavailability and bioequivalence data do not meet the requirements in Part 320 is more informative than the proposed wording and the agency has revised the regulation to retain it. Because an applicant can file an incomplete application over protest, FDA sees a need to retain the provision permitting the agency to refuse to approve an incomplete application. Finally, FDA is obligated to refuse to approve an application if it believes (in the absence of an inspection that would demonstrate otherwise) that the facilities and controls are inadequate or the information in the application based on records holds by the applicant is insufficient to determine that the drug is safe or effective. An inspection under this provision derives from section 505 of the act and the result of an inspection refusal is the possibility that the agency will not have adequate information to approve the application. The agency notes that although it has suggested it would refuse to consider a particular study if records of the study could not be inspected, it does not take the position that it will reject an entire application solely because a part of the records could not be inspected (so long as they were not considered essential to the approval).

*Adequate and Well-Controlled Studies (§ 314.126)*

124. Several comments objected to FDA's statement that the characteristics set forth in its regulations are recognized by the scientific community as the "essentials" of an adequate and well-controlled study. Comments suggested that the listed characteristics do not uniquely define such a study. A study may, according to comments, include an additional characteristic or lack one or more of the listed characteristics and still be adequate and well-controlled. For example, one comment suggested that the characteristics of an adequate

and well-controlled study should include an explanation of the difference between the study's objectives and its results so that deviations from the original objectives can be justified, while other comments urged that the characteristics should not include the method of selection of subjects, the method of assigning subjects to treatment groups, the measures taken to minimize bias on the part of analysts of the data, the method of assessment of subjects' responses, or an assessment of a study's ability to detect more than a "clinically significant" difference between treatments. Another comment suggested that study characteristics should appear in a guideline instead of a regulation. That change, according to the comment, would recognize that appropriate alternative characteristics exist, and would provide clinical investigators and sponsors with flexibility to adopt them without first obtaining a waiver.

FDA has long considered the characteristics listed in the regulation as the essentials of an adequate and well-controlled study, and the proposal modified these characteristics only slightly. In general, the regulation on adequate and well-controlled studies has two overall objectives: (1) To allow the agency to assess methods for minimizing bias; and (2) to assure a sufficiently detailed description of the study to allow scientific assessment and interpretation of it. Many of the characteristics identified in the regulation are relevant to the second objective (rather than the first, as implied by the comments) and are needed by the agency to conduct a proper review of the study. Thus, FDA is not persuaded that these types of changes in the regulation are now warranted. The agency emphasizes, however, that it applies the regulation with judgment, not as a check-list. A scientifically acceptable study is not rejected because of minor technical deficiencies if it is apparent that the study is basically sound. Moreover, the regulation permits applicants to seek a waiver of individual requirements with respect to investigations.

125. Several comments were concerned that the agency's reordering of the types of controls that may be applied in a study was intended to establish a preferential order for the types of studies supporting an application. One comment said that because the proposal listed placebo concurrent control first, it implied that such a study is preferred over, for instance, a study using a historical control that was listed last. Several comments objected to this implied preferential order of studies because it would encourage researchers to adopt one type of study over another based on FDA's views, instead of considerations about the treatment of patients. These comments recommended that the final rule should clearly state that no study method is preferred over another.

Although the final rule lists the types of controlled studies in a different order than in the current regulation, the reordering does not mean that FDA considers one type of control to be necessarily preferred over another. The reordering is intended simply to reflect FDA's experience that some types of studies (e.g., placebo-controlled studies) are often easier to interpret than other kinds of studies (e.g., those using a historical control). Thus, FDA has listed the types of controls in descending order roughly in accordance with the ease of interpretation. (For this reason, the dose-comparison concurrent control has been moved to second on this list, rather than fourth.) FDA recognizes, however, that ethical and practical considerations will play a central role in the type of study selected, a decision that will ordinarily depend upon the type and seriousness of the disease being treated, availability of alternative therapies, and the nature of the drug and the patient population. In each case, applicants must choose the particular type of study they will use based on ethical, scientific, and practical reasons. So long as these judgments are justifiable, and the studies are properly designed, the approvability of an application will not be affected. Thus, the regulation lists five different kinds of controls that are acceptable; it does not state a perference for one kind over another.

126. Two comments suggested that the final rule distinguished between therapeutic and diagnostic new drugs in determining the appropriate features of an adequate and well-controlled study of the drug. For example, according to thes comments, a placebo concurrent control study would neve be indicated for diagnostic products, such as radiopharmaceutical and contrast media that are intended to have no physiological or therapeutic effect. One comment suggested that current regulations be modified to recognized more clearly this distinction.

FDA agrees that there are good reasons for using different study designs in particular situations, and the agency believes that the regulation is sufficiently flexible to accommodate the needs of applicants in this respect. As a matter of past practice, the agency has approved products whose safety and effectiveness were established using each of the controls listed in the regulation. However, because of the many situations involved, the agency believes it is neither necessary nor feasible to describe them specifically in the regulation.

127. One comment urged that the standard for obtaining a waiver from the adequate and well-controlled study criteria should be changed to require a statement of why a particular criterion need not be applied to the particular clinical investigation "in view of other factors," instead of a statement of why the criteria are not "reasonably applicable."

FDA disagrees with the comment and has retained the current wording in the final rule. The act states that adequate and well-controlled studies are needed to demonstrate the effectiveness of drug products. The agency's regulation describing the characteristics of adequate and well-controlled studies, which is modified only slightly in this final rule, has served satisfactorily as a basis for approvals over time and, as discussed above, contains the essential elements of such studies. Thus FDA concludes that a narrow waiver provision that requires well-justified bases for an exemption should be retained.

128. FDA has, on its own initiative, made the following changes in the final rule describing adequate and well-controlled studies.

First, FDA proposed to delete the current requirement that the method of analysis be included in the plan or protocol of a study. The rationale for this proposed change was that, although having the method of analysis in the plan or protocol has been listed as a characteristic of an adequate and well-controlled study, many protocols, especially those developed years ago, lacked this characteristic. While FDA does not believe the omission of this information means a study is not well-controlled, there is no doubt that the development of a tentative plan for analysis: (a) Minimizes the potential for analyst bias; and (b) helps focus attention on whether it is practical to collect the data and whether variables to be obtained are analyzable. Accordingly, the final rule encourages inclusion of such a plan for analysis in the protocol but permits, as an alternative, the study report to include a description of how the analysis was selected.

Second, at a number of points the regulation has been modified to address potential problems associated with multiple or interim data analyses. These

do not render a study less than well-controlled, but they must be described and reflected in the analysis.

Finally, FDA has modified the description of the active treatment concurrent control. This is because a demonstration of effectiveness by means of showing similarity of the test drug to an active control is an indirect demonstration of effectiveness (the active control treatment serving as an intermediary in a comparison between the test drug and placebo). Under this study design, similarity of test drug and active control drug can mean either that both drugs were effective or that neither was effective. Thus, the agency has added a requirement that the analysis of the study provide an explanation of why the active control drug should be considered to have been effective in the completed study, for example, by reference to results in previous placebo-controlled studies of the active control drug.

*Withdrawal of Approval of an Application (§ 314.150)*

129. One comment suggested that the final rule provide that if FDA found a study to be adequate and well-controlled when it approved the application, that conclusion should remain unchanged even if FDA later adopted new standards under which the study would not be considered adequate and well-controlled. The conclusion would thus preclude withdrawal of the drug's approval upon the basis of new information and an FDA determination that there is a lack of substantial evidence from adequate and well-controlled investigations that the drug is effective.

FDA disagrees with the comment. The factors leading to a determination of what is an adequate and well-controlled study, which is the basis for determining drug efficacy, may, as the comment recognizes, evolve. FDA has an obligation to judge a drug's effectiveness by contemporary scientific standards. If those standards change to the extent that it is questionable whether a drug can be regarded as having been shown to be effective, FDA may under the act appropriately review the drug's status.

*Adulteration and Misbranding of an Approved Drug (§ 314.170)*

130. One comment supported FDA's proposed clarification of the relationship between the new drug and antibiotic approval provisions of the act and the adulteration and misbranding provisions. In contrast, several comments urged that this section be deleted, believing that the only lawful procedure for dealing with adulterated or misbranded approved new drugs is by withdrawal of approval of the application.

FDA has retained this provision in the final rule. The comments that opposed it submitted no persuasive argument that FDA is incorrect in its position that the new drug provisions do not insulate approved drugs and antibiotics from the general adulteration and misbranding provisions of the act. As FDA has previously noted, the statutory scheme contemplates FDA's application of the adulteration and misbranding standards to all drugs, irrespective of whether those drugs have been subject to the premarket approval requirements of the act.

*Hearing Procedures for New Drugs (Subpart D)*

131. FDA agrees with one comment that objected to a change in the hearing procedure to remove the requirement that the Director of the Center for Drugs and Biologics serve a proposed order to, and provide for a response from, a person who submits required data or information and requests a hearing following a general or specific notice of an opportunity for hearing. The final rule retains the current requirement.

*Administrative Procedures For Antibiotics (Subpart E)*

132. One comment suggested that the procedure for issuing antibiotic regulations should be revised to make it as consistent as possible with the approval procedure for new drugs and to expedite the petitioning, rulemaking, and hearing process required under section 507(f) of the act (21 U.S.C. 357(f)) when FDA refuses to approve a new antibiotic.

FDA believes it has already taken adequate steps to conform the administrative procedures that apply to refusals to approve (or withdrawals of approval of) antibiotics and new drugs. The procedures for withdrawing approval of an NDA apply to approved antibiotics (which are now all exempt from certification requirements under § 433.1 (21 CFR 433.1)). A full discussion of the regulatory process applicable to antibiotic drugs maybe found in the final rule exempting antibiotic drugs from certification (47 FR 39155; September 7, 1982) and in the proposed rule preceding that action (47 FR 19954; May 7, 1982). Because the potential exists for a manufacturer to apply voluntarily for batch certification of an antibiotic drug or for FDA to revoke the exemption from batch certification requirements granted to a drug, this final rule retains those provisions necessary for certification of an antibiotic drug, if necessary. In the case of refusals to approve an antibiotic application, while the statutorily based regulatory scheme for the publication of monographs has been retained, the procedures preceding the refusal to approve are, as a practical matter, the same as those employed in a refusal to approve a nonantibiotic application.

*Miscellaneous Provisions*

133. *Imports § 314.410(a).* Although several comments supported the agency's proposal to permit an individual to bring into the United States a reasonable quantity of an unapproved drug product that is intended only for personal use, several comments argued that the proposal was illegal and would expand illegal trade in unapproved drugs in this country. These comments were especially concerned about what they believed would constitute FDA's sanctioning of the commercialization of drugs generally regarded by the medical community as being useless. One comment suggested that legislation would be needed to make this change. Another comment suggested that FDA would find it difficult to monitor and regulate this exemption.

The proposal was intended to state the agency's discretionary enforcement policy that it can apply to accommodate the health needs of individuals entering the United States with personal supplies of unapproved drugs. Upon reevaluation, however, FDA finds that policy related to enforcement discretion is better stated in a compliance policy guide. Accordingly, this provision has been deleted from the final rule.

134. *Exports (§ 314.410(b)).* One comment suggested that FDA seek legislative changes to permit the export of new drug substances and products under the same conditions that apply to the export of antibiotics. Others suggested that, even without legislation, FDA could permit the export of unapproved drug products and of bulk substances which are not covered by an approved application for a drug product. Another comment stated that the current restrictions on exports of unapproved new drugs discourage the manufacture of human drugs in the United States before approval for marketing in this country. According to this comment, because U.S. approval often occurs after foreign approval, these restrictions require that foreign facilities be built to supply foreign markets, resulting in a significant loss of domestic jobs.

Although FDA recognizes the practical impact of current restrictions on the export of unapproved new drug products and bulk new drug substances,

FDA believes that it is obligated to reject the comments recommending changes in the final rule. The definition of "interstate commerce" in section 201(b)(1) of the act (21 U.S.C. 321(b)(1)), when read together with the prohibitions on interstate shipment of unapproved new drugs in sections 301(d) and 505(a) (21 U.S.C. 331(d) and 355(a)), prohibit the exportation of an unapproved new drug. Section 801(d) of the act (21 U.S.C. 381(d)), which grants an exemption from the adulteration and misbranding sections of the act for export purposes, does not grant a similar exemption from the new drug provisions. Therefore, FDA has interpreted the act as reflecting a Congressional intent that unapproved new drugs not be exported, though it has, in the past, supported modification of the statutory export provisions (see, for example, proposed section 135 of the Drug Regulation Reform Act of 1978).

135. One comment, believing that the exporter of a drug substance might have no relationship with the domestic marketer of an approved product, expressed concern that the proposal to broaden the rules on exporting a drug substance could result in exports of a drug substance unsuitable for use in an approved product. Thus, the comment recommended that that provision be limited to manufacturers of approved drug products or exporters of bulk substances that have filed drug master files with the agency covering the manufacturing operations and specifications for the drug substance. Another comment suggested that this proposal was inconsistent with § 201.122(c) of FDA's labeling regulations.

Because FDA believes the first comment misunderstood this provision, the agency has revised the final rule to clarify it. The statutory scheme provides that a new drug substance can be exported only if it is the subject of an approved application. Through this new regulation, FDA is interpreting the application approval to extend to a supplier of a new drug substance under that approved application. Currently, only the applicant who holds the approved application may export the drug substance that is used in the manufacture of the approved drug product, whether or not the applicant is itself the manufacturer of the drug substance. The final rule extends to the person (and only to that person or persons) who is identified in an approved application as the source of the drug substance, but is not itself the applicant, permission to export the drug substance, if the substance meets the specifications in the approved application. Thus, FDA will consider the supplier to be covered by the application both when it ships the drug substance to the applicant and when it exports it. Domestic shipment to a party not the applicant, however, will not be permitted.

FDA does not believe this regulatory change will present the safety concerns raised by the comment because FDA will have already conducted a thorough examination of the drug substance, either in the original application or in a supplement.

However, because the drug substance manufacturer's opportunity to export the substance is dependent upon its inclusion in an approved application, it is also dependent on the applicant's continued inclusion as a supplier in its application. The applicant is always free to supplement its application to change suppliers. Such action, under the final rule, would also have the effect of terminating the former supplier's export rights. Moreover, because no approval has been provided to suppliers under the act, FDA does not view the hearing requirement of section 505 of the act to apply to a drug substance supplier who is so terminated by an applicant.

In response to the second comment, FDA does not agree that the filing of a drug master file should be sufficient to acquire a right to export a drug substance. FDA does not review a drug master file except in the context of the agency's review of an application or supplement that references it. Thus, the submission of a drug master file does not now result in any agency action. FDA does not intend to revise this practice by reviewing drug master files independently. Resource constraints on FDA and the lack of a drug product and proper labeling by which to measure the suitability of the drug substance for any purpose warrant maintaining the current practice. Finally, FDA has revised § 201.122(a) to clarify that a drug substance may be exported under the labeling exemption provided by that section, if it is covered by an approved application.

136. *Drug master files (§ 314.420).* Several comments objected to the proposed requirement that a drug master file holder notify each person authorized to refer to information if the holder adds, changes, or deletes the information. Some comments stated that drug master file holders generally give umbrella authorization to others for use of their master files and that the regulations are unclear about how specific a notification must be made to persons authorized to reference information when the holder adds, changes, or deletes information in the file. Thus, according to these comments, the provision is unnecessarily burdensome and could result in the unwarranted disclosure of trade secrets.

FDA has retained the provision in the final rule. FDA believes that applications that depend upon information in drug master files may quickly become outdated if the drug master file holder does not notify the persons authorized to reference the file about changes in the information in it. Because FDA reviews the contents of a drug master file only in the context of its review of an application or a supplement to an application, a change in important information in a drug master file that may affect the safety and effectiveness of a drug product is not likely to be reviewed unless the owner of the master file notifies the applicant who, in turn, submits a supplement to incorporate the change in its approved application. Recognizing that one of the primary functions of the drug master file system is to maintain the confidentiality of trade secret information, FDA agrees that a file holder's notification about changes in the file does not have to be so specific that the confidentiality of information in the file is compromised.

137. One comment asked whether the requirement that the drug master file contain a complete list of persons currently authorized to reference it can be met by individual letters whenever a person is authorized or an authorization is revoked.

FDA notes that some drug master files are voluminous and subject to substantial amendments over time. Thus, it may be impossible to determine from individual letters submitted at different times the person who is currently authorized to reference a file. For that reason, FDA believes that a single list of persons currently authorized to reference the file should be maintained.

138. One comment urged that the changes in the regulation on drug master files should apply only to information added to the master file after the date of publication of the final rule. Another comment urged that the changes apply only to applications submitted after the effective date which incorporate a drug master file reference.

FDA believes that a uniform effective date for changes in the regulation on drug master files is necessary. Applying the regulations only to information added to a file after publication of the final rule, or applications submitted after the effective date of the final rule,

would lead to continual confusion about what part of the file is subject to the rule.

139. *Designated journals (§ 310.9).* One comment objected to FDA removing its list of designated journals from the regulations. The comment urged FDA to retain a list of journals that are available to it and waive requirements for submission or reprints and summaries of reports in those journals.

As discussed elsewhere in this preamble, FDA does not believe it to be a wise expenditure of its resources to retrieve copies of referenced journals from its library, given the minimal burden on applicants to submit relevant copies. FDA notes that the change is more likely to expedite rather than delay review of applications. In addition to removing § 310.9, FDA also is deleting the references to § 310.9 that appear in 21 CFR 510.3(1) and 510.95.

140. *Public information (§ 314.430).* One comment contended that FDA's classification of what constitutes confidential safety and effectiveness data in an application is overbroad and that, instead, the agency should require the applicant to index confidential records within its application in a manner similar to the procedure in § 20.53 (21 CFR 20.53) of FDA's public information regultions. If a person requests a copy of a record the applicant considers confidential, the applicant's reasons for considering it confidential could be forwarded to the requestor, who may then ask the agency to determine whether the record is disclosable.

FDA does not agree with this comment. An applicant is required to itemize and index its records under § 20.53 only in a legal action contesting an FDA denial of a request for records because they are exempt from public disclosure as a trade secret or confidential commercial or financial data and information. The agency believes that the comment's suggestion that this procedure be established absent litigation, and before FDA makes an initial determination about the status of a document, would impose a significant burden on applicants to index large numbers of records whose confidential status will never be disputed. It would also add to FDA's already heavy workload in responding to freedom of information requests by requiring the agency to provide the requestor with a preliminary response detailing the applicant's reasons for considering a record nondisclosable.

141. In § 314.430(f) of the proposal, FDA proposed to modify § 314.14(f) of the current regulations in identifying the situations in which safety and effectiveness data and information are available for public disclosure. Consideration of that proposal, as it relates to disclosure rules for drugs submitted under section 505(b) of the act, was rendered moot, however, by section 104 of the Drug Price Competition and Patent Term Restoration Act of 1984, enacted on September 24, 1984, because the new law itself provides when data and information in such submissions are publicly disclosable. Accordingly, FDA has conformed this final rule (§ 314.430(f)) to be consistent with section 104 of the new law.

In doing so, FDA calls attention to one specific point. Section 314.14(f)(5) of the current regulations provides that safety and effectiveness data and information are publicly disclosable when a final determination has been made that the drug may be approved without the submission of such data and information. In the past, "final determination" (for drugs approved under section 505) was interpreted to require publication of a final **Federal Register** notice under the Drug Efficacy Study Implementation (DESI) program. Under the new law, however, this provision means such data and information are publicly disclosable as soon as an abbreviated application under section 505(j) of the act for the product can be made effective, and that point in time will be identifiable through the list pubished monthly in accordance with section 505(j)(6) of the act.

For applications submitted under sections 505(j), 506, and 507 of the act, FDA has added § 314.430(f)(6) which states that safety and effectiveness data and information will be publicly disclosable when FDA sends an approval letter to the applicant. To prevent redundancy, FDA had deleted proposed § 314.430(e)(1) for the final rule.

142. *Waivers (§ 314.90).* One comment suggested that FDA not issue a final provision permitting it to waive requirements for the submission of information in an application. This comment feared that the waiver provision would permit applicants to market new products without having to submit adequate clinical information and other data about its safety and efficacy.

FDA believes this comment misunderstands the scope of the waiver provision, which is intended to give applicants the flexibility to seek alternative ways of complying with the regulatory requirements for drug approval. FDA is unable, and does not view the provision as authorizing it, to waive statutory requirements.

143. *Other changes.* On its own initiative, FDA has revised the final rule to retain current requirements, described below, that were inadvertently omitted from the proposal in the sections concerning contents of an application (§ 314.50), refusal to file an application (§ 314.101(d)), refusal to approve an application (§ 314.125), and/or withdrawal of approval of an application (§ 314.150).

First, the final rule provides that an application must contain reports of all investigations of the drug sponsored by the applicant, and all other information pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source. To correspond to this requirement, the final rule also provides that FDA may refuse to approve (or withdraw approval of) an application if it does not explain the omission of a report of any investigation of a drug sponsored by the applicant, or the omission of other information pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source. Although the proposal contained a requirement that the applicant submit all information pertinent to the evaluation of the application, it did not clearly require an applicant to submit reports of all the studies it sponsors nor did it provide for FDA to refuse to file or approve, or to withdraw approval of, an application that omits required reports or an explanation of the omission (all of which are current requirements).

Second, the final rule underscores the importance of conducting clinical investigations involving human subjects in compliance with the institutional review board regulations in Part 56 and the informed consent regulations in Part 50. In this regard, the final rule provides that the application must contain a statement for each clinical study subject to those regulations that the study was conducted in compliance with them. The agency may refuse to file an application, under the final rule, if the requisite statement is not provided. Also under the final rule, FDA may refuse to approve (or withdraw approval of) an application if the noncompliance results in the rights or safety of human subjects not being adequately protected. These requirements were added to the current regulations in the **Federal Register** of January 27, 1981 (46 FR 8942, 8954), but they were inadvertently omitted from the proposal. The language used in the final rule constitutes a minor change from current regulations to clarify that FDA would not refuse to approve (or withdraw approval of) an application

because of minor technical deviations from these regulations not affecting the rights of safety of human subjects. For purposes of consistency, FDA is also revising § 312.1(d)(11) to conform the provision respecting termination of an IND to the language used in this final rule.

Similarly, the final rule, like the current regulations and the proposal, underscores the importance of conducting nonclinical laboratory studies in compliance with the good laboratory practice regulations in Part 58. The language in the final rule has been revised to state that for each nonclinical study not conducted in compliance with these regulations, the application must contain a brief statement of the reason for the noncompliance (rather than a detailed description of all differences between the practices used in the study and those in the regulations). The language used in the final rule reflects advice that FDA has been providing to applicants with respect to interpretation of the current regulatory provision. The section on refusing to file an application has been conformed accordingly. For purposes of consistency, FDA is also revising the following sections of Title 21 of the Code of Federal Regulations with respect to applications submitted to FDA for research or marketing permits where the submission includes the results of nonclinical laboratory studies subject to Part 58, in order to conform those sections to the language used in this final rule: §§ 71.1, 71.6, 170.35, 171.1, 171.6, 180.1, 312.1, 330.10, 511.1, 514.1, 514.8, 514.15, 514.110, 570.35, 571.1, 571.6, 602.1, 812.27, 1003.31, 1010.4, and 1010.5.

Finally, also with respect to compliance with Part 58, the final rule, like the proposal, provides that FDA may refuse to approve an application if the nature of the noncompliance does not support the validity of the study. This language is intended to clarify that FDA would not refuse to approve an application because of minor technical deviations from these regulations. The final rule also contains a parallel provision in the section on withdrawal of approval, which was inadvertently omitted from the proposal. For purposes of consistency, FDA is also revising §§ 312.1(d)(12), 514.111(a)(11), and 514.115(b)(4) to conform these provisions governing investigational new drug and new animal drug applications to the language used in this final rule.

**List of Subjects**

*21 CFR Part 71*

Administrative practice and procedure, Color additive certification, Color additive petitions, Color additives, Cosmetics, Drugs.

*21 CFR Part 170*

Administrative practice and procedure, Definitions, Food additives, Food additive safety.

*21 CFR Part 171*

Administrative practice and procedure, Food additive petitions, Food additives.

*21 CFR Part 180*

Food additives, Interim listed food additives.

*21 CFR Part 201*

Drugs, Labeling.

*21 CFR Part 310*

Administrative practice and procedure, Drugs, Medical devices, Reporting requirements.

*21 CFR Part 312*

Drugs, Medical research.

*21 CFR Part 314*

Administrative practice and procedure, Drugs.

*21 CFR Part 330*

Over-the-counter drugs.

*21 CFR Part 430*

Administrative practice and procedure, Antibiotics.

*21 CFR Part 431*

Administrative practice and procedure, Antibiotics.

*21 CFR Part 433*

Antibiotics, Labeling.

*21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting requirements.

*21 CFR Part 511*

Animal drugs, Medical research.

*21 CFR Part 514*

Administrative practice and procedure, Animal drugs.

*21 CFR Part 570*

Animal feeds, Animal foods, Food additives.

*21 CFR Part 571*

Administrative practice and procedure, Animal feeds, Animal foods, Food additives.

*21 CFR Part 601*

Biologics.

*21 CFR Part 812*

Health records, Investigational device exemptions, Medical devices, Medical device research, Reporting requiements.

*21 CFR Part 1003*

Administrative practice and procedure, Defects, Electronic products, Noncompliance, Radiation protection.

*21 CFR Part 1010*

Administrative practice and procedure, Electronic products, Exemptions, Exports, Radiation protection, Standards, Variances.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 409, 501, 502, 503, 505, 506, 507, 512–516, 520, 701, 706, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–407 as amended, 82 Stat. 343–351, 90 Stat. 540–560 (21 U.S.C. 348, 351, 352, 353, 355, 356, 357, 360b–360f, 371, 376)) and the Public Health Service Act (secs. 215, 301, 351, 354–360f, 58 Stat. 690, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 241, 262, 263b–263n)) and under 21 CFR 5.11, Parts 71, 170, 171, 180, 201, 310, 312, 314, 430, 431, 433, 510, 511, 514, 570, 601, 812, 1003, and 1010 are amended as follows:

## PART 71—COLOR ADDITIVE PETITIONS

1. Part 71 is amended:

a. In § 71.1 by revising paragraph (g), to read as follows:

**§ 71.1 Petitions.**

* * * * *

(g) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 706(b) of the act shall include with respect to each nonclinical study contained in the petition, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

* * * * *

b. In § 71.6 by revising the third sentence of paragraph (b), to read as follows:

**§ 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.**

* * * * *

(b) * * * If nonclinical laboratory studies are involved, additional information and data submitted in

support of filed petitions shall include, with respect to each nonclinical laboratory study contained in the petition, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. * * *

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## PART 170—FOOD ADDITIVES

2. Part 170 is amended in § 170.35 by revising paragraph (c)(1)(vi), to read as follows:

**§ 170.35 Affirmation of generally recognized as safe (GRAS) status.**

* * * * *

(c) * * *

(1) * * *

(vi) If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

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## PART 171—FOOD ADDITIVE PETITIONS

3. Part 171 is amended:

a. In § 171.1 by revising paragraph (k), to read as follows:

**§ 171.1 Petitions.**

* * * * *

(k) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

* * * * *

b. By revising § 171.6, to read as follows:

**§ 171.6 Amendment of petition.**

After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amount to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. Where the substantive amendment proposes a substantial change to any petition that may affect the quality of the human environment, the petitioner is required to submit an environmental analysis report pursuant to § 25.1 of this chapter. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

## PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

4. Part 180 is amended in § 180.1 by revising paragraph (c)(4), to read as follows:

**§ 180.1 General.**

* * * * *

(c) * * *

(4) If nonclinical laboratory studies are involved, studies filed with the Commissioner shall include, with respect to each study, either a statement that the study has been or will be conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

* * * * *

## PART 201—LABELING

5. Part 201 is amended in § 201.122 by revising paragraph (a), to read as follows:

**§ 201.122 Drugs for processing, repacking, or manufacturing.**

* * * * *

(a) An approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder by persons named in the application, and, for a new drug substance, the export of it by such persons under § 314.410 of this chapter; or

* * * * *

## PART 310—NEW DRUGS

6. Part 310 is amended:

**§ 310.3 [Amended]**

a. In § 310.3 *Definitions and interpretations* by removing and reserving paragraph (m).

**§ 310.9 [Removed]**

b. By removing § 310.9 *Designated journals.*

**§ 310.300 [Removed]**

c. By removing § 310.300 *Records and reports concerning experience on drugs for which an approval is in effect.*

**§ 310.301 [Removed]**

d. By removing § 310.301 *Reporting of adverse drug experiences.*

**§ 310.302 [Removed]**

e. By removing § 310.302 *Records and reports on new drugs and antibiotics for use by man for which applications or certification forms 5 and 6 became effective or were approved prior to June 20, 1963.*

## PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

7. Part 312 is amended:

a. In § 312.1 by revising item 16 in Form FD–1571 in paragraph (a)(2) and by revising paragraph (d) (11) and (12), to read as follows:

**§ 312.1 Conditions for exemption of new drugs for investigational use.**

(a) * * *

(2) * * *

Form FD-1571 * * *

16. A statement that all nonclinical laboratory studies have been, or will be, conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if such studies have not been conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

* * * * *

(d) * * *

(11) Any clinical investigation involving human subjects, subject to the institutional review board regulations in Part 56 of this chapter or informed consent regulations in Part 50 of this chapter, is not being conducted in compliance with those regulations such that the rights or safety of human subjects are not adequately protected; or

(12) Any nonclinical laboratory study that is described in the notice of claimed investigational exemption and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter and no reason for the

noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study; or

* * * * *

b. In § 312.20 by revising paragraph (c), to read as follows:

**§ 312.20 Clinical data generated outside the United States and not subject to a "Notice of Claimed Investigational Exemption for a New Drug."**

* * * * *

(c) Data from studies performed outside the United States and conducted in accordance with the requirements of this section may be utilized without duplication of the studies in the United States, as appropriate.

* * * * *

8. By revising Part 314 to read as follows:

## PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

### Subpart A—General Provisions

Sec.
314.1 Scope of this part.
314.2 Purpose.
314.3 Definitions.

### Subpart B—Applications

314.50 Content and format of an application.
314.55 Abbreviated application.
314.56 Drug products for which abbreviated applications are suitable.
314.60 Amendments to an unapproved application.
314.65 Withdrawal by the applicant of an unapproved application.
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314.71 Procedures for submission of a supplement to an approved application.
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### Subpart C—FDA Action on Applications

314.100 Time frames for reviewing applications.
314.101 Filing and application.
314.102 Communications between FDA and applicants.
314.103 Dispute resolution.
314.104 Drugs with potential for abuse.
314.105 Approval of an application.
314.106 Foreign data.
314.110 Approvable letter to the applicant.
314.120 Not approvable letter to the applicant.
314.125 Refusal to approve an application.
314.126 Adequate and well-controlled studies.
314.150 Withdrawal of approval of an application.
314.152 Notice of withdrawal of approval of an application for a new drug.
Sec.
314.160 Approval of an application for which approval was previously refused, suspended, or withdrawn.
314.170 Adulteration and misbranding of an approved drug.

### Subpart D—Hearing Procedures for New Drugs

314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.
314.201 Procedure for hearings.
314.235 Judicial review.

### Subpart E—Administrative Procedures for Antibiotics

314.300 Procedure for the issuance, amendment, or repeal of regulations.

### Subpart F—Miscellaneous Provisions

314.410 Imports and exports of new drugs and antibiotics.
314.420 Drug master files.
314.430 Availability for public disclosure of data and information in an application.
314.440 Addresses for applications.
314.445 Guidelines.

**Authority:** Secs. 409, 501, 502, 503, 505, 506, 507, 512–516, 520, 701, 706, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 55 Stat. 851, 59 stat. 463 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–407 as amended, 82 Stat. 343–351, 90 Stat. 540–560 (21 U.S.C. 351, 352, 353, 355, 356, 357, 360b–360f, 371, 376); sec. 215, 301, 351, 354–360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 241, 262, 263b–263n).

### Subpart A—General Provisions

**§ 314.1 Scope of this part.**

(a) This part sets forth procedures and requirements for the submission to, and the review by, the Food and Drug Administration fo applications and abbreviated applications, as well as amendments, supplements, and postmarketing reports to them, by persons seeking or holding approval from FDA of the following:

(1) An application under section 505 of the Federal Food, Drug, and Cosmetic Act to market a new drug.

(2) An application under section 507 of the Federal Food, Drug, and Cosmetic Act to market an antibiotic drug.

(b) This part does not apply to drug products subject to licensing by FDA under the Public Health Service Act (58 Stat. 632 as amended (42 U.S.C. 201 et seq.)) and Subchapter F of Chapter I of Title 21 of the Code of Federal Regulations.

(c) References in this part to regulations in the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

**§ 314.2 Purpose.**

The purpose of this part is to establish an efficient and thorough drug review process in order to: (a) Facilitate the approval of drugs shown to be safe and effective; and (b) ensure the disapproval of drugs not shown to be safe and effective. These regulations are also intended to establish and effective system for FDA's surveillance of marketed drugs. These regulations shall be construed in light of these objectives.

**§ 314.3 Definitions.**

(a) The definitions and interpretations contained in section 201 of the act apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

"Act" means the Federal Food, Drug, and Cosmetic Act (sections 201–901, 52 Stat. 1040 et seq., as amended (21 U.S.C. 301–392)).

"Applicant" means any person who submits an application or abbreviated application or an amendment or supplement to them under this part to obtain Food and Drug Administration approval of a new drug or an antibiotic drug and any person who owns an approved application.

"Application" means both the application described under § 314.50 and the abbreviated application under § 314.55, including all amendments and supplements.

"Approvable letter" means a written communication to an applicant from FDA stating that the agency will approve the application if specific additional information or material is submitted or specific conditions are met. An approvable letter does not constitute approval of any part of an application and does not permit marketing of the drug that is the subject of the application.

"Approval letter" means a written communication to an applicant from FDA approving an application. An approval letter permits marketing of the drug product that is the subject of the application.

"Drug product" means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

"Drug substance" means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure of any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

"FDA" means the Food and Drug Administration.

"Not approvable letter" means a written communication to an applicant

from FDA stating that the agency does not consider the application approvable because one or more deficiencies in the application preclude the agency from approving it.

## Subpart B—Applications

### § 314.50 Content and format of an application.

Applications, including abbreviated applications, and supplements to approved applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section. Two copies of the application are required, an archival copy and a review copy. An application for a new chemical entity will generally contain an application form, an index, a summary, five or six technical sections, case report tabulations of patient data, case report forms, drug samples, and labeling. Other applications will generally contain only some of those items, and information will be limited to that needed to support the particular submission. These include an application for a duplicate of a marketed drug product (such as a "paper NDA," which relies primarily on published literature to provide substantial evidence of effectiveness and adequate scientific evidence of safety for the claimed indications), an abbreviated application, an amendment, and a supplement. The application is required to contain reports of all investigations of the drug product sponsored by the applicant, and all other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source. The Food and Drug Administration will maintain guidelines on the format and content of applications to assist applicants in their preparation.

(a) *Application form.* The applicant shall submit a completed and signed application form that contains the following:

(1) The name and address of the applicant; the date of the application; the application number if previously issued (for example, if the application is a resubmission, an amendment, or a supplement); the name of the drug product, including its established, proprietary, code, and chemical names; the dosage form and strength; the route of administration; the identification numbers of all investigational new drug applications that are referenced in the application; the identification numbers of all drug master files and other applications under this part that are referenced in the application; and the drug product's proposed indications for use.

(2) A statement whether the submission is an original submission, a resubmission, an abbreviated application under § 314.55, or a supplement to an application under § 314.70.

(3) A statement whether the applicant proposes to market the drug product as a prescription or an over-the-counter product.

(4) A check-list identifying what enclosures required under this section the applicant is submitting.

(5) The applicant, or the applicant's attorney, agent, or other authorized official shall sign the application. If the person signing the application does not reside or have a place of business within the United States, the application is required to contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.

(b) *Index.* The archival copy of the application is required to contain a comprehensive index by volume number and page number to the summary under paragraph (c) of this section, the technical sections under paragraph (d) of this section, and the supporting information under paragraph (f) of this section.

(c) *Summary.* (1) An application is required to contain a summary of the application in enough detail that the reader may gain a good general understanding of the data and information in the application, including an understanding of the quantitative aspects of the data. The summary is not required for abbreviated applications under § 314.55 and supplements under § 314.70. Resubmissions of an application should contain an updated summary, as appropriate. The summary should discuss all aspects of the application, and synthesize the information into a well-structured and unified document. The summary should be written at approximately the level of detail required for publication in, and meet the editorial standards generally applied by, refereed scientific and medical journals. In addition to the agency personnel reviewing the summary in the context of their review of the application, FDA may furnish the summary to FDA advisory committee members and agency officials whose duties require an understanding of the application. To the extent possible, data in the summary should be presented in tabular and graphic forms. FDA has prepared a guideline under § 10.90(b) that provides information about how to prepare a summary. The summary required under this paragraph may be used by FDA or the applicant to prepare the Summary Basis of Approval document for public disclosure (under § 314.430(e)(2)(ii)) when the application is approved.

(2) The summary is required to contain the following information:

(i) The proposed text of the labeling for the drug, with annotations to the information in the summary and technical sections of the application that support the inclusion of each statement in the labeling, and, if the application is for a prescription drug, statements describing the reasons for omitting a section or subsection of the labeling format in § 201.57.

(ii) A statement identifying the pharmacologic class of the drug and a discussion of the scientific rationale for the drug, its intended use, and the potential clinical benefits of the drug product.

(iii) A brief description of the marketing history, if any, of the drug outside the United States, including a list of the countries in which the drug has been marketed, a list of any countries in which the drug has been withdrawn from marketing for any reason related to safety or effectiveness, and a list of countries in which applications for marketing are pending. The description is required to describe both marketing by the applicant and, if known, the marketing history of other persons.

(iv) A summary of the chemistry, manufacturing, and controls section of the application.

(v) A summary of the nonclinical pharmacology and toxicology section of the application.

(vi) A summary of the human pharmacokinetics and bioavailability section of the application.

(vii) A summary of the microbiology section of the application (for anti-infective drugs only).

(viii) A summary of the clinical data section of the application, including the results of statistical analyses of the clinical trials.

(ix) A concluding discussion that presents the benefit and risk considerations related to the drug, including a discussion of any proposed additional studies or surveillance the applicant intends to conduct postmarketing.

(d) *Technical sections.* The application is required to contain the technical sections described below. Each technical section is required to contain data and information in sufficient detail to permit the agency to

make a knowledgeable judgment about whether to approve the application or whether grounds exist under section 505(d) or 507 of the act to refuse to approve the application. The required technical sections are as follows:

(1) *Chemistry, manufacturing, and controls section.* A section describing the composition, manufacture, and specification of the drug substance and the drug product, including the following:

(i) *Drug substance.* A full description of the drug substance including its physical and chemical characteristics and stability; the name and address of its manufacturer; the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality, and purity of the drug substance and the bioavailability of the drug products made from the substance, including, for example, specifications relating to stability, sterility, particle size, and crystalline form. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative sources, process controls, methods, and specifications. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may satisfy relevant requirements in this paragraph.

(ii) *Drug product.* A list of all components used in the manufacture of the drug product (regardless of whether they appear in the drug product); and a statement of the composition of the drug product; a statement of the specifications and analytical methods for each component; the name and address of each manufacturer the drug product; a description of the manufacturing and packaging procedures and in-process controls for the drug product; such specifications and analytical methods as are necessary to assure the identity, strength, quality, purity, and bioavailability of the drug product, including, for example, specifications relating to sterility, dissolution rate, containers and closure systems; and stability data with proposed expiration dating. The application may provide additionally for the use of alternatives to meet any of these requirements, including alternative components, manufacturing and packaging procedures, in-process controls, methods, and specifications. Reference to the current edition of the U.S. Pharmacopeia and the National Formulary may satisfy relevant requirements in this paragraph.

(iii) *Environmental impact analysis report.* An environmental impact analysis report under § 25.1 analyzing the environmental impact of the manufacturing process and the ultimate use of the drug product.

(iv) The applicant may, at its option, submit a complete chemistry, manufacturing, and controls section 90 to 120 days before the anticipated submission of the remainder of the application. FDA will review such early submissions as resources permit.

(2) *Nonclinical pharmacology and toxicology section.* A section describing, with the aid of graphs and tables, the nonclinical laboratory studies with the drug, including the following:

(i) Studies of the pharmacological actions of the drug in relation to its proposed therapeutic indication and studies otherwise define the pharmacologic properties of the drug or are pertinent to possible adverse effects.

(ii) Studies of the toxicological effects of the drug as they relate to the drug's intended clinical uses, including, as appropriate, studies assessing the drug's acute, subacute, and chronic toxicity; carcinogenicity; and studies of toxicities related to the drug's particular mode of administration or conditions of use.

(iii) Studies, as appropriate, of the effects of the drug on reproduction and on the developing fetus.

(iv) Any studies of the absorption, distribution, metabolism, and excretion of the drug in animals.

(v) For each nonclinical laboratory study a statement that it was conducted in compliance with the good laboratory practice regulations in Part 58, or, if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(3) *Human pharmacokinetics and bioavailability section.* A section describing the human pharmacokinetic data and human bioavailability data, or information supporting a waiver of the submission of in vivo bioavailability data under Subpart B of Part 320, including the following:

(i) A description of each of the bioavailability and pharmacokinetic studies of the drug in humans performed by or on behalf of the applicant that includes a description of the analytical and statistical methods used in each study and a statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in Part 56, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in Part 50.

(ii) If the application describes in the chemistry, manufacturing, and controls section specifications or analytical methods needed to assure the bioavailability of the drug product or drug substance, or both, a statement in this section of the rationale for establishing the specification or analytical methods, including data and information supporting the rationale.

(iii) A summarizing discussion and analysis of the pharmacokinetics and metabolism of the active ingredients and the bioavailability or bioequivalence, or both, of the drug product.

(4) *Microbiology section.* If the drug is an anti-infective drug, a section describing the microbiology data, including the following:

(i) A description of the biochemical basis of the drug's action on microbial physiology.

(ii) A description of the antimicrobial spectra of the drug, including results of in vitro preclinical studies to demonstrate concentrations of the drug required for effective use.

(iii) A description of any known mechanisms of resistance to the drug, including results of any known epidemiologic studies to demonstrate prevalence of resistance factors.

(iv) A description of clinical microbiology laboratory methods (for example, in vitro sensitivity discs) needed for effective use of the drug.

(5) *Clinical data section.* A section describing the clinical investigations of the drug, including the following:

(i) A description and analysis of each clinical pharmacology study of the drug, including a brief comparison of the results of the human studies with the animal pharmacology and toxicology data.

(ii) A description and analysis of each controlled clinical study pertinent to a proposed use of the drug, including the protocol and a description of the statistical analyses used to evaluate the study. If the study report is an interim analysis, this is to be noted and a projected completion date provided. Controlled clinical studies that have not been analyzed in detail for any reason (e.g., because they have been discontinued or are incomplete) are to be included in this section, including a copy of the protocol and a brief description of the results and status of the study.

(iii) A description of each uncontrolled clinical study, a summary of the results, and a brief statement explaining why the study is classified as uncontrolled.

(iv) A description and analysis of any other data or information relevant to an

evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from clinical investigations, including controlled and uncontrolled studies of uses of the drug other than those proposed in the application, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers.

(v) An integrated summary of the data demonstrating substantial evidence of effectiveness for the claimed indications. Evidence is also required to support the dosage and administration section of the labeling, including support for the dosage and dose interval recommended, and modifications for specific subgroups (for example, pediatrics, geriatrics, patients with renal failure).

(vi) A summary and updates of safety information, as follows:

(*a*) The applicant shall submit an integrated summary of all available information about the safety of the drug product, including pertinent animal data, demonstrated or potential adverse effects of the drug, clinically significant drug/drug interactions, and other safety considerations, such as data from epidemiological studies of related drugs. A description of any statistical analyses performed in analyzing safety data should also be included, unless already included under paragraph (a)(5)(ii) of this section.

(*b*) The applicant shall, under section 505(i) of the act, update periodically its pending application with new safety information learned about the drug that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. These "safety update reports" are required to include the same kinds of information (from clinical studies, animal studies, and other sources) and are required to be submitted in the same format as the integrated summary in paragraph (d)(5)(vi)(*a*) of this section. In addition, the reports are required to include the case report forms for each patient who died during a clinical study or who did not complete the study because of an adverse event (unless this requirement is waived). The applicant shall submit these reports (*1*) 4 months after the initial submission; (*2*) following receipt of an approvable letter; and (*3*) at other times as requested by FDA. Prior to the submission of the first such report, applicants are encouraged to consult with FDA regarding further details on its form and content.

(vii) If the drug has a potential for abuse, a description and analysis of studies or information related to abuse of the drug, including a proposal for scheduling under the Controlled Substances Act. A description of any studies related to overdosage is also required, including information on dialysis, antidotes, or other treatments, if known.

(viii) An integrated summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks under the conditions stated in the labeling.

(ix) A statement with respect to each clinical study involving human subjects that it either was conducted in compliance with the institutional review board regulations in Part 56, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in Part 50.

(6) *Statistical section.* A section describing the statistical evaluation of clinical data, including the following:

(i) A copy of the information submitted under paragraph (d)(5)(ii) of this section concerning the description and analyses of each controlled clinical study, and the documentation and supporting statistical analysis used in evaluating the controlled clinical studies.

(ii) A copy of the information submitted under paragraph (d)(5)(vi)(*a*) of this section concerning a summary of information about the safety of the drug product, and the documentation and supporting statistical analyses used in evaluating the safety information.

(e) *Samples and labeling.* (1) Upon request from FDA, the applicant shall submit the samples described below to the places identified in the agency's request. FDA will generally ask applicants to submit samples directly to two or more agency laboratories that will perform all necessary tests on the samples and validate the applicant's analytical methods.

(i) Four representative samples of the following, each sample in sufficient quantity to permit FDA to perform three times each test described in the application to determine whether the drug substance and the drug product meet the specifications given in the application:

(*a*) The drug product proposed for marketing;

(*b*) The drug substance used in the drug product from which the samples of the drug product were taken; and

(*c*) Reference standards and blanks (except that reference standards recognized in an official compendium need not be submitted).

(ii) Samples of the finished market package, if requested by FDA.

(2) The applicant shall submit the following in the archival copy of the application:

(i) Three copies of the analytical methods and related descriptive information contained in the chemistry, manufacturing, and controls section under paragraph (d)(1) of this section for the drug substance and the drug product that are necessary for FDA's laboratories to perform all necessary tests on the samples and to validate the applicant's analytical methods. The related descriptive information includes a description of each sample; the proposed regulatory specifications for the drug; a detailed description of the methods of analysis; supporting data for accuracy, specificity, precision and ruggedness; and complete results of the applicant's tests on each sample.

(ii) Copies of the label and all labeling for the drug product (4 copies of draft labeling or 12 copies of final printed labeling).

(f) *Case report forms and tabulations.* The archival copy of the application is required to contain the following case report tabulations and case report forms:

(1) *Case report tabulations.* The application is required to contain tabulations of the data from each adequate and well-controlled study under § 314.126 (Phase 2 and Phase 3 studies as described in § 312.1(a)(2), Form FDA–1571), tabulations of the data from the earliest clinical pharmacology studies (Phase 1 studies as described in § 312.1(a)(2), Form FDA–1517), and tabulations of the safety data from other clinical studies. Routine submission of other patient data from uncontrolled studies is not required. The tabulations are required to include the data on each patient in each study, except that the applicant may delete those tabulations which the agency agrees, in advance, are not pertinent to a review of the drug's safety or effectiveness. Upon request, FDA will discuss with the applicant in a "pre-NDA" conference those tabulations that may be appropriate for such deletion. Barring unforeseen circumstances, tabulations agreed to be deleted at such a conference will not be requested during the conduct of FDA's review of the application. If such unforeseen circumstances do occur, any request for deleted tabulations will be made by the director of the FDA division responsible for reviewing the application, in

accordance with paragraph (f)(3) of this section.

(2) *Case report forms.* The application is required to contain copies of individual case report forms for each patient who died during a clinical study or who did not complete the study because of an adverse event, whether believed to be drug related or not, including patients receiving reference drugs or placebo. This requirement may be waived by FDA for specific studies if the case report forms are unnecessary for a proper review of the study.

(3) *Additional data.* The applicant shall submit to FDA additional case report forms and tabulations needed to conduct a proper review of the application, as requested by the director of the FDA division responsible for reviewing the application. The applicant's failure to submit information requested by FDA within 30 days after receipt of the request may result in the agency viewing any eventual submission as a major amendment under § 314.60 and extending the review period as necessary. If desired by the applicant, the FDA division director will verify in writing any request for additional data that was made orally.

(4) Applicants are invited to meet with FDA before submitting an application to discuss the presentation and format of supporting information. If the applicant and FDA agree, the applicant may submit tabulations of patient data and case report forms in a form other than hard copy, for example, on microfiche or computer tapes.

(g) *Other.* The following general requirements apply to the submission of information within the summary under paragraph (c) of this section and within the technical sections under paragraph (d) of this section.

(1) The applicant ordinarily is not required to resubmit information previously submitted, but may incorporate the information by reference. A reference to information submitted previously is required to identify the file by name, reference number, volume, and page number in the agency's records where the information can be found. A reference to information submitted to the agency by a person other than the applicant is required to contain a written statement that authorizes the reference and that is signed by the person who submitted the information.

(2) The applicant shall submit an accurate and complete English translation of each part of the application that is not in English. The applicant shall submit a copy of each original literature publication for which an English translation is submitted.

(h) *Format of an original application.* (1) The applicant shall submit a complete archival copy of the application that contains the information required under paragraphs (a) through (f) of this section. FDA will maintain the archival copy during the review of the application to permit individual reviewers to refer to information that is not contained in their particular technical sections of the application, to give other agency personnel access to the application for official business, and to maintain in one place a complete copy of the application. An applicant may submit on microfiche the portions of the archival copy of the application described in paragraphs (b) through (d) of this section. Information relating to samples and labeling, described in paragraph (e) of this section, is required to be submitted in hard copy. Tabulations of patient data and case report forms, described in paragraph (f) of this section, may be submitted on microfiche only if the applicant and FDA agree. If FDA agrees, the applicant may use another suitable microform system.

(2) The applicant shall submit a review copy of the application. Each of the technical sections (described in paragraph (d) (1) through (6) of this section) in the review copy is required to be separately bound with a copy of the application form required under paragraph (a) of this section and a copy of the summary required under paragraph (c) of this section. The applicant may obtain from FDA sufficient folders to bind the archival and review copies of the application.

**§ 314.55 Abbreviated application.**

(a) An abbreviated application is an application in which reports of nonclinical laboratory studies and reports of clinical investigations (except those pertaining to in vivo bioavailability of the drug product) may be omitted. The information may be omitted when the Food and Drug Administration has determined that the information already available to it is adequate to establish that a particular dosage form of a drug meets the statutory standards for safety and effectiveness. An abbreviated application will usually be reserved for duplicates of drug products previously approved under a full application under §314.50. An abbreviated application is not required to comply with the requirements in § 314.50 (c), (d)(2), (4), (5), (6), and (f).

(b) FDA will file an abbreviated application only if it has made a finding that an abbreviated application is suitable for a drug product. If FDA finds that a drug product may be approved for marketing on the basis of an abbreviated application, it will make that finding publicly available, as follows:

(1) If the finding applies to a broad category of drug products, the agency will amend § 314.56 to identify the category in that section.

(2) If the finding applies to a drug product because it is so closely related to a product for which an abbreviated application is suitable that the same conclusions about safety and effectiveness apply to it, the agency will make the finding public by updating its list of drug products for which abbreviated applications are suitable. The list is available from the National Technical Information Service, Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161.

(3) If the finding applies to duplicates of a drug product that is subject to FDA's Drug Efficacy Study Implementation program (a review of drug products approved as safe between 1938 and 1962), the agency will make that finding public through a notice published in the **Federal Register.**

(c)(1) A finding by FDA that an abbreviated application is suitable for a drug product applies only to a product that is the same in active ingredient, dosage form and strength, route of administration, and conditions of use as the drug product that was the subject of the finding. For drug product that is similar but different in one or more of these characteristics, an abbreviated application will be accepted only if FDA has made a separate finding of suitability. However, filing of an abbreviated application for a drug product does not signify that the product is safe and effective until the application is approved.

(2) A finding that a drug product is a new drug because it is similar to a product that is a new drug, and is therefore subject to the requirements of this part, does not include a finding that an abbreviated application is suitable for the similar product.

(3) A finding that a single-active-entity drug product is safe and effective and that an abbreviated application is suitable is not a basis for determining that a combination drug product containing that entity as one of its ingredients is either safe or effective or that an abbreviated application is suitable. The finding also is not a basis for determining that the combination drug product meets all of the requirements for combination drugs as described in § 300.50.

(d) (1) A person may seek a determination of the suitability of an abbreviated application for a product that the person believes is similar or related to a drug product that has been declared to be suitable for an abbreviated application. Extension of the finding that a drug product is safe and effective to another product will ordinarily be limited to other dosage forms for the same route of administration or to closely related ingredients. If preclinical or clinical evidence is needed to support the safety, or if clinical evidence is needed to support the effectiveness, of the proposed product, then an abbreviated application is not appropriate for the similar or related drug product.

(2) A person seeking a determination that an abbreviated application is suitable for a similar or related drug product shall use the petition procedures established in § 10.30. The petitioner shall set forth the reasons that justify extending the finding that an abbreviated application is suitable for one product to the similar or related product proposed to be marketed.

(3) An application submitted in the form of an abbreviated application for a drug product that has not been the subject of a finding that allows an abbreviated application for the product will be considered to be a petition under § 10.30 and will be processed as such.

(e) Each abbreviated application is required to contain a reference to FDA's finding that an abbreviated application is suitable for the specific product that is the subject of the application and to contain both an archival and a review copy of the application.

(1) The applicant shall submit a complete archival copy of the application that contains the information required under § 314.50 (a), (b), (d)(1) and (3), (e), and (g). An applicant may submit the archival copy of the application on microfiche or, if FDA agrees, another suitable microform system.

(2) The applicant shall submit a review copy that contains the technical sections described in § 314.50(d)(1) and (3). Each of the technical sections in the review copy is required to be separately bound with a copy of the application form required under § 314.50(a).

(3) The applicant may obtain from FDA sufficient folders to bind the archival and the review copies of the application.

**§ 314.56 Drug products for which abbreviated applications are suitable.**

Abbreviated applications are suitable for the following drugs within the limits set forth in § 314.55(c):

(a) Duplicates of drug products that were first approved before October 10, 1962, and reformulations of these products, if the original or reformulated product has been evaluated as part of the drug efficacy study and announced by notice in the **Federal Register** as effective for one or more indications, and if the Food and Drug Administration has made a finding that an abbreviated application is suitable.

(b) [Reserved]

(c) Drug products that are very closely related to a product described in paragraph (a) of this section and that are subject to a separate finding of suitability for marketing under an abbreviated application.

(d) Drug products that contain a chlorofluorocarbon determined to be an essential use and identified in § 2.125(h)(2) as suitable for an abbreviated application.

(e) Duplicates of an antibiotic drug for which FDA has approved an application.

**§ 314.60 Amendments to an unapproved application.**

The applicant may submit an amendment to an application that is filed under § 314.100, but not yet approved. The submission of a major amendment (for example, an amendment that contains significant new data from a previously unreported study or detailed new analyses of previously submitted data), whether on the applicant's own initiative or at the invitation of the agency, constitutes an agreement by the applicant under section 505(c) of the act to extend the date by which the agency is required to reach a decision on the application. Ordinarily, the agency will extend the review period for a major amendment but only for the time necessary to review the new information. However, the agency may not extend the review period more than 180 days. If the agency extends the review period for the application, the director of the division responsible for reviewing the application will notify the applicant of the length of the extension. The submission of an amendment that is not a major amendment will not extend the review period.

**§ 314.65 Withdrawal by the applicant of an unapproved application.**

An applicant may at any time withdraw an application that is not yet approved by notifying the Food and Drug Administration in writing. The agency will consider an applicant's failure to respond within 10 days to an approvable letter under § 314.110 or a not approvable letter under § 314.120 to be a request by the applicant to withdraw the application. A decision to withdraw the application is without prejudice to refiling. The agency will retain the application and will provide a copy to the applicant on request under the fee schedule in § 20.42 of FDA's public information regulations.

**§ 314.70 Supplements and other changes to an approved application.**

(a) *Changes to an approved application.* The applicant shall notify the Food and Drug Administration about each change in each condition established in an approved application beyond the variations already provided for in the application. The notice is required to describe the change fully. Depending on the type of change, the applicant shall notify FDA about it in a supplemental application under paragraph (b) or (c) of this section or by inclusion of the information in the annual report to the application under paragraph (d) of this section. Notwithstanding the requirements of paragraphs (b) and (c) of this section, an applicant shall make a change provided for in those paragraphs (for example, the deletion of an ingredient common to many drug products) in accordance with a guideline, notice, or regulation published in the **Federal Register** that provides for a less burdensome notification of the change (for example, by notification at the time a supplement is submitted or in the next annual report).

(b) *Supplements requiring FDA approval before the change is made.* An applicant shall submit a supplement, and obtain FDA approval of it, before making the changes listed below in the conditions in an approved application, unless the change is made to comply with an official compendium. An applicant may ask FDA to expedite its review of a supplement if a delay in making the change described in it would impose an extraordinary hardship on the applicant. Such a supplement and its mailing cover should be plainly marked: "Supplement—Expedited Review Requested."

(1) *Drug substance.* A change affecting the drug substance to accomplish any of the following:

(i) To relax the limits for a specification;

(ii) To establish a new regulatory analytical method;

(iii) To delete a specification or regulatory analytical method;

(iv) To change the synthesis of the drug substance, including a change in solvents and a change in the route of synthesis.

(v) To use a different facility or establishment to manufacture the drug substance, where: (*a*) the manufacturing process in the new facility or established differs materially from that in the former facility or establishment, or (*b*) the new facility or establishment has not received a satisfactory current good manufacturing practice (CGMP) inspection within the previous 2 years covering that manufacturing process.

(2) *Drug product.* A change affecting the drug product to accomplish any of the following:

(i) To add or delete an ingredient, or otherwise to change the composition of the drug product, other than deletion of an ingredient intended only to affect the color of the drug product;

(ii) To relax the limits for a specification;

(iii) To establish a new regulatory analytical method;

(iv) To delete a specification or regulatory analytical method;

(v) To change the method of manufacture of the drug product, including changing or relaxing an in-process control;

(vi) To use a different facility or establishment, including a different contract laboratory or labeler, to manufacture, process, or pack the drug product;

(vii) To change the container and closure system for the drug product (for example, glass to high density polyethylene (HDPE), or HDPE to polyvinyl chloride) or change a specification or regulatory analytical method for the container and closure system;

(viii) To change the size of the container, except for solid dosage forms, without a change in the container and closure system.

(ix) To extend the expiration date of the drug product based on data obtained under a new or revised stability testing protocol that has not been approved in the application.

(x) To establish a new procedure for reprocessing a batch of the drug product that fails to meet specifications.

(3) *Labeling.* Any change in labeling, except one described in paragraph (c)(2) or (d) of this section.

(c) *Supplements for changes that may be made before FDA approval.* An applicant shall submit a supplement at the time the applicant makes any kind of change listed below in the conditions in an approved application, unless the change is made to comply with an official compendium. A supplement under this paragraph is required to give a full explanation of the basis for the change, identify the date on which the change is made, and, if the change concerns labeling, include 12 copies of final printed labeling. The applicant shall promptly revise all promotional labeling and drug advertising to make it consistent with any change in the labeling. The supplement and its mailing cover should be plainly marked: "Special Supplement—Changes Being Effected."

(1) Adds a new specification or test method or changes in the methods, facilities (except a change to a new facility), or controls to provide increased assurance that the drug will have the characteristics of identity, strength, quality, and purity which it purports or is represented to possess;

(2) Changes labeling to accomplish any of the following:

(i) To add or strengthen a contraindication, warning, precaution, or adverse reaction;

(ii) To add or strengthen a statement about drug abuse, dependence, or overdosage; or

(iii) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the product.

(iv) To delete false, misleading, or unsupported indications for use or claims for effectiveness.

(3) To use a different facility or establishment to manufacture the drug substance, where: (i) The manufacturing process in the new facility or establishment does not differ materially from that in the former facility or establishment, and (ii) the new facility or establishment has received a satisfactory current good manufacturing practice (CGMP) inspection within the previous 2 years covering that manufacturing process.

(d) *Changes described in the annual report.* An applicant shall not submit a supplement to make any change in the conditions in an approved application, unless otherwise required under paragraph (b) or (c) of this section, but shall describe the change in the next annual report required under § 314.81. Some examples of changes that can be described in the annual report are the following:

(1) Any change made to comply with an official compendium.

(2) A change in the labeling concerning the description of the drug product or in the information about how the drug product is supplied, that does not involve a change in the dosage strength or dosage form.

(3) An editorial or similar minor change in labeling.

(4) The deletion of an ingredient intended only to affect the color of the drug product.

(5) An extension of the expiration date based upon full shelf-life data obtained from a protocol approved in the application.

(6) A change within the container and closure system for the drug product (for example, a change from one high density polyethylene (HDPE) to another HDPE), except a change in container size for nonsolid dosage forms, based upon a showing of equivalency to the approved system under a protocol approved in the application or published in an official compendium.

(7) The addition or deletion of an alternate analytical method.

(8) A change in the size of a container for a solid dosage form, without a change from one container and closure system to another.

**§ 314.71 Procedures for submission of a supplement to an approved application.**

(a) Only the applicant may submit a supplement to an application.

(b) All procedures and actions that apply to an application under § 314.50 and an abbreviated application under § 314.55 also apply to supplements, except that the information required in the supplement is limited to that needed to support the change. A supplement is required to contain an archival copy and a review copy that include an application form and appropriate technical sections, samples, and labeling.

(c) All procedures and actions that apply to applications under this part, including actions by applicants and the Food and Drug Administration, also apply to supplements.

**§ 314.72 Change in ownership of an application.**

(a) An applicant may transfer ownership of its application. At the time of transfer the new and former owners are required to submit information to the Food and Drug Administration as follows:

(1) The former owner shall submit a letter or other document that states that all rights to the application have been transferred to the new owner.

(2) The new owner shall submit an application form signed by the new owner and a letter or other document containing the following:

(i) The new owner's commitment to agreements, promises, and conditions made by the former owner and contained in the application;

(ii) The date that the change is ownership is effective; and

(iii) Either a statement that the new owner has a complete copy of the approved application, including

supplements and records that are required to be kept under § 314.81, or a request for a copy of the application from FDA's files. FDA will provide a copy of the application to the new owner under the fee schedule in § 20.42 of FDA's public information regulations.

(b) The new owner shall advise FDA about any change in the conditions in the approved application under § 314.70, except the new owner may advise FDA in the next annual report about a change in the drug product's label or labeling to change the product's brand or the name of its manufacturer, packer, or distributor.

**§ 314.80 Postmarketing reporting of adverse drug experiences.**

(a) *Definitions.* The following definitions of terms apply to this section:

"Adverse drug experience" means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any significant failure of expected pharmacological action.

"Increased frequency" means an absolute increase in the number of reports of an adverse drug experience received during a specified time period compared to the number of similar adverse drug experience reports received during an equivalent time period in the past.

"Serious" means an adverse drug experience that is life threatening, is permanently disabling, requires inpatient hospitalization, or requires prescription drug therapy. In addition, an adverse drug experience with one of the following outcomes is always considered serious: death, congenital anomaly, cancer, or overdose.

"Unexpected" means an adverse drug experience that is not listed in the current labeling for the drug and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of greater severity or specificity. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the labeling only listed cerebral vascular accidents.

(b) *Review of adverse drug experiences.* Each applicant having an approved application under § 314.50 or § 314.55 shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.

(c) *Reporting requirements.* The applicant shall report to FDA adverse drug experience information, as described in this section. The applicant shall submit two copies of each report described in this section to the Division of Drug and Biological Product Experience (HFN-70), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. FDA may waive the requirement for the second copy in appropriate instances.

(1) *Fifteen-day "Alert reports."* (i) The applicant shall report each adverse drug experience that is both serious and unexpected, regardless of source, as soon as possible but in any case within 15 working days of initial receipt of the information. These reports are required to be submitted on Form FDA-1639 (Drug Experience Report). The applicant shall promptly investigate all adverse drug experiences that are the subject of these 15-day Alert reports and shall submit followup reports within 15 working days of receipt of new information or as requested by FDA. If additional information is not obtainable, a followup report may be required that describes briefly the steps taken to seek additional information and the reasons why it could not be obtained. These 15-day Alert reports and followups to them are required to be submitted under separate cover and may not be included, except for summary or tabular purposes, in a periodic report.

(ii) The applicant shall review periodically (at least as often as the periodic reporting cycle) the frequency of reports of adverse drug experiences that are both serious and expected, regardless of source, and report any significant increase in frequency as soon as possible but in any case within 15 working days of determining that a significant increase in frequency exists. Upon written notice, FDA may require that applicants review the frequency of reports of serious, expected adverse drug experiences at intervals different than the periodic reporting cycle. Reports of a significant increase in frequency are required to be submitted in narrative form (including the time period on which the increased frequency is based, the method of analysis, and the interpretation of the results), rather than using Form FDA-1639. Fifteen-day Alert reports based on increased frequency are required to be submitted under separate cover and may not be included, except for summary purposes, in a periodic report.

(iii) The requirements of paragraph (c)(1) (i) and (ii) of this section, concerning the submission of 15-day alert reports, shall also apply to any person (other than the applicant) whose name appears on the label of an approved drug product as a manufacturer, packer, or distributor. However, in order to avoid unnecessary duplication in the submission to FDA, and followup to, reports required by paragraph (c)(1) (i) and (ii) of this section, obligations of a nonapplicant may be met by submission of all reports of serious adverse drug experiences to the applicant. If a nonapplicant elects to submit adverse drug experience reports to the applicant rather than to FDA, it shall submit each report to the applicant within 3 working days of its receipt by the nonapplicant, and the applicant shall then comply with the requirements of this section. Under this circumstance, the nonapplicant shall maintain a record of this action which shall include:

(*a*) A copy of the drug experience report.

(*b*) Date the report was received by the nonapplicant.

(*c*) Date the report was submitted to the applicant.

(*d*) Name and address of the applicant.

(iv) Each report submitted under this paragraph shall bear prominent identification as to its contents, i.e., "15-day Alert report" or "15-day Alert report—followup."

(2) *Periodic adverse drug experience reports.* (i) The applicant shall report each adverse drug experience not reported under paragraph (c)(1)(i) of this section at quarterly intervals, for 3 years from the date of approval of the application, and then at annual intervals. The applicant shall submit each quarterly report within 30 days of the close of the quarter (the first quarter beginning on the date of approval of the application) and each annual report within 60 days of the anniversary date of approval of the application. Upon written notice, FDA may extend or reestablish the requirement that an applicant submit quarterly reports, or require that the applicant submit reports under this section at different times than those stated. For example, the agency

may reestablish a quarterly reporting requirement following the approval of a major supplement. Followup information to adverse drug experiences submitted in a periodic report may be submitted in the next periodic report.

(ii) Each periodic report is required to contain: (*a*) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval (all 15-day Alert reports being appropriately referenced by the applicant's patient identification number, adverse reaction term(s), and date of submission to FDA); (*b*) a Form FDA–1639 (Drug Experience Report) for each adverse drug experience not reported under paragraph (c)(1)(i) of this section (with an index consisting of a line listing of the applicant's patient identification number and adverse reaction term(s); and (*c*) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

(iii) Periodic reporting, except for information regarding 15-day Alert reports, does not apply to adverse drug experience information obtained from postmarketing clinical trials (whether or not conducted under an investigational new drug application), from reports in the scientific literature, and from foreign marketing experience.

(d) *Scientific literature.* (1) A 15-day Alert report based on information from the scientific literature is required to be accompanied by a copy of the published article. The 15-day reporting requirements in paragraph (c)(1)(i) of this section (i.e., serious, unexpected adverse drug experiences) apply only to reports found in scientific and medical journals either as case reports or as the result of a formal clinical trial. The 15-day reporting requirements in paragraph (c)(1)(ii) of this section (i.e., a significant increase in frequency of a serious, expected adverse drug experience) apply only to reports found in scientific and medical journals either as the result of a formal clinical trial, or from epidemiologic studies or analyses of experience in a monitored series of patients.

(2) As with all reports submitted under paragraph (c)(1)(i) of this section, reports based on the scientific literature shall be submitted on Form FDA–1639 or comparable format as prescribed by paragraph (f) of this section. In cases where the applicant believes that preparing the Form FDA–1639 constitutes an undue hardship, the applicant may arrange with the Division of Drug and Biological Product Experience for an acceptable alternative reporting format.

(e) *Postmarketing epidemiological/surveillance studies.* Adverse drug experiences from postmarketing epidemiological/surveillance studies, except for 15-day Alert reports, may be submitted following the completion of the study in the next periodic report. (A study is considered completed 1 year after it is concluded.) The applicant shall separate and clearly mark reports of adverse drug experiences that occur during such a postmarketing study as being distinct from those experiences that are being reported spontaneously to the applicant. Applicants are encouraged to submit such reports utilizing an alternative format to Form FDA–1639, as provided in paragraph (f)(3) of this section.

(f) *Reporting Form FDA–1639.* (1) Except as provided in paragraphs (c)(1)(ii) and (f)(3) of this section, the applicant shall complete a Form FDA–1639 (Drug Experience Report) for each report of an adverse drug experience.

(2) Each completed Form FDA–1639 should refer only to an individual patient or a single attached publication.

(3) Instead of using Form FDA–1639, an applicant may use a computer-generated FDA–1639 or other alternative format (e.g., a computer-generated tape or tabular listing) provided that: (i) The content of the alternative format is equivalent in all elements of information to those specified in Form FDA–1639; and (ii) the format is agreed to in advance by the Division of Drug and Biological Experience (HFN–730).

(4) Single copies of Form FDA–1639 may be obtained from the Division of Drug and Biological Product Experience (HFN–730), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Supplies of Form FDA–1639 may be obtained from the PHS Forms and Publications Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857.

(g) *Multiple reports.* An applicant should not include in reports under this section any adverse drug experiences that occurred in clinical trials if they were previously submitted as part of the approved application. If a report applies to a drug for which an applicant holds more than one approved application, the applicant should submit the report to the application that was first approved. If a report refers to more than one drug marketed by an applicant, the applicant should submit the report to the application for the drug listed first in the report.

(h) *Patient privacy.* An applicant should not include in reports under this section the names and addresses of individual patients; instead, the applicant should assign a unique code number to each report, preferably not more than eight characters in length. The applicant should include the name of the reporter from whom the information was received. Names of patients, health care professionals, hospitals, and geographical identifiers in adverse drug experience reports are not resaleable to the public under FDA's public information regulations in Part 20.

(i) *Recordkeeping.* The applicant shall maintain for a period of 10 years records of all adverse drug experiences known to the applicant, including raw data and any correspondence relating to adverse drug experiences.

(j) *Guideline.* FDA has prepared under § 10.90(b) a guideline for the submission of reports of adverse drug experiences and suggested followup investigation of reports.

(k) *Withdrawal of approval.* If an applicant fails to establish and maintain records and make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.

(l) *Disclaimer.* A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect. An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the drug caused or contributed to an adverse effect. For purposes of this provision, the term "applicant" also includes any person reporting under paragraph (c)(1)(iii) of this section.

**§ 314.81 Other postmarketing reports.**

(a) *Applicability.* Each applicant shall make the reports for each of its approved applications and abbreviated applications required under this section and sections 505(j) and 507(g) of the act.

(b) *Reporting requirements.* The applicant shall submit to the Food and Drug Administration at the specified times two copies of the following reports:

(1) *NDA—Field alert report.* The applicant shall submit information of the following kinds about distributed drug products and articles to the FDA district office that is responsible for the facility

involved within 3 working days of receipt by the applicant. The information may be provided by telephone or other rapid communication means, with prompt written followup. The report and its mailing cover should be plainly marked: "NDA—Field Alert Report."

(i) Information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article.

(ii) Information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of the drug product to meet the specifications established for it in the application.

(2) *Annual report.* The applicant shall submit the following information in the order listed each year within 60 days of the anniversary date of approval of the application. The applicant shall submit the report to the FDA division responsible for reviewing the application. Each annual report is required to be accompanied by a completed transmittal Form FDA-2252 (Transmittal of Periodic Reports for Drugs for Human Use) which may be obtained from the PHS Forms and Publications Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857, and is required to include all the information required under this section that the applicant received or otherwise obtained during the annual reporting interval which ends on the anniversary date. The report is required to contain the following:

(i) *Summary.* A brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of the new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

(ii) *Distribution data.* Information about the quantity of the drug product distributed under the approved application, including that distributed to distributors. The information is required to include the National Drug Code (NDC) number, the total number of dosage units of each strength or potency distributed (e.g., 100,000/5 milligram tablets, 50,000/10 milliliter vials), and the quantities distributed for domestic use and the quantities distributed for foreign use. Disclosure of financial or pricing data is not required.

(iii) *Labeling.* Currently used professional labeling, patient brochures or package inserts (if any), a representative sample of the package labels, and a summary of any changes in labeling that have been made since the last report listed by date in the order in which they were implemented, or if no changes, a statement of that fact.

(iv) *Chemistry, manufacturing, and controls changes.* (*a*) Reports of experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties of the drug (such as the drug's behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effects of microorganisms on the drug). These reports are only required for new information that may affect FDA's previous conclusions about the safety or effectiveness of the drug product.

(*b*) A full description of the manufacturing and controls changes not requiring a supplemental application under § 314.70 (b) and (c), listed by date in the order in which they were implemented.

(v) *Nonclinical laboratory studies.* Copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the applicant concerning the ingredients in the drug product. The applicant shall submit a copy of a published report if requested by FDA.

(vi) *Clinical data.* (*a*) Published clinical trials of the drug (or abstracts of them), including clinical trials on safety and effectiveness; clinical trials on new uses; biopharmaceutic, pharmacokinetic, and clinical pharmacology studies; and reports of clinical experience pertinent to safety (for example, epidemiologic studies or analyses of experience in a monitored series of patients) conducted by or otherwise obtained by the applicant. Review articles, papers describing the use of the drug product in medical practice, papers and abstracts in which the drug is used as a research tool, promotional articles, press clippings, and papers that do not contain tabulations or summaries of original data should not be reported.

(*b*) Summaries of completed unpublished clinical trials, or prepublication manuscripts if available, conducted by, or otherwise obtained by, the applicant. Supporting information should not be reported. (A study is considered completed 1 year after it is concluded.)

(vii) *Status reports.* A statement on the current status of any postmarketing studies performed by, or on behalf of, the applicant. To facilitate communications between FDA and the applicant, the report may, at the applicant's discretion, also contain a list of any open regulatory business with FDA concerning the drug product subject to the application.

(3) *Other reporting*—(i) *Advertisements and promotional labeling.* The applicant shall submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Mailing pieces and labeling that are designed to contain samples of a drug product are required to be complete, except the sample of the drug product may be omitted. Each submission is required to be accompanied by a completed transmittal Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) and is required to include a copy of the product's current professional labeling. Form FDA-2253 may be obtained from the PHS Forms and Publications Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857.

(ii) *Special reports.* Upon written request the agency may require that the applicant submit the reports under this section at different times than those stated.

(c) *General requirements*—(1) *Multiple applications.* For all reports required by this section, the applicant shall submit the information common to more than one application only to the application first approved, and shall not report separately on each application. The submission is required to identify all the applications to which the report applies.

(2) *Patient identification.* Applicants should not include in reports under this section the names and addresses of individual patients; instead, the applicant should code the patient names whenever possible and retain the code in the applicant's files. The applicant shall maintain sufficient patient identification information to permit FDA, by using that information alone or along with records maintained by the investigator of a study, to identify the name and address of individual patients; this will ordinarily occur only when the agency needs to investigate the reports further or when there is reason to believe that the reports do not represent actual results obtained.

(d) *Withdrawal of approval.* If an applicant fails to make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug

product that is the subject of the application.

**§ 314.90 Waivers.**

(a) An applicant may ask the Food and Drug Administration to waive under this section any requirement that applies to the applicant under §§ 314.50 through 314.81. An applicant may ask FDA to waive under § 314.126(c) any criteria of an adequate and well-controlled study described in § 314.126(b). A waiver request under this section is required to be submitted with supporting documentation in an application, or in an amendment or supplement to an application. The waiver request is required to contain one of the following:

(1) An explanation why the applicant's compliance with the requirement is unnecessary or cannot be achieved;

(2) A description of an alternative submission that satisfies the purpose of the requirement; or

(3) Other information justifying a waiver.

(b) FDA may grant a waiver if it finds one of the following:

(1) The applicant's compliance with the requirement is unnecessary for the agency to evaluate the application or compliance cannot be achieved;

(2) The applicant's alternative submission satisfies the requirement; or

(3) The applicant's submission otherwise justifies a waiver.

## Subpart C—FDA Action on Applications

**§ 314.100 Time frames for reviewing applications.**

(a) Within 180 days of receipt of an application, the Food and Drug Administration will review it and send the applicant either an approval letter under § 314.105, an approvable letter under § 314.110, or a not approvable letter under § 314.120. This 180-day period is called the "review clock."

(b) During the review period an applicant may withdraw an application under § 314.65 and later resubmit it. FDA will then follow the same procedure as if a new application were submitted.

(c) The time period may be extended by mutual agreement between FDA and an applicant or, as provided in § 314.60, as the result of a major amendment.

**§ 314.101 Filing an application.**

(a) Within 60 days after the Food and Drug Administration receives an application, the agency will determine whether the application may be filed. The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review.

(b) If FDA finds that none of the reasons in paragraphs (d) and (e) of this section for refusing to file the application apply, the agency will file the application and notify the applicant in writing. The date of filing will be the date 60 days after the date FDA received the application. The date of filing begins the 180-day period described in section 505(c) of the act. This 180-day period is called the "filing clock."

(c) If FDA refuses to file the application, the agency will notify the applicant in writing and state the reason under paragraph (d) or (e) of this section for the refusal. If FDA refuses to file the application under paragraph (d) of this section, the applicant may request in writing within 30 days of the date of the agency's notification an informal conference with the agency about whether the agency should file the application. If following the informal conference the applicant requests that FDA file the application (with or without amendments to correct the deficiencies), the agency will file the application over protest under paragraph (b) of this section, notify the applicant in writing, and review it as filed. If the application is filed over protest, the date of filing will be the date 60 days after the date the applicant requested the informal conference. The applicant need not resubmit a copy of an application that is filed over protest. If FDA refuses to file the application under paragraph (e) of this section, the applicant may amend the application and resubmit it and the agency will make a determination under this section whether it may be filed.

(d) FDA may refuse to file an application if any of the following applies.

(1) The application does not contain a completed application form.

(2) The application is not submitted in the form required under § 314.50 or § 314.55.

(3) The application is incomplete because it does not on its face contain information required under section 505(b) (1), (2), (3), (4), (5), and (6) or section 507 of the act and § 314.50 or § 314.55.

(4) The application does not contain an environmental impact analysis report analyzing under § 25.1 the environmental impact of the manufacturing process and the ultimate use or consumption of the drug.

(5) The application does not contain an accurate and complete English translation of each part of the application that is not in English.

(6) The application does not contain a statement for each nonclinical laboratory study that it was conducted in compliance with the requirements set forth in Part 58, or, for each study not conducted in compliance with Part 58, a brief statement of the reason for the noncompliance.

(7) The application does not contain a statement for each clinical study that it was conducted in compliance with the institutional review board regulations in Part 56, or was not subject to those regulations, and that it was conducted in compliance with the informed consent regulations in Part 50; or, if the study was subject to but was not conducted in compliance with those regulations, the application does not contain a brief statement of the reason for the noncompliance.

(e) The agency will refuse to file an application if any of the following applies:

(1) The drug product that is the subject of the submission is already coverd by an approved application.

(2) The submission purports to be an abbreviated application under § 314.55, but the drug product is not one for which FDA has made a finding that an abbreviated application is acceptable under § 314.55(b). FDA will file a copy of the application as a citizen petition under § 10.30 seeking a finding under § 314.55 that an abbreviated application is acceptable for the drug product, and so notify the applicant in writing.

(3) The drug product is subject to licensing by FDA under the Public Health Service Act (58 Stat. 632 as amended (42 U.S.C. 201 et seq.)) and Subchapter F of Chapter I of Title 21 of the Code of Federal Regulations.

(f) (1) Within 180 days after the date of filing, plus the period of time the review period was extended (if any), FDA will either (i) approve the application or (ii) issue a notice of opportunity for hearing if the applicant asked FDA to provide it an opportunity for a hearing on an application in response to an approvable letter or a not approvable letter.

(2) This paragraph does not apply to applications that have been withdrawn from FDA review by the applicant.

**§ 314.102 Communication between FDA and applicants.**

(a) *General principles.* During the course of reviewing an application, FDA shall communicate with applicants about scientific, medical, and procedural issues that arise during the review process. Such communication may take the form of telephone conversations, letters, or meetings, whichever is most

appropriate to discuss the particular issue at hand. Communications shall be appropriately documented in the application in accordance with § 10.65. Further details on the procedures for communication between FDA and applicants are contained in a staff manual guide that is publicly available.

(b) *Notification of easily correctable deficiencies.* FDA reviewers shall make every reasonable effort to communicate promptly to applicants easily correctable deficiencies found in an application when those deficiencies are discovered, particularly deficiencies concerning chemistry, manufacturing, and controls issues. The agency will also inform applicants promptly of its need for more data or information or for technical changes in the application needed to facilitate the agency's review. This early communication is intended to permit applicants to correct such readily identified deficiencies relatively early in the review process and to submit an amendment before the review period has elapsed. Such early communication would not ordinarily apply to major scientific issues, which require consideration of the entire pending application by agency managers as well as reviewing staff. Instead, these major scientific issues will ordinarily be addressed in an action letter.

(c) *Ninety-day conference.* Approximately 90 days after the agency receives the application, FDA will provide applicants with an opportunity to meet with agency reviewing officials. The purpose of the meeting will be to inform applicants of the general progress and status of their applications, and to advise applicants of deficiencies which have been identified by that time and which have not already been communicated. This meeting will be available on applications for all new chemical entities and major new indications of marketed drugs. Such meetings will be held at the applicant's option, and may be held by telephone if mutually agreed upon.

(d) *End-of-review conference.* At the conclusion of FDA's review of an application, as designated by the issuance of an approvable or not approvable letter, FDA will provide applicants with an opportunity to meet with agency reviewing officials. The purpose of the meeting will be to discuss what further steps need to be taken by the applicant before the application can be approved. This meeting will be available on all applications, with priority given to applications for new chemical entities and major new indications for marketed drugs. Requests for such meetings shall be directed to the director of the division responsible for reviewing the application.

(e) *Other meetings.* Other meetings between FDA and applicants may be held, with advance notice, to discuss scientific, medical, and other issues that arise during the review process. Requests for meetings shall be directed to the director of the division responsible for reviewing the application. FDA will make every attempt to grant requests for meetings that involve important issues and that can be scheduled at mutually convenient times. However, "drop-in" visits (i.e., an unannounced and unscheduled visit by a company representative) are discouraged except for urgent matters, such as to discuss an important new safety issue.

**§ 314.103 Dispute resolution.**

(a) *General.* The Food and Drug Administration is committed to resolving differences between applicants and FDA reviewing divisions with respect to technical requirements for applications as quickly and amicably as possible through the cooperative exchange of information and views.

(b) *Administrative and procedural issues.* When administrative or procedural disputes arise, the applicant should first attempt to resolve the matter with the division responsible for reviewing the application, beginning with the consumer safety officer assigned to the application. If resolution is not achieved, the applicant may raise the matter with the person designated as ombudsman, whose function shall be to investigate what has happened and to facilitate a timely and equitable resolution. Appropriate issues to raise with the ombudsman include resolving difficulties in scheduling meetings, obtaining timely replies to inquiries, and obtaining timely completion of pending reviews. Further details on this procedure are contained in a staff manual guide that is publicly available under FDA's public information regulations in Part 20.

(c) *Scientific and medical disputes.* (1) Because major scientific issues are ordinarily communicated to applicants in an approvable or not approvable letter pursuant to § 314.110 or § 314.120, respectively, the "end-of-review conference" described in § 314.102(d) will provide a timely forum for discussing and resolving, if possible, scientific and medical issues on which the applicant disagrees with the agency. In addition, the "ninety-day conference" described in § 314.102(c) will provide a timely forum for discussing and resolving, if possible, issues identified by that date.

(2) When scientific or medical disputes arise at other times during the review process, applicants should discuss the matter directly with the responsible reviewing officials. If necessary, applicants may request a meeting with the appropriate reviewing officials and management representatives in order to seek a resolution. Ordinarily, such meetings would be held first with the Division Director, then with the Office Director, and finally with the Center Director if the matter is still unresolved. Requests for such meetings shall be directed to the director of the division responsible for reviewing the application. FDA will make every attempt to grant requests for meetings that involve important issues and that can be scheduled at mutually convenient times.

(3) In requesting a meeting designed to resolve a scientific or medical dispute, applicants may suggest that FDA seek the advice of outside experts, in which case FDA may, in its discretion, invite to the meeting one or more of its advisory committee members or other consultants, as designated by the agency. Applicants may also bring their own consultants. For major scientific and medical policy issues not resolved by informal meetings, FDA may refer the matter to one of is standing advisory committees for its consideration and recommendations.

**§ 314.104 Drugs with potential for abuse.**

The Food and Drug Administration will inform the Drug Enforcement Administration under section 201(f) of the Controlled Substances Act (21 U.S.C. 801) when an application is submitted for a drug that appears to have an abuse potential.

**§ 314.105 Approval of an application.**

(a) The Food and Drug Administration will approve an application and send the applicant an approval letter if none of the reasons in § 314.125 for refusing to approve the application apply. The date of the agency's approval letter is the date of approval of the application. When FDA sends an applicant an approval letter for an antibiotic, it will promulgate a regulation under § 314.300 providing for certification of the drug, if necessary. A new drug product or antibiotic may not be marketed until an approval letter is issued. Marketing of an antibiotic need not await the promulgation of a regulation under § 314.300.

(b) FDA will approve an application and issue the applicant an approval

letter (rather than an approvable letter under § 314.110) on the basis of draft labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.

(c) FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling. While the statutory standards apply to all drugs, the many kinds of drugs that are subject to them and the wide range of uses for those drugs demand flexibility in applying the standards. Thus FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet them. FDA makes its views on drug products and classes of drugs available through guidelines, recommendations, and other statements of policy.

**§ 314.106 Foreign data.**

(a) *General.* The acceptance of foreign data in an application generally is governed by § 312.20.

(b) *As sole basis for marketing approval.* An application based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if: (1) The foreign data are applicable to the U.S. population and U.S. medical practice; (2) the studies have been performed by clinical investigators of recognized competence; and (3) the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means. Failure of an application to meet any of these criteria will result in the application not being approvable based on the foreign data alone. FDA will apply this policy in a flexible manner according to the nature of the drug and the data being considered.

(c) *Consultation between FDA and applicants.* Applicants are encouraged to meet with agency officials in a "presubmission" meeting when approval based solely on foreign data will be sought.

**§ 314.110 Approvable letter to the applicant.**

In selected circumstances it is useful at the end of the review period for the Food and Drug Administration to indicate to the applicant that the application is basically approvable providing certain issues are resolved. An approvable letter may be issued in such circumstances. FDA will send the applicant an approvable letter if the application substantially meets the requirements of this part and the agency believes that it can approve the application if specific additional information or material is submitted or specific conditions (for example, certain changes in labeling) are agreed to by the applicant. The approvable letter will describe the information or material FDA requires or the conditions the applicant is asked to meet. As a practical matter, the approvable letter will serve in most instances as a mechanism for resolving outstanding issues on drugs that are about to be approved and marketed. Within 10 days after the date of the approvable letter, the applicant shall either:

(a) Amend the application or notify FDA of an intent to file an amendment. The filing of an amendment or notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period for 45 days after the date FDA receives the amendment. The extension is to permit the agency to review the amendment.

(b) Withdraw the application. FDA will consider the applicant's failure to respond within 10 days to an approvable letter to be a request by the applicant to withdraw the application under § 314.65. A decision to withdraw an application is without prejudice to a refiling.

(c) For a new drug, ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) of the act. The applicant shall submit the request to the Division of Regulatory Affairs (HFN-360), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Within 60 days of the date of the approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application under § 314.105 or refuse to approve the application under § 314.125 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(2) of the act on the question of whether there are grounds for denying approval of the application under section 505(d) of the act.

(d) For an antibiotic, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(f) of the act.

(e) Notify FDA that the applicant agrees to an extension of the review period under section 505(c) of the act, so that the applicant can determine whether to respond further under paragraph (a), (b), (c), or (d) of this section. The applicant's notice is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will consider the applicant's failure to respond further within the extended review period to be a request to withdraw the application under § 314.65. A decision to withdraw an application is without prejudice to a refiling.

**§ 314.120 Not approvable letter to the applicant.**

The Food and Drug Administration will send the applicant a not approvable letter if the agency believes that the application may not be approved for one of the reasons given in § 314.125. The not approvable letter will describe the deficiencies in the application. Within 10 days after the date of the not approvable letter, the applicant shall either:

(a) Amend the application or notify FDA of an intent to file an amendment. The filing of an amendment or a notice of intent to file an amendment constitutes an agreement by the applicant to extend the review period under § 314.60.

(b) Withdraw the application. FDA will consider the applicant's failure to respond within 10 days to a not approvable letter to be a request by the applicant to withdraw the application under § 314.65. A decision to withdraw the application is without prejudice to refiling.

(c) For a new drug, ask the agency to provide the applicant an opportunity for a hearing on the question of whether there are grounds for denying approval of the application under section 505(d) of the act. The applicant shall submit the request to the Division of Regulatory Affairs (HFN-360), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Within 60 days of the date of the not approvable letter, or within a different time period to which FDA and the applicant agree, the agency will either approve the application under § 314.105 or refuse to approve the application under § 314.125 and give the applicant written notice of an opportunity for a hearing under § 314.200 and section 505(c)(2) of the act on the question of whether there are grounds for denying approval of the

application under section 505(d) of the act.

(d) For an antibiotic, file a petition or notify FDA of an intent to file a petition proposing the issuance, amendment, or repeal of a regulation under § 314.300 and section 507(f) of the act.

(e) Notify FDA that the applicant agrees to an extension of the review period under section 505(c) of the act, so that the applicant can determine whether to respond further under paragraph (a), (b), (c), or (d) of this section. The applicant's notice is required to state the length of the extension. FDA will honor any reasonable request for such an extension. FDA will consider the applicant's failure to respond further within the extended review period to be a request to withdraw the application under § 314.65. A decision to withdraw an application is without prejudice to a refiling.

**§ 314.125 Refusal to approve an application.**

(a) The Food and Drug Administration will refuse to approve the application and for a new drug give the applicant written notice of an opportunity for a hearing under § 314.200 on the question of whether there are grounds for denying approval of the application under section 505(d) of the act, or for an antibiotic publish a proposed regulation based on an acceptable petition under § 314.300, if:

(1) FDA sends the applicant an approvable or a not approvable letter under § 314.110 or § 314.120;

(2) The applicant requests an opportunity for hearing for a new drug on the question of whether the application is approvable or files a petition for an antibiotic proposing the issuance, amendment, or repeal of a regulation; and

(3) FDA finds that any of the reasons given in paragraph (b) of this section apply.

(b) FDA may refuse to approve an application for any of the following reasons:

(1) The methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance or the drug product are inadequate to preserve its identity, strength, quality, purity, stability, and bioavailability.

(2) The investigations required under section 505(b) or 507 of the act do not include adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.

(3) The results of the tests show that the drug is unsafe for use under the conditions prescribed, recommended, or suggested in its proposed labeling or the results do not show that the drug product is safe for use under those conditions.

(4) There is insufficient information about the drug to determine whether the product is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.

(5) There is a lack of substantial evidence consisting of adequate and well-controlled investigations, as defined in § 314.126, that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling.

(6) The proposed labeling is false or misleading in any particular.

(7) The application contains an untrue statement of a material fact.

(8) The drug product's proposed labeling does not comply with the requirements for labels and labeling in Part 201.

(9) The application does not contain bioavailability or bioequivalence data required under Part 320.

(10) A reason given in a letter refusing to file the application under § 314.101(d), if the deficiency is not corrected.

(11) The drug will be manufactured or processed in whole or in part in an establishment that is not registered and not exempt from registration under section 510 of the act and Part 207.

(12) The applicant does not permit a properly authorized officer or employee of the Department of Health and Human Services an adequate opportunity to inspect the facilities, controls, and any records relevant to the application.

(13) The methods to be used in, and the facilities and controls used for, the manufacture, processing, packing, or holding of the drug substance or the drug product do not comply with the current good manufacturing practice regulations in Parts 210 and 211.

(14) The application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source.

(15) A nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations in Part 58 and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(16) Any clinical investigation involving human subjects described in the application, subject to the institutional review board regulations in Part 56 or informed consent regulations in Part 50, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

**§ 314.126 Adequate and well-controlled studies.**

(a) The purpose of conducting clinical investigations of a drug is to distinguish the effect of a drug from other influences, such as spontaneous change in the course of the disease, placebo effect, or biased observation. The characteristics described in paragraph (b) of this section have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation. The Food and Drug Administration considers these characteristics in determining whether an investigation is adequate and well-controlled for purposes of sections 505 and 507 of the act. Reports of adequate and well-controlled investigations provide the primary basis for determining whether there is "substantial evidence" to support the claims of effectiveness for new drugs and antibiotics. Therefore, the study report should provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.

(b) An adequate and well-controlled study has the following characteristics:

(1) There is a clear statement of the objectives of the investigation and a summary of the proposed or actual methods of analysis in the protocol for the study and in the report of its results. In addition, the protocol should contain a description of the proposed methods of analysis, and the study report should contain a description of the methods of analysis ultimately used. If the protocol does not contain a description of the proposed methods of analysis, the study report should describe how the methods used were selected.

(2) The study uses a design that permits a valid comparison with a control to provide a quantitative

assessment of drug effect. The protocol for the study and report of results should describe the study design precisely; for example, duration of treatment periods, whether treatments are parallel, sequential, or crossover, and whether the sample size is predetermined or based upon some interim analysis. Generally, the following types of control are recognized:

(i) *Placebo concurrent control.* The test drug is compared with an inactive preparation designed to resemble the test drug as far as possible. A placebo-controlled study may include additional treatment groups, such as an active treatment control or a dose-comparison control, and usually includes randomization and blinding of patients or investigators, or both.

(ii) *Dose-comparison concurrent control.* At least two doses of the drug are compared. A dose-comparison study may include additional treatment groups, such as placebo control or active control. Dose-comparison trials usually include randomization and blinding of patients or investigators, or both.

(iii) *No treatment concurrent control.* Where objective measurements of effectiveness are available and placebo effect is negligible, the test drug is compared with no treatment. No treatment concurrent control trials usually include randomization.

(iv) *Active treatment concurrent control.* The test drug is compared with known effective therapy; for example, where the condition treated is such that administration of placebo or no treatment would be contrary to the interest of the patient. An active treatment study may include additional treatment groups, however, such as a placebo control or a dose-comparison control. Active treatment trials usually include randomization and blinding of patients or investigators, or both. If the intent of the trial is to show similarity of the test and control drugs, the report of the study should assess the ability of the study to have detected a difference between treatments. Similarity of test drug and active control can mean either that both drugs were effective or that neither was effective. The analysis of the study should explain why the drugs should be considered effective in the study, for example, by reference to results in previous placebo-controlled studies of the active control drug.

(v) *Historical control.* The results of treatment with the test drug are compared with experience historically derived from the adequately documented natural history of the disease or condition, or from the results of active treatment, in comparable patients or populations. Because historical control populations usually cannot be as well assessed with respect to pertinent variables as can concurrent control populations, historical control designs are usually reserved for special circumstances. Examples include studies of diseases with high and predictable mortality (for example, certain malignancies) and studies in which the effect of the drug is self-evident (general anesthetics, drug metabolism).

(3) The method of selection of subjects provides adequate assurance that they have the disease or condition being studied, or evidence of susceptibility and exposure to the condition against which prophylaxis is directed.

(4) The method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables such as age, sex, severity of disease, duration of disease, and use of drugs or therapy other than the test drug. The protocol for the study and the report of its results should describe how subjects were assigned to groups. Ordinarily, in a concurrently controlled study, assignment is by randomization, with or without stratification.

(5) Adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data. The protocol and report of the study should describe the procedures used to accomplish this, such as blinding.

(6) The methods of assessment of subjects' response are well-defined and reliable. The protocol for the study and the report of results should explain the variables measured, the methods of observation, and criteria used to assess response.

(7) There is an analysis of the results of the study adequate to assess the effects of the drug. The report of the study should describe the results and the analytic methods used to evaluate them, including any appropriate statistical methods. The analysis should assess, among other things, the comparability of test and control groups with respect to pertinent variables, and the effects of any interim data analyses performed.

(c) The Director of the Center for Drugs and Biologics may, on the Director's own initiative or on the petition of an interested person, waive in whole or in part any of the criteria in paragraph (b) of this section with respect to a specific clinical investigation, either prior to the investigation or in the evaluation of a completed study. A petition for a waiver is required to set forth clearly and concisely the specific criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical investigation, what alternative procedures, if any, are to be, or have been employed, and what results have been obtained. The petition is also required to state why the clinical investigations so conducted will yield, or have yielded, substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(d) For an investigation to be considered adequate for approval of a new drug, it is required that the test drug be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(e) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

**§ 314.150 Withdrawal of approval of an application.**

(a) The Food and Drug Administration will notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act under the procedure in § 314.300, if any of the following applies:

(1) The Secretary of Health and Human Services has suspended the approval of the application for a new drug on a finding that there is an imminent hazard to the public health. FDA will promptly afford the applicant an expedited hearing following summary suspension on a finding of imminent hazard to health.

(2) FDA finds:

(i) That clinical or other experience, tests, or other scientific data show that the drug is unsafe for use under the

conditions of use upon the basis of which the application was approved; or

(ii) That new evidence of clinical experience, not contained in the application or not available to FDA until after the application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when the application was approved, evaluated together with the evidence available when the application was approved, reveal that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or

(iii) Upon the basis of new information before FDA with respect to the drug, evaluated together with the evidence available when the application was approved, that there is a lack of substantial evidence from adequate and well-controlled investigations as defined in § 314.126, that the drug will have the effect it is purported or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling; or

(iv) That the application contains any untrue statement of a material fact.

(b) FDA may notify the applicant, and, if appropriate, all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, and for a new drug afford an opportunity for a hearing on a proposal to withdraw approval of the application under section 505(e) of the act and under the procedure in § 314.200, or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and the procedure in § 314.300, if the agency finds:

(1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports under section 505(j) or 507(g) of the act and §§ 314.80 and 314.81, or that the applicant has refused to permit access to, or copying or verification of, its records.

(2) That on the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the agency.

(3) That on the basis of new information before FDA, evaluated together with the evidence available when the application was approved, the labeling of the drug, based on a fair evaluation of all material facts, is false or misleading in any particular; and the labeling was not corrected by the applicant within a reasonable time after receipt of written notice from the agency.

(4) That the applicant has failed to comply with the notice requirements of section 510(j)(2) of the act.

(5) That the applicant has failed to submit bioavailability or bioequivalence data required under Part 320.

(6) The application does not contain an explanation of the omission of a report of any investigation of the drug product sponsored by the applicant, or an explanation of the omission of other information about the drug pertinent to an evaluation of the application that is received or otherwise obtained by the applicant from any source.

(7) That any nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its labeling was not conducted in compliance with the good laboratory practice regulations in Part 58 and no reason for the noncompliance was provided or, if it was, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(8) Any clinical investigation involving human subjects described in the application, subject to the institutional review board regulations in Part 56 or informed consent regulations in Part 50, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(c) FDA will withdraw approval of an application if the applicant requests its withdrawal because the drug subject to the application is no longer being marketed, provided none of the conditions listed in paragraphs (a) and (b) of this section apply to the drug. FDA will consider a written request for withdrawal under this paragraph to be a waiver of an opportunity for hearing otherwise provided for in this section. Withdrawal of approval of an application under this paragraph is without prejudice to refiling.

(d) FDA may notify an applicant that it believes a potential problem associated with a drug is sufficiently serious that the drug should be removed from the market and may ask the applicant to waive the opportunity for hearing otherwise provided for under this section, to permit FDA to withdraw approval of the application for the product, and to remove voluntarily the product from the market. If the applicant agrees, the agency will not make a finding under paragraph (b) of this section, but will withdraw approval of the application in a notice published in the **Federal Register** that contains a brief summary of the agency's and the applicant's views of the reasons for withdrawal.

#### § 314.152 Notice of withdrawal of approval of an application for a new drug.

If the Food and Drug Administration withdraws approval of an application for a new drug, FDA will publish a notice in the **Federal Register** announcing the withdrawal of approval.

#### § 314.160 Approval of an application for which approval was previously refused, suspended, or withdrawn.

Upon the Food and Drug Administration's own initiative or upon request of an applicant, FDA may, on the basis of new data, approve an application which it had previously refused, suspended, or withdrawn approval. FDA will publish a notice in the **Federal Register** announcing the approval.

#### § 314.170 Adulteration and misbranding of an approved drug.

All drugs, including those the Food and Drug Administration approves, or provides for certification of, under sections 505, 506, and 507 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the act. FDA is authorized to regulate approved new drugs and approved antibiotic drugs by regulations issued through informal rulemaking under sections 501, 502, and 503 of the act.

### Subpart D—Hearing Procedures for New Drugs

#### § 314.200 Notice of opportunity for hearing; notice of participation and request for hearing; grant or denial of hearing.

(a) *Notice of opportunity for hearing.* The Director of the Center for Drugs and Biologics, Food and Drug Administration, will give the applicant, and all other persons who manufacture or distribute identical, related, or similar drug products as defined in § 310.6, notice and an opportunity for a hearing on the Center's proposal to refuse to approve an application or to withdraw the approval of an application. The notice will state the reasons for the action and the proposed grounds for the order.

(1) The notice may be general (that is, simply summarizing in a general way

the information resulting in the notice) or specific (that is, either referring to specific requirements in the statute and regulations with which there is a lack of compliance, or providing a detailed description and analysis of the specific facts resulting in the notice).

(2) FDA will publish the notice in the **Federal Register** and will state that the applicant, and other persons subject to the notice under § 310.6, who wishes to participate in a hearing, has 30 days after the date of publication of the notice to file a written notice of participation and request for hearing. The applicant, or other persons subject to the notice under § 310.6, who fails to file a written notice of participation and request for hearing within 30 days, waives the opportunity for a hearing.

(3) It is the responsibility of every manufacturer and distributor of a drug product to review every notice of opportunity for a hearing published in the **Federal Register** to determine whether it covers any drug product that person manufactures or distributes. Any person may request an opinion of the applicability of a notice to a specific product that may be identical, related, or similar to a product listed in a notice by writing to the Division of Drug Labeling Compliance (HFN–310), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. A person shall request an opinion within 30 days of the date of publication of the notice to be eligible for an opportunity for a hearing under the notice. If a person requests an opinion, that person's time for filing an appearance and request for a hearing and supporting studies and analyses begins on the date the person receives the opinion from FDA.

(b) FDA will provide the notice of opportunity for a hearing to applicants and to other persons subject to the notice under § 310.6, as follows:

(1) To any person who has submitted an application, by delivering the notice in person or by sending it by registered or certified mail to the last address shown in the application.

(2) To any person who has not submitted an application but who is subject to the notice under § 310.6, by publication of the notice in the **Federal Register**.

(c) (1) *Notice of participation and request for a hearing, and submission of studies and comments.* The applicant, or any other person subject to the notice under § 310.6, who wishes to participate in a hearing, shall file with the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, Rockville, MD 20857, (i) within 30 days after the date of the publication of the notice (or of the date of receipt of an opinion requested under paragraph (a)(3) of this section) a written notice of participation and request for a hearing and (ii) within 60 days after the date of publication of the notice, unless a different period of time is specified in the notice of opportunity for a hearing, the studies on which the person relies to justify a hearing as specified in paragraph (d) of this section. The applicant, or other person, may incorporate by reference the raw data underlying a study if the data were previously submitted to FDA as part of an application or other report.

(2) FDA will not consider data or analyses submitted after 60 days in determining whether a hearing is warranted unless they are derived from well-controlled studies begun before the date of the notice of opportunity for hearing and the results of the studies were not available within 60 days after the date of publication of the notice. Nevertheless, FDA may consider other studies on the basis of a showing by the person requesting a hearing of inadvertent omission and hardship. The person requesting a hearing shall list in the request for hearing all studies in progress, the results of which the person intends later to submit in support of the request for a hearing. The person shall submit under paragraph (c)(1)(ii) of this section a copy of the complete protocol, a list of the participating investigators, and a brief status report of the studies.

(3) Any other interested person who is not subject to the notice of opportunity for a hearing may also submit comments on the proposal to withdraw approval of the application. The comments are required to be submitted within the time and under the conditions specified in this section.

(d) The person requesting a hearing is required to submit under paragraph (c)(1)(ii) of this section the studies (including all protocols and underlying raw data) on which the person relies to justify a hearing with respect to the drug product. Except, a person who requests a hearing on the refusal to approve an application is not required to submit additional studies and analyses if the studies upon which the person relies have been submitted in the application and in the format and containing the summaries required under § 314.50.

(1) If the grounds for FDA's proposed action concern the effectiveness of the drug, each request for hearing is required to be supported only by adequate and well-controlled clinical studies meeting all of the precise requirements of § 314.126 and, for combination drug products, § 300.50, or by other studies not meeting those requirements for which a waiver has been previously granted by FDA under § 314.126. Each person requesting a hearing shall submit all adequate and well-controlled clinical studies on the drug product, including any unfavorable analyses, views, or judgments with respect to the studies. No other data, information, or studies may be submitted.

(2) The submission is required to include a factual analysis of all the studies submitted. If the grounds for FDA's proposed action concern the effectiveness of the drug, the analysis is required to specify how each study accords, on a point-by-point basis, with each criterion required for an adequate well-controlled clinical investigation established under § 314.126 and, if the product is a combination drug product, with each of the requirements for a combination drug established in § 300.50, or the study is required to be accompanied by an appropriate waiver previously granted by FDA. If a study concerns a drug or dosage form or condition of use or mode of administration other than the one in question, that fact is required to be clearly stated. Any study conducted on the final marketed form of the drug product is required to be clearly identified.

(3) Each person requesting a hearing shall submit an analysis of the data upon which the person relies, except that the required information relating either to safety or to effectiveness may be omitted if the notice of opportunity for hearing does not raise any issue with respect to that aspect of the drug; information on compliance with § 300.50 may be omitted if the drug product is not a combination drug product. FDA can most efficiently consider submissions made in the following format.

I. Safety data.

A. Animal safety data.

1. Individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

2. Combinations of the individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

B. Human safety data.

1. Individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

c. Documented case reports.

d. Pertinent marketing experiences that may influence a determination about the safety of each individual active component.

2. Combinations of the individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

c. Documented case reports.

d. Pertinent marketing experiences that may influence a determination about the safety of each individual active component.

II. Effectiveness data.

A. Individual active components: Controlled studies, with an analysis showing clearly how each study satisfies, on a point-by-point basis, each of the criteria required by § 314.126.

B. Combinations of individual active components.

1. Controlled studies with an analysis showing clearly how each study satisfies on a point-by-point basis, each of the criteria required by § 314.126.

2. An analysis showing clearly how each requirement of § 300.50 has been satisfied.

III. A summary of the data and views setting forth the medical rationale and purpose for the drug and its ingredients and the scientific basis for the conclusion that the drug and its ingredients have been proven safe and/or effective for the intended use. If there is an absence of controlled studies in the material submitted or the requirements of any element of § 300.50 or § 314.126 have not been fully met, that fact is required to be stated clearly and a waiver obtained under § 314.126 is required to be submitted.

IV. A statement signed by the person responsible for such submission that it includes in full (or incorporates by reference as permitted in § 314.200(c)(2)) all studies and information specified in § 314.200(d).

(Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001.)

(e) *Contentions that a drug product is not subject to the new drug requirements.* A notice of opportunity for a hearing encompasses all issues relating to the legal status of each drug product subject to it, including identical, related, and similar drug products as defined in § 310.6. A notice of appearance and request for a hearing under paragraph (c)(1)(i) of this section is required to contain any contention that the product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act, or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, contained in section 201(p) of the act or under section 107(c) of the Drug Amendments of 1962, or for any other reason. Each contention is required to be supported by a submission under paragraph (c)(1)(ii) of this section and the Commissioner of Food and Drugs will make an administrative determination on each contention. The failure of any person subject to a notice of opportunity for a hearing, including any person who manufactures or distributes an identical, related, or similar drug product as defined in § 310.6, to submit a notice of participation and request for hearing or to raise all such contentions constitutes a waiver of any contentions not raised.

(1) A contention that a drug product is generally recognized as safe and effective within the meaning of section 201(p) of the act is required to be supported by submission of the same quantity and quality of scientific evidence that is required to obtain approval of an application for the product, unless FDA has waived a requirement for effectiveness (under § 314.126) or safety, or both. The submission should be in the format and with the analyses required under paragraph (d) of this section. A person who fails to submit the required scientific evidence required under paragraph (d) waives the contention. General recognition of safety and effectiveness shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.

(2) A contention that a drug product is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, contained in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962, is required to be supported by evidence of past and present quantitative formulas, labeling, and evidence of marketing. A person who makes such a contention should submit the formulas, labeling, and evidence of marketing in the following format.

I. Formulation.

A. A copy of each pertinent document or record to establish the exact quantitative formulation of the drug (both active and inactive ingredients) on the date of initial marketing of the drug.

B. A statement whether such formulation has at any subsequent time been changed in any manner. If any such change has been made, the exact date, nature, and rational for each change in formulation, including any deletion or change in the concentration of any active ingredient and/or inactive ingredient, should be stated, together with a copy of each pertinent document or record to establish the date and nature of each such change, including, but not limited to, the formula which resulted from each such change. If no such change has been made, a copy of representative documents or records showing the formula at representative points in time should be submitted to support the statement.

II. Labeling.

A. A copy of each pertinent document or record to establish the identity of each item of written, printed, or graphic matter used as labeling on the date the drug was initially marketed.

B. A statement whether such labeling has at any subsequent time been discontinued or changed in any manner. If such discontinuance or change has been made, the exact date, nature, and rationale for each discontinuance or change and a copy of each pertinent document or record to establish each such discontinuance or change should be submitted, including, but not limited to, the labeling which resulted from each such discontinuance or change. If no such discontinuance or change has been made, a copy of representative documents or records showing labeling at representative points in time should be submitted to support the statement.

III. Marketing.

A. A copy of each pertinent document or record to establish the exact date the drug was initially marketed.

B. A statement whether such marketing has at any subsequent time been discontinued. If such marketing has been discontinued, the exact date of each such discontinuance should be submitted, together with a copy of each pertinent document or record to establish each such date.

IV. Verification.

A statement signed by the person responsible for such submission, that all appropriate records have been searched and to the best of that person's knowledge and belief it includes a true and accurate presentation of the facts.

(Warning: A willfully false statement is a criminal offense, 18 U.S.C. 1001.)

(3) The Food and Drug Administration will not find a drug product, including any active ingredient, which is identical, related, or similar, as described in § 310.6, to a drug product, including any active ingredient for which an application is or at any time has been effective or deemed approved, or approved under section 505 of the act, to be exempt from part or all of the new drug provisions of the act.

(4) A contention that a drug product is not a new drug for any other reason is required to be supported by submission of the factual records, data, and information that are necessary and appropriate to support the contention.

(5) It is the responsibility of every person who manufactures or distributes a drug product in reliance upon a "grandfather" provision of the act to maintain files that contain the data and information necessary fully to document and support that status.

(f) *Separation of functions.* Separation of functions commences upon receipt of a request for hearing. The Director of the Center for Drugs and Biologics, Food and Drug Administration, will prepare an analysis of the request and a proposed order ruling on the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response under paragraph (g) (2) or (3) of this section will be submitted to the Office of the Commissioner of Food and Drugs for

review and decision. When the Center for Drugs and Biologics recommends denial of a hearing on all issues on which a hearing is requested, no representative of the Center will participate or advise in the review and decision by the Commissioner. When the Center for Drugs and Biologics recommends that a hearing be granted on one or more issues on which a hearing is requested, separation of functions terminates as to those issues, and representatives of the Center may participate or advise in the review and decision by the Commissioner on those issues. The Commissioner may modify the text of the issues, but may not deny a hearing on those issues. Separation of functions continues with respect to issues on which the Center for Drugs and Biologics has recommended denial of a hearing. The Commissioner will neither evaluate nor rule on the Center's recommendation on such issues and such issues will not be included in the notice of hearing. Participants in the hearing may make a motion to the presiding officer for the inclusion of any such issue in the hearing. The ruling on such a motion is subject to review in accordance with § 12.35(b). Failure to so move constitutes a waiver of the right to a hearing on such an issue. Separation of functions on all issues resumes upon issuance of a notice of hearing. The Office of the General Counsel, Department of Health and Human Services, will observe the same separation of functions.

(g) *Summary judgment.* A person who requests a hearing may not rely upon allegations or denials but is required to set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing with respect to a particular drug product specified in the request for hearing.

(1) Where a specific notice of opportunity for hearing (as defined in paragraph (a)(1) of this section) is used, the Commissioner will enter summary judgment against a person who requests a hearing, making findings and conclusions, denying a hearing, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or the withdrawal of approval of the application; for example, no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.126 and, for a combination drug product, § 300.50, showing effectiveness have been identified. Any order entering summary judgment is required to set forth the Commissioner's findings and conclusions in detail and is required to specify why each study submitted fails to meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact.

(2) When following a general notice of opportunity for a hearing (as defined in paragraph (a)(1) of this section) the Director of the Center for Drugs and Biologics concludes that summary judgment against a person requesting a hearing should be considered, the Director will serve upon the person requesting a hearing by registered mail a proposed order denying a hearing. This person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(3) When following a general or specific notice of opportunity for a hearing a person requesting a hearing submits data or information of a type required by the statute and regulations, and the Director of the Center for Drugs and Biologics concludes that summary judgment against the person should be considered, the Director will serve upon the person by registered mail a proposed order denying a hearing. The person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(4) If review of the data, information, and analyses submitted show that the grounds cited in the notice are not valid, for example, that substantial evidence of effectiveness exists, the Commissioner will enter summary judgment for the person requesting the hearing, and rescind the notice of opportunity for hearing.

(5) If the Commissioner grants a hearing, it will begin within 90 days after the expiration of the time for requesting the hearing unless the parties otherwise agree in the case of denial of approval, and as soon as practicable in the case of withdrawal of approval.

(6) The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest.

(7) If the manufacturer or distributor of an identical, related, or similar drug product requests and is granted a hearing, the hearing may consider whether the product is in fact identical, related, or similar to the drug product named in the notice of opportunity for a hearing.

(8) A request for a hearing, and any subsequent grant or denial of a hearing, applies only to the drug products named in such documents.

(h) FDA will issue a notice withdrawing approval and declaring all products unlawful for drug products subject to a notice of opportunity for a hearing, including any identical, related, or similar drug product under § 310.6, for which an opportunity for a hearing is waived or for which a hearing is denied. The Commissioner may defer or stay the action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

**§ 314.201 Procedure for hearings.**

Parts 10 through 16 apply to hearings relating to new drugs under section 505 (d) and (e) of the act.

**§ 314.235 Judicial review.**

(a) The Commissioner of Food and Drugs will certify the transcript and record. In any case in which the Commissioner enters an order without a hearing under §314.200(g), the record certified by the Commissioner is required to include the requests for hearing together with the data and information submitted and the Commissioner's findings and conclusion.

(b) A manufacturer or distributor of an identical, related, or similar drug product under § 310.6 may seek judicial review of an order withdrawing approval of a new drug application, whether or not a hearing has been held, in a United States court of appeals under section 505(h) of the act.

## Subpart E—Administrative Procedures for Antibiotics

**§ 314.300 Procedure for the issuance, amendment, or repeal of regulations.**

(a) The procedures in Part 10 apply to the issuance, amendment, or repeal of regulations under section 507 of the act.

(b) (1) The Commissioner of Food and Drugs, on his or her own initiative or on the application or request of any interested person, may publish in the **Federal Register** a notice of proposed rulemaking and order to issue, amend, or repeal any regulation contemplated by section 507 of the act.

The notice and order may be general (that is, simply summarizing in a general way the information resulting in the notice and order) or specific (that is, either referring to specific requirements in the statute and regulations with which there is a lack of compliance, or

providing a detailed description and analysis of the specific facts resulting in the notice and order).

(2) The Food and Drug Administration will give interested persons an opportunity to submit written comments and to request an informal conference on the proposal, unless the notice and opportunity for comment and informal conference have already been provided in connection with the announcement of the reports of the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, to persons who will be adversely affected, or as provided in §§ 10.40(e) and 12.20(c)(2). A person is required to request an informal conference within 30 days of the notice of proposed rulemaking unless otherwise specified in the notice. If an informal conference is requested and granted, those persons participating in the conference may submit comments, within 30 days of the conference, unless otherwise specified in the proposal.

(3) It is the responsibility of every manufacturer and distributor of an antibiotic drug product to review every proposal published in the **Federal Register** to determine whether it covers any drug product that person manufactures or distributes.

(4) After considering the written comments, the results of any conference, and the data available, the Commissioner will publish an order in the **Federal Register** acting on the proposal, with an opportunity for any person who will be adversely affected to file objections, to request a hearing, and to show reasonable grounds for the hearing. Any person who wishes to participate in a hearing, shall file with the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, (i) within 30 days after the date of the publication of the order a written notice of participation and request for a hearing and (ii) within 60 days after the date of publication of the order, unless a different period of time is specified in the order, the studies on which the person relies to justify a hearing as specified in paragraph (b)(6) of this section. The person may incorporate by reference the raw data underlying a study if the data were previously submitted to FDA as part of an application or other report.

(5) FDA will not consider data or analysis submitted after 60 days in determining whether a hearing is warranted unless they are derived from well-controlled studies begun before the date of the order and the results of the studies were not available within 60 days after the date of publication of the order. Nevertheless, FDA may consider other studies on the basis of a showing by the person requesting a hearing of inadvertent omission and hardship. The person requesting a hearing shall list in the request for hearing all studies in progress, the results of which the person intends later to submit in support of the request for hearing. The person shall submit under paragraph (b)(4)(ii) of this section a copy of the complete protocol, a list of the participating investigators, and a brief status report of the studies.

(6) The person requesting a hearing is required to submit as required under § 314.200(c)(1)(ii) the studies (including all protocols and underlying raw data) on which the person relies to justify a hearing with respect to the drug product. Except, a person who requests a hearing on a proposal is not required to submit additional studies and analyses if the studies upon which the person relies have been submitted in an application and in the format and containing the summaries required under § 314.50.

(i) If the grounds for DFA proposed action concern the effectiveness of the drug, each request for hearing is required to be supported only by adequate and well-controlled clinical studies meeting all of the precise requirements of § 314.126 and, for combination drug products, § 300.50, or by other studies not meeting those requirements for which a waiver has been previously granted by FDA under § 314.126. Each person requesting a hearing shall submit all adequate and well-controlled clinical studies on the drug product, any unfavorable analyses, views, or judgements with respect to the studies. No other data, information, or studies may be submitted.

(ii) The submission is required to include a factual analyses of all the studies submitted. If the grounds for FDA proposed action concern the effectiveness of the drug, the analysis is required to specify how each study accords, on a point-by-point basis, with each criterion required for an adequate well-controlled clinical investigation established under § 314.126 and, if the product is a combination drug product, with each of the requirements for a combination drug established in § 300.50, or the study is required to be accompanied by an appropriate waiver previously granted by FDA. If a study concerns a drug entity or dosage form or condition of use or mode of administration other than the one in question, that fact is required to be clearly stated. Any study conducted on the final marketed form of the drug product is required to be clearly identified.

(iii) Each person requesting a hearing shall submit an analysis of the data upon which the person relies, except that the required information relating either to safety or to effectiveness may be omitted if the notice of opportunity for hearing does not raise any issue with respect to that aspect of the drug; information on compliance with § 300.50 may be omitted if the drug product is not a combination drug product. FDA can most efficiently consider submissions made in the following format.

I. Safety data.

A. Animal safety data.

1. Individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

2. Combinations of the individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

B. Human safety data.

1. Individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

c. Documented case reports.

d. Pertinent marketing experiences that may influence a determination about the safety of each individual active component.

2. Combinations of the individual active components.

a. Controlled studies.

b. Partially controlled or uncontrolled studies.

c. Documented case reports.

d. Pertinent marketing experiences that may influence a determination about the safety of each individual active component.

II. Effectiveness data.

A. Individual active components: Controlled studies, with an analysis showing clearly how each study satisfies, on a point-by-point basis, each of the criteria required by § 314.126.

B. Combinations of individual active components.

1. Controlled studies with an analysis showing clearly how each study satisfies on a point-by-point basis, each of the criteria required by § 314.126.

2. An analysis showing clearly how each requirement of § 300.50 has been satisfied.

III. A summary of the data and views setting forth the medical rationale and purpose for the drug and its ingredients and the scientific basis for the conclusion that the drug and its ingredients have been proven safe and/or effective for the intended use. If there is an absence of controlled studies in the material submitted or the requirements of any element of § 300.50 or § 314.126 have not been fully met, that fact is required to be stated clearly and a waiver obtained under § 314.126 is required to be submitted.

IV. A statement signed by the person responsible for such submission that it includes in full (or incorporates by reference as permitted in § 314.200(c)(2)) all studies and information specified in § 314.200(d).

(**Warning**: A willfully false statement is a criminal offense, 18 U.S.C. 1001.)

(7) *Separation of functions.* Separation of functions commences upon receipt of a request for hearing. The Director of the Center for Drugs and Biologics will prepare an analysis of the request and a proposed order ruling on the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response under paragraph (b)(8) (ii) or (iii) of this section will be submitted to the Office of the Commissioner for review and decision. When the Center for Drugs and Biologics recommends denial of a hearing on all issues on which a hearing is requested, no representative of the Center will participate or advise in the review and decision by the Commissioner. When the Center for Drugs and Biologics recommends that a hearing be granted on one or more issues on which a hearing is requested, separation of functions terminates as to those issues, and representatives of the Center may participate or advise in the review and decision by the Commissioner on those issues. The Commissioner may modify the text of the issues, but may not deny a hearing on those issues. Separation of functions continues with respect to issues on which the Center for Drugs and Biologics has recommended denial of a hearing. The Commissioner will neither evaluate nor rule on the Center's recommendation on such issues and such issues will not be included in the notice of hearing. Participants in the hearing may make a motion to the presiding officer for the inclusion of any such issue in the hearing. The ruling on such a motion is subject to review in accordance with § 12.35(b). Failure to so move constitutes a waiver of the right to a hearing on such an issue. Separation of functions on all issues resumes upon issuance of a notice of hearing. The Office of the General Counsel, Department of Health and Human Services, will observe the same separation of functions.

(8) *Summary judgment.* A person who requests a hearing may not rely upon allegations or denials but is required to set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing with respect to a particular drug product specified in the request for hearing.

(i) Where a specific notice of opportunity for hearing (as defined in paragraph (b)(1) of this section) is used, the Commissioner will enter summary judgment against a person who requests a hearing, making findings and conclusions, denying a hearing, if it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact which precludes the refusal to approve the application or the withdrawal of approval of the application; for example, no adequate and well-controlled clinical investigations meeting each of the precise elements of § 314.126 and, for a combination drug product, § 300.50, showing effectiveness have been identified. Any order entering summary judgment is required to set forth the Commissioner's findings and conclusions in detail and is required to specify why each study submitted fails to meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact.

(ii) When following a general notice of opportunity for a hearing (as defined in paragraph (b)(1) of this section) the Director of the Center for Drugs and Biologics concludes that summary judgment against a person requesting a hearing should be considered, the Director will serve upon the person requesting a hearing by registered mail a proposed order denying a hearing. This person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(iii) When following a general or specific notice of opportunity for a hearing a person requesting a hearing submits data or information of a type required by the statute and regulations, and the Director of the Center for Drugs and Biologics concludes that summary judgment against the person should be considered, the Director will serve upon the person by registered mail a proposed order denying a hearing. The person has 60 days after receipt of the proposed order to respond with sufficient data, information, and analyses to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(iv) If review of the data, information, and analyses submitted show that the basis for the order is not valid, for example, that substantial evidence of effectiveness exists, the Commissioner will enter summary judgment for the person requesting the hearing, and revoke the order. If a hearing is not requested, the order will become effective as published.

(v) If the Commissioner grants a hearing, it will be conducted under Part 12.

(vi) The Commissioner will grant a hearing if there exists a genuine and substantial issue of fact or if the Commissioner concludes that a hearing would otherwise be in the public interest.

(9) The repeal of any regulation constitutes a revocation of all outstanding certificates based upon such regulation. However, the Commissioner may, in his or her discretion, defer or stay such action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

(c) Whenever any interested person submits an application or request under section 507 of the act and Part 314 and FDA sends the person an approvable letter under § 314.110 or a not approvable letter under § 314.120, the person may file a petition proposing the issuance, amendment, or repeal of the regulation under the provisions of section 507(f) of the act and Part 10. The Commissioner shall cause the regulations proposed in the petition to be published in the **Federal Register** within 60 days of the receipt of an acceptable petition and further proceedings shall be in accord with the provisions of sections 507(f) and 701 (f) and (g) of the act and Part 10.

(d) (1) FDA will no promulgate a regulation providing for the certification of any batch of any drug composed wholly or in part of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, intended for human use and no existing regulation will be continued in effect unless it is established by substantial evidence that the drug will have such characteristics of identity, strength, quality, and purity necessary to adequately ensure safety and efficacy of use. "Substantial evidence" has been defined by Congress to mean "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions prescribed, recommended, or suggested in the labeling or proposed labeling thereof." This definition is made applicable to a number of antibiotic drugs by section 507(h) of the act and it is the test of efficacy that FDA will apply in promulgating, amending, or repealing regulations for all antibiotics under section 507(a) of the act as well.

(2) The scientific essentials of an adequate and well-controlled clinical investigation are described in § 314.126.

## Subpart F—Miscellaneous Provisions

### § 314.410 Imports and exports of new drugs and antibiotics.

(a) *Imports.* (1) A new drug or an antibiotic may be imported into the United States if: (i) It is the subject of an approved application under this part or, in the case of an antibiotic not exempt from certification under Part 433, it is also certified or released; or (ii) it complies with the regulations pertaining to investigational new drugs under Part 312; and it complies with the general regulations pertaining to imports under Subpart E of Part 1.

(2) A drug substance intended for use in the manufacture, processing, or repacking of a new drug may be imported into the United States if it complies with the labeling exemption in § 201.122 pertaining to shipments of drug substances in domestic commerce.

(b) *Exports.* (1) A new drug or an antibiotic may be exported if it is the subject of an approved application under this part, and, in the case of an antibiotic, it is certified or released, or it complies with the regulations pertaining to investigational new drugs under Part 312.

(2) A new drug substance that is covered by an application approved under this part for use in the manufacture of an approved drug product may be exported by the applicant or any person listed as a supplier in the approved application, provided the drug substance intended for export meets the specifications of, and is shipped with a copy of the labeling required for, the approved drug product.

(3) An antibiotic drug product or drug substance that is subject to certification under section 507 of the act, but which has not been certified or released, may be exported under section 801(d) of the act if it meets the following conditions:

(i) It meets the specifications of the foreign purchaser;

(ii) It is not in conflict with the laws of the country to which it is intended for export;

(iii) It is labeled on the outside of the shipping package that it is intended for export; and

(iv) It is not sold or offered for sale in the United States.

### § 314.420 Drug master files.

(a) A drug master file is a submission of information to the Food and Drug Administration by a person (the drug master file holder) who intends it to be used for one of the following purposes: To permit the holder to incorporate the information by reference when the holder submits an investigational new drug application under Part 312 or submits an application or an abbreviated application or an amendment or supplement to them under this part, or to permit the holder to authorize other persons to rely on the information to support a submission to FDA without the holder having to disclose the information to the person. FDA ordinarily neither independently reviews drug master files nor approves or disapproves submissions to a drug master file. Instead, the agency customarily reviews the information only in the context of an application under Part 312 or this part. A drug master file may contain information of the kind required for any submission to the agency, including information about the following:

(1) Facilities and operating procedures used to manufacture a drug substance or drug product;

(2) Drug substances or components used in the manufacture of a drug product, or drug products;

(3) Packaging materials;

(4) Components used in drug products, including colors, flavors, and essences; or

(5) Preclinical or clinical data.

(b) An investigational new drug application or an application, abbreviated application, amendment, or supplement may incorporate by reference all or part of the contents of any drug master file in support of the submission if the holder authorizes the incorporation in writing. Each incorporation by reference is required to describe the incorporated material by name, reference number, volume, and page number of the drug master file.

(c) A drug master file is required to be submitted in three copies. The agency has prepared under § 10.90(b) a guideline that provides information about how to prepare a well-organized drug master file. If the drug master file holder adds, changes, or deletes any information in the file, the holder shall notify in writing, each person authorized to reference that information. Any addition, change, or deletion of information in a drug master file (except the list required under paragraph (d) of this section) is required to be submitted in three copies and to describe by name, reference number, volume, and page number the information affected in the drug master file.

(d) The drug master file is required to contain a complete list of each person currently authorized to incorporate by reference any information in the file, identifying by name, reference number, volume, and page number the information that each person is authorized to incorporate. If the holder restricts the authorization to particular drug products, the list is required to include the name of each drug product and the application number, if known, to which the authorization applies.

(e) The public availability of data and information in a drug master file, including the availability of data and information in the file to a person authorized to reference the file, is determined under Part 20 and § 314.430.

### § 314.430 Availability for public disclosure of data and information in an application.

(a) The Food and Drug Administration will determine the public availability of any part of an application under this section and Part 20. For purposes of this section, the application includes all data and information submitted with or incorporated by reference in the application, including investigational new drug applications, drug master files under § 314.420, supplements submitted under § 314.70, reports under § 314.80, and other submissions. For purposes of this section, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests of the drug for identity, stability, purity, potency, and bioavailability.

(b) FDA will not publicly disclose the existence of an application before an approvable letter is sent to the applicant under § 314.110, unless the existence of the application has been previously publicly disclosed or acknowledged. The Center for Drugs and Biologics will maintain and make available for public disclosure a list of applications for which the agency has sent an approvable letter to the applicant.

(c) If the existence of an unapproved application has not been publicly disclosed or acknowledged, no data or information in the application is available for public disclosure.

(d) If the existence of an application has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application is available for public disclosure before the agency sends an approval letter, but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue, for example, for consideration of an issue at an open session of an FDA advisory committee.

(e) After FDA sends an approval letter to the applicant, the following data and information in the application are immediately available for public disclosure, unless the applicant shows that extraordinary circumstances exist. A list of approved applications is publicly available from the Government Printing Office, Washington, DC 20402. The list is updated monthly.

(1) [Reserved]

(2) If the application applies to a new drug, all safety and effectiveness data previously disclosed to the public as set forth in § 20.81 and a summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the application. The summaries do not constitute the full reports of investigations under section 505(b)(1) of the act (21 U.S.C. 355(b)(1)) on which the safety or effectiveness of the drug may be approved. The summaries consist of the following:

(i) For an application approved before July 1, 1975, internal agency records that describe safety and effectiveness data and information, for example, a summary of the basis for approval or internal reviews of the data and information, after deletion of the following:

(*a*) Names and any information that would identify patients or test subjects or investigators.

(*b*) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an application approved on or after July 1, 1975, a Summary Basis of Approval (SBA) document that contains a summary of the safety and effectiveness data and information evaluated by FDA during the drug approval process. The SBA is prepared in one of the following ways:

(*a*) Before approval of the application, the applicant may prepare a draft SBA which the Center for Drugs and Biologics will review and may revise. The draft may be submitted with the application or as an amendment.

(*b*) The Center for Drugs and Biologics may prepare the SBA.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information after deletion of the following:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as set forth in § 20.81.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61.

(7) All correspondence and written summaries of oral discussions between FDA and the applicant relating to the application, under the provisions of Part 20.

(8) All records showing the testing of an action on a particular lot of a certifiable antibiotic by FDA.

(f) All safety and effectiveness data and information which have been submitted in an application and which have not previously been disclosed to the public are available to the public, upon request, at the time any one of the following events occurs unless extraordinary circumstances are shown:

(1) No work is being or will be undertaken to have the application approved.

(2) A final determination is made that the application is not approvable and all legal appeals have been exhausted.

(3) Approval of the application is withdrawn and all legal appeals have been exhausted.

(4) A final determination has been made that the drug is not a new drug.

(5) For applications submitted under section 505(b) of the act, the effective date of the approval of the first application submitted under section 505(j) of the act which refers to such drug, or the date on which the approval of an application under section 505(j) which refers to such drug could be made effective if such an application had been submitted.

(6) For applications submitted under sections 505(j), 506, and 507 of the act, when FDA sends an approval letter to the applicant.

(g) The following data and information in an application are not available for public disclosure unless they have been previously disclosed to the public as set forth in § 20.81 or they relate to a product or ingredient that has been abandoned and they do not represent a trade secret or confidential commercial or financial information under § 20.61:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales distribution, and similar data and information, except that any compilation of that data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) The compilations of information specified in § 20.117 are available for public disclosure.

**§ 314.440 Addresses for applications.**

(a) Applicants shall send applications and other correspondence relating to matters covered by this part, except for products listed in paragraph (b) of this section, to the Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and directed to the appropriate office identified below:

(1) An application under § 314.50 submitted for filing should be directed to the Document and Records Section (HFN–106). Applicants may obtain folders for binding applications from that office. After FDA has filed the application, the agency will inform the applicant which one of the divisions in the Office of New Drug Evaluation is responsible for the application. Amendments, supplements, resubmissions, requests for waivers, and other correspondence about an application that has been filed should be directed to the appropriate division.

(2) An abbreviated application under § 314.55, and amendments, supplements, resubmissions, and other correspondence about an abbreviated application should be directed to the Division of Generic Drugs (HFN–230). Applicants may obtain folders for binding abbreviated applications from that office.

(3) A request for an opportunity for a hearing under § 314.110 or § 314.120 on the question of whether there are grounds for denying approval of an application, except an application under paragraph (b) of this section, should be directed to the Division of Regulatory Affairs (HFN–360).

(b) Applicants shall send applications and other correspondence relating to matters covered by this part for the drug products listed below to the Office of Biologics Research and Review (HFN–825), Center for Drugs and Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, except applicants shall send a request for an opportunity for a hearing under § 314.110 or § 314.120 on the question of whether these are grounds for denying

approval of an application to the Director, Office of Biologics Research and Review (HFN–800), at the same address.

(1) Ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components.

(2) Urokinase products.

(3) Plasma volume expanders and hydroxyethyl starch for leukapheresis.

**§ 314.445 Guidelines.**

(a) The Food and Drug Administration prepares guidelines under § 10.90(b) to help persons comply with requirements in this part.

(b) The Center for Drugs and Biologics will maintain and make publicly available a list of guidelines that apply to the Center's regulations. The list states how a person can obtain a copy of each guideline. A request for a copy of the list should be directed to the Office of Consumer and Professional Affairs (HFN–10), Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

## PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND NOT MISBRANDED

9. Part 330 is amended in § 330.10 by revising paragraph (c), to read as follows:

**§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.**

* * * * *

(c) Information and data submitted under this section shall include, with respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

## PART 430—ANTIBIOTIC DRUGS; GENERAL

10. Part 430 is amended:

a. By revising Subpart B to read as follows:

### Subpart B—Antibiotic Drugs Affected by the Drug Amendments of 1962

**§ 430.10 Certification or release of antibiotic drugs affected by the drug amendments of 1962.**

(a) Before the 1962 amendments to it, the Federal Food, Drug, and Cosmetic Act only permitted the Food and Drug Administration to provide for the certification of batches of antibiotic drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative of them. FDA certified those drugs under regulations promulgated on the basis of scientific proof of the drugs' safety and effectiveness. Most drugs containing an antibiotic other than one of those listed were subject to the new drug provisions of the act, which required that an applicant show that the drug was safe and obtain FDA approval of a new drug application before marketing it. An affirmative showing of effectiveness was not then required to obtain approval. Some antibiotic drugs that were not subject to certification, however, were also not subject to the new drug provisions of the act under informal FDA opinions that the drug was "not a new drug" or "no longer a new drug." FDA revoked those opinions under § 310.100 of this chapter.

(b) The 1962 amendments amended section 507 of the act to require the certification, release without certification, or exemption from certification, of all antibiotic drugs on the basis of scientific proof of safety and effectiveness. The amendments provided that FDA implement them for antibiotic drugs that were marketed on April 30, 1963 and were not subject to the certification provisions on that date. FDA is implementing the amendments with respect to antibiotic drugs formerly subject to the new drug provisions of the act through its Drug Efficacy Study Implementation (DESI) program under which the agency is evaluating those antibiotic drugs for efficacy. Until FDA completes that evaluation it will permit continued marketing of those antibiotic drugs under paragraph (c) of this section. The agency is also implementing the 1962 amendments with respect to antibiotic drugs formerly not subject to either the certification or new drug provisions of the act and the agency is evaluating those antibiotic drugs for both safety and efficacy. Until FDA completes that evaluation, it will permit continued marketing of those antibiotic drugs under paragraph (d) of this section.

(c) Unless exempted from certification, FDA will certify or release antibiotic drugs which on April 30, 1963 were the subject of an approved new drug application under section 505 of the act, under regulations providing for certification of the drugs. Although the initial regulation for each of these drugs established under section 507(h) of the act was not conditioned upon an affirmative finding of the effectiveness of the drug, FDA is proceeding under its DESI program to amend or repeal those regulations to provide for certification of those drugs only if they had been shown to be both safe and effective.

(d) Unless exempted from certification, FDA will release without certification an antibiotic drug that was marketed on April 30, 1963, but not subject to certification, and not subject to an approved new drug application on that date, unless FDA has made a determination that the drug has not been shown to be safe or lacks substantial evidence of effectiveness under the DESI program. FDA is proceeding under its DESI program to establish regulations under section 507 to provide for certification of those drugs only if they have been shown to be safe and effective.

**§ 430.20 [Removed]**

b. By removing § 430.20 *Procedure for the issuance, amendment, or repeal of regulations.*

## PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

11. Part 431 is amended:

**§ 431.1 [Amended]**

a. In § 431.1 *Requests for certification, check tests and assays, and working standards; information and samples required* by removing and reserving paragraph (b).

**§ 431.16 [Removed]**

b. By removing § 431.16 *Changes in facilities or controls; changes in mailing or promotional pieces.*

c. By revising § 431.17, to read as follows:

**§ 431.17 Request to provide for certification of an antibiotic drug.**

A request under section 507 of the Federal Food, Drug, and Cosmetic Act to provide for certification of an antibiotic drug is required to comply with the procedures and meet the requirements applicable to the submission to the Food and Drug Administration and review by the agency of applications and abbreviated applications, and amendments and supplements to them, under Part 314 of this chapter.

**§ 431.50 [Amended]**

d. In § 431.50 *Forms for certification or exemption of antibiotic drugs* by removing the entries for Form 5 and Form 6.

**§ 431.60 [Removed]**

e. By removing § 431.60 *Records and reports concerning experience with*

*antibiotic drugs for human use for which a certificate or release has been issued.*

**§ 431.70 [Amended]**

f. In § 431.70 *Confidentiality of data and information in an investigational new drug notice for an antibiotic drug,* paragraphs (b) and (c) are amended by changing the references "§ 431.71" to "§ 314.430 of this chapter".

**§ 431.71 [Removed]**

g. By removing §431.71 *Confidentiality of data and information in an antibiotic drug file.*

## PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

**§ 433.25 [Removed]**

12. Part 433 is amended by removing § 433.25 *Antibiotic drugs intended for export.*

## PART 510—NEW ANIMAL DRUGS

**§ 510.3 [Amended]**

8. Part 510 is amended:

a. In § 510.3 *Definitions and interpretations* in paragraph (1) by removing the words "and § 310.9 of this chapter".

b. In § 510.95 by revising the first sentence, to read as follows:

**§ 510.95 Designated journals.**

The following journals are available to the Food and Drug Administration and thus permit waiving of the submission of reprints and summaries covering reports contained in these journals to the extent that such requirements are waived in the regulations in this part:

* * * * *

## PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

13. Part 511 is amended in § 511.1 by revising paragraph (b)(4)(ii), to read as follows:

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

* * * * *

(b) * * *

(4) * * *

(ii) All labeling and other pertinent information to be supplied to the investigators. When such pertinent information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

* * * * *

## PART 514—NEW ANIMAL DRUG APPLICATIONS

14. Part 514 is amended:

a. In § 514.1 by revising paragraph (b)(12)(iii), to read as follows:

**§ 514.1 Applications.**

* * * * *

(b) * * *

(12) * * *

(iii) Will respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

* * * * *

b. In § 514.8 by revising paragraph (l), to read as follows:

**§ 514.8 Supplemental new animal drug applications.**

* * * * *

(l) A supplemental application that contains nonclinical laboratory studies shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

c. In § 514.15 by revising paragraph (c), to read as follows:

**§ 514.15 Untrue statements in applications.**

* * * * *

(c) Any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, and the application fails to include a brief statement of the reason for the noncompliance.

d. In § 514.110 by revising paragraph (b)(8), to read as follows:

**§ 514.110 Reasons for refusing to file applications.**

* * * * *

(b) * * *

(8) It fails to include, with respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reasons for the noncompliance.

* * * * *

e. In § 514.111 by revising paragraph (a)(11), to read as follows:

**§ 514.111 Refusal to approve an application.**

(a) * * *

(11) Any nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

* * * * *

f. In § 514.115 by revising paragraph (b)(4), to read as follows:

**§ 514.115 Withdrawal of approval of applications.**

* * * * *

(b) * * *

(4) That any nonclinical laboratory study that is described in the application and that is essential to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

* * * * *

## PART 570—FOOD ADDITIVES

15. Part 570 is amended in § 570.35 by revising paragraph (c)(1)(vi), to read as follows:

**§ 570.35 Affirmation of generally recognized as safe (GRAS) status.**

* * * * *

(c) * * *

(1) * * *

(vi) If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set

forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

* * * * *

## PART 571—FOOD ADDITIVE PETITIONS

16. Part 571 is amended:

a. In § 571.1 by revising paragraph (k), to read as follows:

**§ 571.1 Petitions.**

* * * * *

(k) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

b. In § 571.6 by revising the last sentence of the section to read as follows:

**§ 571.6 Amendment of petition.**

* * * If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason or the noncompliance.

## PART 601—LICENSING

17. Part 601 is amended in § 601.2 by revising the first sentence of paragraph (a), to read as follows:

**§ 601.2 Applications for establishment and product licenses; procedures for filing.**

(a) *General.* To obtain a license for any establishment or product, the manufacturer shall make application to the Director, Office of Biologics Research and Review, on forms prescribed for such purposes, and in the case of an application for a product license, shall submit data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance; statements regarding each clinical investigation involving human subjects contained in the application, that it either was conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter or was not subject to such requirements in accordance with § 56.104 or § 56.105, and was conducted in compliance with requirements for informed consent set forth in Part 50 of this chapter; a full description of manufacturing methods; data establishing stability of the product through the dating period; sample(s) representative of the product to be sold, bartered, or exchanged or offered, sent, carried or brought for sale, barter, or exchange; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); and specimens of the labels, enclosures, and containers proposed to be used for the product.

* * *

* * * * *

## PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

18. Part 812 is amended in § 812.27 by revising paragraph (b)(3), to read as follows:

**§ 812.27 Report of prior investigations.**

* * * * *

(b) * * *

(3) If information on nonclinical laboratory studies is provided, a statement that all such studies have been conducted in compliance with applicable requirements in the good laboratory practice regulations in Part 58, or if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with this requirement does not justify failure to provide information on a relevant nonclinical test study.

## PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

19. Part 1003 is amended in § 1003.31 by revising paragraph (b), to read as follows:

**§ 1003.31 Granting the exemption.**

* * * * *

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable. Where such evidence includes nonclinical laboratory studies, the data submitted shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. When such evidence includes clinical investigations involving human subjects, the data submitted shall include, with respect to each clinical investigation either a statement that each investigation was conducted in compliance with the requirements set forth in Part 56 of this chapter, or a statement that the investigation is not subject to such requirements in accordance with § 56.104 or § 56.105, and a statement that each investigation was conducted in compliance with the requirements set forth in Part 50 of this chapter.

* * * * *

## PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

20. Part 1010 is amended:

a. In § 1010.4 by revising paragraph (b)(1)(ix), to read as follows:

**§ 1010.4 Variances.**

* * * * *

(b) * * *

(1) * * *

(ix) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

* * * * *

b. In § 1010.5 by revising paragraph (c)(13), to read as follows:

**§ 1010.5 Exemptions for products intended for United States Government use.**

* * * * *

(c) * * *

(13) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

* * * * *

*Effective date.* These regulations are effective May 23, 1985, except § 314.80 is effective August 22, 1985.

(Secs. 409, 501, 502, 503, 505, 506, 507, 512–516, 520, 701, 706, 52 Stat. 1049–1053 as amended, 1055, 1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended, 72 Stat. 1785–1788 as amended, 74 Stat. 399–407 as amended, 82 Stat. 343–351, 90 Stat. 540–560 (21 U.S.C. 348, 351, 352, 353, 355, 356, 357, 360b–360f, 371, 376); sec. 215, 301, 351, 354–360F, 58 Stat. 609, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 241, 262, 263b–263n)

Frank E. Young,

*Commissioner of Food and Drugs.*

Margaret M. Heckler,

*Secretary of Health and Human Services.*

Dated: December 7, 1984.

[FR Doc. 85–4071 Filed 2–21–85; 8:45 am]

BILLING CODE 4160–01–M

federal register

Friday
February 22, 1985

Part III

# Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701, 736, 740, 746, 750, and 772

Surface Coal Mining and Reclamation Operations; Proposed Rule

**DEPARTMENT OF THE INTERIOR**

**Office of Surface Mining Reclamation and Enforcement**

**30 CFR Parts 701, 736, 740, 746, 750, and 772**

# Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Application Fee for Permit To Conduct Surface Coal Mining and Reclamation Operations; Application Fee for Coal Exploration Permit; Fee for Processing Mining Plan; Fee for Mid-Term Review of Surface Coal Mining and Reclamation Permit

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Proposed rule.

**SUMMARY:** The Office of Surface Mining Reclamation and Enforcement (OSM) of the U.S. Department of the Interior (the Department) proposes a rule which would govern the collection by OSM of application fees for permits to conduct surface coal mining and reclamation operations, and for permits to conduct coal exploration, as well as fees for processing mining plans and for mid-term review of surface coal mining and reclamation permits. Recipients of these services would be required to reimburse OSM for the actual cost incurred by the Department in providing the service.

The rule would apply to applications for mining on Indian lands, in the Federal Program States (Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee and Washington), and on Federal lands in States not having State-Federal cooperative agreements. The rule would also require payment to the Department for costs the Department incurs in reviewing and approving mining plans.

**DATES:**

*Proposed Implementation:* After promulgation of the final rule, OSM proposes to bill the recipient of a covered service for all costs incurred by the Department beginning February 22, 1985. (Other possible alternatives are discussed in this preamble.)

*Written Comments:* OSM will accept written comments on the proposed rule until 5 p.m. eastern time on May 3, 1985.

*Public Hearings:* Upon request, OSM will hold public hearings on the proposed rule in Washington, D.C., Denver, Colorado, and Knoxville, Tennessee at 9:30 a.m. local time on April 26, 1985. Upon request, OSM also will hold public hearings in the States of Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, and Washington at times and on dates to be announced. The deadline for requesting a hearing is 5:00 p.m. eastern time on April 5, 1985.

**ADDRESSES:**

*Written Comments:* Hand-deliver to the Office of Surface Mining, Administrative Record, Room 5315, 1100 L Street, NW., Washington, D.C.; or mail to the Office of Surface Mining, Administrative Record, Room 5315L, 1951 Constitution Avenue, NW., Washington, D.C. 20240.

*Public Hearings:* Department of the Interior Auditorium, 18th and C Streets, NW., Washington, D.C.; Brooks Towers, 2d Floor Conference Room, 1020 15th Street, Denver, Colorado; and the Hyatt House, 500 Hill Avenue, SE., Knoxville, Tennessee. The address for any hearing scheduled in the States of Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, or Washington will be announced prior to the hearing.

**FOR FURTHER INFORMATION CONTACT:** Murray Newton, Chief, Branch of Regulatory Programs, Office of Surface Mining, U.S. Department of the Interior, 1951 Constitution Avenue, NW., Washington, DC 20240; Telephone: 202–343–5866 (Commercial or FTS).

**SUPPLEMENTARY INFORMATION:**

I. Public Comment Procedures
II. Background
III. Discussion of Proposed Rule
IV. Procedural Matters

## I. Public Comment Procedures

### *Written Comments*

Written comments submitted on the proposed rule should be specific, should be confined to issues pertinent to the proposed rule, and should explain the reason for any change that is recommended. Comments received after the close of the comment period (see **"DATES"**) may not be considered or included in the Administrative Record for the final rule.

### *Public Hearings*

OSM will hold public hearings on the proposed rule on request only. The times and locations scheduled for three of the hearings are specified previously in this notice (see **"DATES"** and **"ADDRESSES"**). Additional times and locations will be announced later for hearings requested in any of the remaining States.

Any person interested in making an oral or written presentation at a hearing should inform Mr. Newton (see **"FOR FURTHER INFORMATION CONTACT"**) of the desired hearing location by 5:00 p.m. eastern time on April 5, 1985. If no one has contacted Mr. Newton to express an interest in participating in a hearing at a given location by that date, the hearing will not be held.

If a hearing is held, it will continue until all persons wishing to testify have been heard. To assist the transcriber and ensure an accurate record, OSM requests that persons who testify at a hearing give the transcriber a written copy of their testimony. To assist OSM in preparing appropriate questions, OSM also requests that persons who plan to testify submit to OSM, at the address previously specified for the submission of written comments (see **"ADDRESSES"**), an advance copy of their testimony.

## II. Background

The following discussion is divided under six major headings. Under the first heading four significant issues considered by OSM in drafting the proposed rule are identified. Under the next four headings each of these four issues is discussed in its relevant statutory and regulatory context. Under the last heading the typical costs incurred by OSM in processing applications for surface coal mining and reclamation permits and mining plans are described.

### *A. Significant Issues*

In drafting the proposed rule, OSM confronted four significant issues: For which OSM services is the collection of a fee appropriate? Should OSM set a fixed fee schedule, or charge the recipient of a service for actual costs? Where a fee is appropriate, what specific items or activities involved in providing a service should the fee cover? What provision should be made for small operators?

The following four sections discuss OSM's tentative resolution of each of these issues. The public is encouraged to comment on these issues, to identify others, and to submit any additional information or analysis that might assist OSM in drafting the final rule.

### *B. For Which OSM Services Is a Fee Appropriate?*

OSM has identified the following services it provides to identifiable private recipients where a fee may be appropriate: (1) The processing of applications for surface coal mining and reclamation permits, including the renewal of, revision of, or transfer, assignment or sale of rights in an existing permit. (2) The review of existing State permits upon substituting Federal enforcement for the permitting portion of a State program, or upon implementing the permitting portion of a

Federal program. (3) The processing of mining plans and mining plan modifications. (4) The processing of coal exploration permits. (5) Inspection and enforcement. And (6) the mid-term review of surface coal mining and reclamation permits.

The rule as proposed today would provide for the collection of a fee for all of these services except (2) the review of existing State permits upon substituting Federal enforcement, and (5) inspection and enforcement. OSM seeks comments on which of these services should be included in the final rule.

1. Processing of Applications for Surface Coal Mining and Reclamation Permits

Section 507(a) of the Surface Mining Control and Reclamation Act of 1977 (the Act or SMCRA), 30 U.S.C. 1257(a), provides that:

> Each application for a surface coal mining and reclamation permit pursuant to an approved State program or a Federal program under the provisions of this Act shall be accompanied by a fee as determined by the regulatory authority. Such fee may be less than but shall not exceed the actual or anticipated cost of reviewing, administering, and enforcing such permit issued pursuant to a State or Federal program. The regulatory authority may develop procedures so as to enable the cost of the fee to be paid over the term of the permit.

There are four situations where the requirements of § 507(a) apply to OSM for processing surface coal mining and reclamation permit applications: (a) Under a Federal program for a State, (b) on Federal lands, (c) on Indian lands, and (d) upon substituting Federal enforcement for the permitting portion of a State program. In these situations OSM processes four different types of permit applications: (1) For an original permit, (2) for the renewal of an existing permit, (3) for the revision of an existing permit, and (4) for the transfer, assignment or sale of rights in an existing permit. The following discussion first covers each of the four potential fee situations, and then the four different types of permit applications.

*Federal Programs for States.* With respect to regulatory programs for States, the requirements of section 507(a) have been incorporated into the OSM rule at 30 CFR 777.17. Section 777.17 requires that the regulatory authority determine and the applicant pay a fee with each application for a surface coal mining and reclamation permit.

Where OSM implements a Federal program for a State, and thus becomes the regulatory authority, 30 CFR 736.22(b) requires that the Federal program comply with 30 CFR Chapter VII, Subchapter G, which in § 777.17 provides for the collection of a fee. Currently, there is no corresponding Federal program rule which implements this requirement and provides a means for determining the amount of the fee. To remedy this deficiency, OSM proposes to add to 30 CFR Part 736—which governs the promulgation of a Federal program for a State—a new § 736.25 which would require that, as the application fee for a permit to conduct surface coal mining and reclamation operations, an applicant reimburse OSM for the actual cost incurred by the Department in processing the application.

OSM has promulgated Federal programs for the States of Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee and Washington. OSM solicits public comment on the effect of the proposed rule in each of these Federal program States.

*Federal Lands.* The Federal lands program rules are found at 30 CFR Chapter VII, Subchapter D. Part 740 of Subchapter D provides for the regulation of surface coal mining and reclamation operations on Federal lands. Part 745 sets forth the requirements for cooperative agreements for State regulation of operations on Federal lands under section 523(c) of SMCRA.

Under the Federal lands program rules, regulatory jurisdiction over operations on Federal lands may be exercised by OSM, the State or jointly. Where there is an approved State program but no cooperative agreement, OSM is the regulatory authority on Federal lands. In a State with a State-Federal cooperative agreement under Section 523(c) of the Act, the State is the regulatory authority. Finally, cooperative agreements may require OSM concurrence with, or other OSM action related to, the permitting decision of the State regulatory authority for operations on Federal lands.

Section 740.11 provides that upon approval or promulgation of a regulatory program for a State, that program applies to surface coal mining and reclamation operations on Federal lands. Existing § 740.13(b) requires that an application for a permit on Federal lands include a fee determined by the criteria of the applicable regulatory program. Under existing § 740.13(b), in States with approved programs the State fee criteria apply on Federal lands, whether or not there is a cooperative agreement.

OSM proposes to revise § 740.13(b) to require that: (1) Notwithstanding § 740.11, where OSM is the regulatory authority for Federal lands the applicant shall reimburse OSM for actual costs as provided in proposed § 701.12; and (2) where a State is the regulatory authority under a cooperative agreement the applicant shall reimburse the State as provided by the fee criteria of the State regulatory program. OSM proposes this provision because State fee schedules are based upon the State's needs. Where it is the Department rather than the State which is incurring the costs of the subject activity, the State's schedules would not reflect OSM's costs.

In addition, OSM proposes to add to § 740.13(b) a new provision applicable in States where a cooperative agreement requires OSM concurrence with, or other OSM action related to, the permitting decision of the State regulatory authority.

Other OSM actions related to the State permitting decision for operations on Federal lands include, for example, findings of compatibility under § 522(e)(2) of SMCRA, and associated environmental assessments and impact statements. Proposed § 740.13(b)(iii) would require applicants to reimburse OSM for the actual cost incurred by the Department in making the decision on concurrence or taking other action.

With respect to the fee for OSM concurrence or other action, authority for § 740.13(b)(iii) is provided both by SMCRA and by § 9701 of the Independent Offices Appropriation Act, which is discussed in greater detail in this preamble under subsequent heading "II.B.3. *Processing of Mining Plans.*"

*Indian Lands.* OSM has recently promulgated a rule for regulating surface coal mining and reclamation operations on Indian lands, to be codified at 30 CFR Chapter VII, Subchapter E. *See* 49 FR 38462 (September 28, 1984). The Indian lands rule provides in § 750.12(a) for the payment of a permit application fee as determined by OSM. (49 FR 38478).

Consistent with the previously described proposals for Federal programs for States, and for the Federal lands program, OSM proposes to revise § 750.12(a) to require that an applicant for a permit to conduct surface coal mining and reclamation operations on Indian lands reimburse OSM for the actual cost incurred by the Department in processing the application.

As indicated in the preamble to the Indian lands rule, until the final version of this proposed rule is promulgated OSM will not enforce the requirement for payment of a permit application fee for operations on Indian lands. (49 FR 38470, September 28, 1984). However, upon promulgation of a final rule in this rulemaking, OSM would bill for costs

incurred from this date forward (unless a different implementation is chosen).

*Federal Enforcement of a State Program.* Where OSM enforces the permitting portion of a State regulatory program under 30 CFR 733.12, the fee criteria of the State program apply to permit applications processed by OSM for operations in the State. OSM is the regulatory authority for permitting purposes under these circumstances, and the applicable fee is payable to OSM. However, because the State regulatory program remains in effect, the State fee criteria govern the payment of permit application fees.

Because the existing rule governing Federal enforcement appear to include sufficient provisions to cover the payment of permit application fees in this situation, the proposed rule does not include any corresponding revision of 30 CFR Part 733. Nevertheless, there are four situations involving pending permit applications in which determination of the applicable fee criteria may be somewhat ambiguous.

One situation is where OSM as regulatory authority processes a permit application that was pending when OSM instituted Federal enforcement of the permitting portion of a State program, and for which the applicant already had paid a fee to the State. In this situation the fee criteria of the State program apply, and since the applicant already had paid the required fee to the State, OSM would collect no additional fee for processing the application. Due to the difficulty of determining the equitable State and Federal shares of the fee in this situation, and in the absence of any corresponding rule, OSM would not seek to recoup from the State any part of the fee to defray its processing costs.

The second situation is where OSM, after withdrawing approval of a State program, substitutes a Federal program and processes a permit application that was submitted to the State regulatory authority before the State program was withdrawn, and for which the applicant already had paid a fee to the State. In this situation the fee criteria of the State program would have applied when the application was filed, but would be superseded by the fee criteria of the Federal program. So even though the applicant already had paid a fee to the State, the Federal program under the proposed rule would require that the applicant reimburse OSM for the actual cost incurred by the Department in processing the application.

In this latter situation, OSM would consider the date on which the State program was withdrawn as the date of receipt of the application, and bill the applicant for actual costs incurred from that date onward. To insure that an applicant did not pay twice for the same service, in calculating the actual balance due under proposed § 701.12(b) OSM would credit the applicant for any fee previously paid to the State. The fee provisions of the proposed rule otherwise would apply in full.

The third situation is where a State regains permitting authority from OSM upon termination of Federal enforcement of a State program, and the State as regulatory authority takes over the processing of a permit application for which the applicant had paid a fee to OSM. Due to the difficulty of determining the equitable State and Federal shares of the fee, OSM in this situation would keep the entire fee payable to OSM under the State fee criteria, and not transfer any part of it to the State. Nevertheless, the State as the new regulatory authority could charge the applicant an additional fee authorized by the fee criteria of the State program.

The fourth situation is where a State, upon OSM approval of the State program, takes over the processing of a permit application that was pending before OSM under a Federal program, and for which the applicant is required to reimburse OSM for actual costs under the fee criteria of the Federal program. In this situation, upon approval of the State program the fee criteria of the State program would apply. Nevertheless, under the proposed rule the applicant would be required to reimburse OSM for the actual costs incurred by the Department in processing the application while the Federal program was in effect. As in the preceding situation, the State as the new regulatory authority could charge the applicant an additional fee authorized by the fee criteria of the State program.

OSM solicits public comment on the implementation of the proposed rule in these four situations. OSM also seeks comment on whether the final rule should amend 30 CFR Part 733 to include specific provisions covering the application of the proposed rule to these or other situations involved in Federal enforcement of a State program.

*Types of Permit Applications.* In the previously described permitting situations, OSM as regulatory authority processes four different types of permit applications: (1) For a new (original) permit, (2) for the renewal of an existing permit, (3) for the revision of an existing permit, and (4) for the transfer, assignment or sale of rights in an existing permit. The fee requirement of section 507(a) of SMCRA applies to each of these four types of applications. Each type of application conveys a similar benefit to the applicant, and notwithstanding their varying degrees of complexity each requires similar processing by OSM. Accordingly, in the proposed rule each independent fee regulation governing an application for a permit to conduct surface coal mining and reclamation operations explicitly would apply not only to an application for a new permit, but also to these other types of applications.

2. Review of Existing Permits Upon Substituting Federal Enforcement of a State Program, or Implementing a Federal Program

Upon substituting Federal enforcement for the permitting portion of a State program, or implementing the permitting portion of a Federal program, OSM may review existing State permits to determine compliance with SMCRA, the applicable regulatory program, and any additional regulation OSM may promulgate. OSM tentatively has concluded that it would be inappropriate to charge the affected operators a fee for such review.

The need for this review is not caused by any request or other action of any identifiable permit holder, but rather by a deficiency in the administration of the State regulatory program in general. To charge permit holders a fee under such circumstances would expose them to potentially significant, but unforeseen and unpredictable expense over which they have little or no control. While OSM would not charge a fee for the review itself, the fee provisions of the proposed rule would apply in full to any permit revision required to correct a deficiency identified during review.

3. Processing of Mining Plans

The Mineral Leasing Act of 1920 (MLA), as amended, 30 U.S.C. 181 *et seq.*, provides for the exploration, leasing and development of Federal coal deposits. Section 202(a) of 30 U.S.C. provides for the review and approval of mining plans by the Secretary of the Interior for coal mining operations on Federal lands.

Under 30 CFR 740.4 the Secretary is responsible for approval, disapproval or conditional approval of a mining plan or modification thereto, and OSM is responsible for preparing and submitting to the Secretary a corresponding decision document. The review and decision process is governed by the OSM rules at 30 CFR Part 746.

Currently, Part 746 contains no requirement that an operator/lessee pay a fee or otherwise reimburse OSM for the cost incurred by the Department in

the mining plan review and decision process. However, this process confers a substantial benefit on the operator/lessee at considerable cost to the Department. Therefore, consistent with the previously described fee proposals for regulatory programs, OSM proposes to add to Part 746 a new § 746.12 which would require an operator/lessee to reimburse OSM for the actual cost incurred by the Department in processing a mining plan, including a modification of an existing plan.

The reimbursement provision in § 746.12 is proposed under the authority of section 9701 of Pub. L. 97–258, 96 Stat. 1051 (31 U.S.C. 9701), which prior to editorial revision and recodification was section 501 (31 U.S.C. 483(a)) of the Independent Offices Appropriation Act (IOAA). Section 9701 of the IOAA authorizes an agency to prescribe regulations establishing the charge for a service or thing of value provided by the agency.

Under section 9701 the charge shall be fair and based on the costs to the government, the value of the thing or service to the recipient, the public policy or interest served, and other relevant facts. Guidance to the Federal agencies for interpreting section 9701 is provided by Bureau of the Budget Circular No. A–25 of September 23, 1959, and by related judicial precedent.

Requiring an operator/lessee to reimburse OSM for the actual cost incurred by the Department in processing a mining plan is authorized by the IOAA. OSM tentatively has concluded that not requiring such reimbursement would be inconsistent with sound budgetary principles.

The term "operator/lessee" used in the proposed rule is defined by 43 CFR 3480.0–5(a)(27) as a "lessee, licensee, and/or one conducting operations on a Federal lease or license under a written contract or written agreement with the lessee or licensee." Section 746.12 would apply only to operator/lessees who submit mining plans or mining plan modifications for operations on lands containing Federal coal. It would not apply to the review and approval of mining plans under 25 CFR 216.7 for operations on Indian lands, as OSM is not responsible for such review.

4. Processing of Coal Exploration Permits

The OSM rules at 30 CFR Part 772 govern "coal exploration operations on all lands except for Federal lands subject to the requirements of 43 CFR Parts 3480–3487." Section 772.12(a) requires that before conducting exploration removing more than 250 tons of coal, any person who meets specified criteria must "submit an application and obtain written approval from the regulatory authority in an exploration permit."

Currently, an application fee is not required for a coal exploration permit. The procedures employed and the types of costs incurred by OSM in the review and decision process for a coal exploration permit are similar to those for a surface coal mining and reclamation permit although the magnitude of costs associated with processing exploration permits would likely be much smaller than those in processing mining permits. Thus, it would be inconsistent to charge a fee for the latter but not the former. For this reason OSM proposes to revise § 772.12(a) to require that where OSM is the regulatory authority, an applicant for a coal exploration permit shall reimburse OSM for the actual cost incurred by the Department in processing the application.

The reimbursement provision in § 772.12(a) is proposed under the authority of §9701 of the IOAA, as was described previously for proposed § 746.12 under the heading "II.B.3. *Processing of Mining Plans.*"

Related to the requirement for a coal exploration permit in § 772.12(a) is the notice requirement in § 772.11 for exploration removing 250 tons of coal or less. OSM does not propose to charge a fee for the submission of a written notice of intent to explore under § 772.11 because no readily definable costs are incurred by OSM in processing this notice.

5. Inspection and Enforcement

Two essential activities of OSM in administering the requirements of SMCRA are inspection and enforcement. Inspection is governed by section 517 of SMCRA, 30 U.S.C. 1267, and enforcement by § 521, 30 U.S.C. 1271. Rules governing these two activities are found at 30 CFR Chapter VII, Subchapter L.

As noted previously, section 507(a) of SMCRA authorizes OSM to collect a permit application fee, which may reflect the anticipated cost of "administering . . . and enforcing" the permit, which would include both inspection and enforcement.

Additional authority to recover the cost of inspection and enforcement is provided by the IOAA. *Mississippi Power & Light* v. *U.S. Nuclear Regulatory Comm'n*, 601 F.2d 223, 231 (5th Cir. 1979) ("In conducting routine inspections, the Commission provides a service to the licensee by assisting him in complying with those statutory and regulatory requirements necessary for retention of his licensee. . . . We hold that the Commission may properly assess a fee for the cost of providing this service.")

Notwithstanding this statutory authority for recovering the cost of inspection and enforcement, the Congress in section 507(a) of SMCRA expressly recognized that OSM may elect to recover "less than [its] actual or anticipated cost" for a particular service. OSM has not determined whether to charge either applicants or permit holders a fee for inspection and enforcement, but encourages comment on this issue. Not charging for such activities would ensure that the frequency and intensity of inspection and enforcement practices fully reflect OSM's firm commitment to the goals of SMCRA, and are not inhibited by any inadvertent concern for the costs that might be imposed on surface mining operators resulting from such activities. Moreover, OSM is concerned about imposing economic burdens on operators in addition to the permit application fees, Abandoned Mine Reclamation Fees, and, for non-complying operators, civil penalties, all of which are charged under SMCRA.

Approval of a permit application confers on an operator a specific benefit, as, in certain respects, do inspection and enforcement. While inspection and enforcement protect the health and safety of the public and help preserve important agricultural, environmental, historic and mineral resources, these efforts also benefit operators by enabling the lawful continuation of responsible mining, and by reducing the likelihood of citizen complaints.

Although the proposed rule includes no specific provision for the collection by OSM of a fee for either inspection or enforcement, OSM solicits comment on several possible alternatives for the final rule which could include a fee for inspection and enforcement. Under one alternative, such a fee might be based on an estimate of the inspection and enforcement costs OSM would incur over the life of the permit, and be collected by OSM as part of the permit application fee. Under another alternative, it might be based on actual expenses, and be collected by OSM, perhaps on an annual basis, after the permit is issued and inspection and enforcement are carried out. Under either of these alternatives, OSM might collect a fee based on all or some lesser part of its inspection and enforcement costs, such as fifty percent, and special provision might be made for a reduced

inspection and enforcement fee for small operators.

While estimating in advance the cost of inspection and enforcement might seem less difficult than estimating the cost of permit review, since the number and cost of the inspections required for a given operation are relatively constant, this alternative does present a number of potential problems. To account for differences in the size of permitted operations, and the corresponding differences in inspection costs, OSM either would have to vary the fee estimate from permit-to-permit, or collect a single fee based on an average of the inspection costs for all operations. And since enforcement costs are a function of permit non-compliance, OSM would either have to predict in advance the enforcement actions required for each permit, or again collect a single fee based on an average of the enforcement costs anticipated for all operations. Under either system it is likely that some permittees would pay more than their share of inspection and enforcement costs, and others less. Under an averaging system, smaller operations might bear a disproportionate share of these costs. Under either system of estimated costs some permittees would be required to pay enforcement costs notwithstanding their strict permit compliance. And under either system it would be difficult to determine precisely which enforcement costs properly are reimbursable by a permittee.

An inspection and enforcement fee based on actual costs would eliminate some of the drawbacks of an estimated fee system, but not entirely. While the costs attributable to a given permittee would be more clearly defined, there still would remain the question of which enforcement costs properly are reimbursable. For permittees on relatively small operations in remote locations, actual inspection costs might be disproportionately large due to the time required for an inspector to travel to and from the operation, or the need to maintain an inspection staff for a relatively small number of operations in an area with little mining activity. And under either alternative there may be an economic hardship to some permittees on marginal operations.

OSM requests that commenters on the preceding alternative rule proposals give their views on these and any other issues they believe are relevant to the collection of a fee for inspection and enforcement.

6. Mid-Term Permit Review

Under 30 CFR 788.11 the regulatory authority is required to review outstanding surface coal mining and reclamation permits not later than the middle of the permit term. Where OSM is the regulatory authority under a Federal program for a State, on Federal lands, on Indian lands, or upon substituting Federal enforcement for the permitting portion of a State program, OSM is required to conduct this mid-term review. OSM proposes to charge permit holders a fee for this service.

Under section 507 of SMCRA, OSM is authorized to charge applicants for the cost of administering the permit. This includes the cost of mid-term review, a process in which the Department may incur substantial cost. OSM is not aware of any reason that militates against charging a fee for mid-term review.

Although section 507(a) of SMCRA specifies that a fee shall accompany a surface coal mining and reclamation permit application, rather than applying directly to the permit itself, OSM interprets section 507(a) as also authorizing a fee for review of the permit. This interpretation is based on the provision of section 507(a) that "[t]he regulatory authority may develop procedures so as to enable the cost of the fee to be paid over the term of the permit."

By charging permittees after mid-term review, rather than requiring an applicant to pay the estimated cost of this review at the time a permit application is filed, the payment for this service would be postponed, as contemplated by section 507(a). Also, this procedure would facilitate an accurate assessment of the costs. Thus, OSM tentatively has concluded that it is perferable to charge the permit holder after the review is completed.

Additional authority for charging a fee for mid-term permit review is provided by § 9701 of the IOAA, as was described previously under the heading "II.B.3. *Processing of Mining Plans.*"

For these reasons, where OSM is the regulatory authority under a Federal program for a State, on Federal lands, or on Indian lands, OSM proposes to charge a permittee for the actual cost incurred by the Department in performing a mid-term permit review. Where OSM is the regulatory authority upon substituting Federal enforcement for the permitting portion of a State program, OSM would charge the holder of a State permit the mid-term review fee specified by the State fee criteria.

*C. Should OSM Set a Fixed Fee Schedule, or Charge the Recipient of a Service for Actual Costs?*

OSM has identified two alternative mechanisms by which it might structure a fee for its services—(1) a fixed fee schedule, and (2) actual costs. Due to the legal and practical difficulties associated with the development of a fixed fee schedule for the essentially open-ended services it provides, OSM tentatively has concluded that the better alternative is to recover actual costs.

The United States Supreme Court, in interpreting the IOAA, has held that under that statute an agency must base a fee for a service on its value to an identifiable recipient. *National Cable Television Assn. (NCTA), Inc.* v. *United States*, 415 U.S. 336 (1974); *Federal Power Comm'n* v. *New England Power Co.*, 415 U.S. 345 (1974). In a series of contemporaneous cases on this issue, the United States Court of Appeals for the District of Columbia Circuit specified the requirements an agency must meet to justify a particular fee. *National Cable Television* v. *Federal Communications Comm'n*, 554 F.2d 1094 (D.C. Cir. 1976); *Electronics Industries Ass'n* v. *Federal Communications Comm'n*, 554 F.2d 1109 (D.C. Cir. 1976); *National Ass'n of Broadcasters* v. *Federal Communications Comm'n*, 554 F.2d 1118 (D.C. Cir. 1976); *Capital Cities Communications, Inc.* v. *Federal Communications Comm'n*, 554 F.2d 1135 (D.C. Cir. 1976).

Summarizing its interpretation of the "value to the recipient" standard as laid down in *NCTA*, the D.C. Circuit in *National Association of Broadcasters* stated:

> Briefly, we have interpreted the "value to the recipient" standard to include a number of specific requirements. First, the Commission must *justify* the assessment of a fee by a clear statement of the particular service or benefit which it is expected to reimburse. Second, it must calculate the *cost basis* for each fee assessed. This involves (a) an allocation of the specific expenses which form the cost basis for the fee to the smallest practical unit; (b) exclusion of any expenses incurred to serve an independent public interest; and (c) a public explanation of the specific expenses included in the cost basis for a particular fee, and an explanation of the criteria used to include or exclude particular items. Finally, the Commission must set a fee calculated to return this cost basis at a *rate* which reasonably reflects the cost of the services performed or the value conferred upon the payer. The fees may be imposed on beneficiaries of agency services who satisfy the criteria of *NCTA* and *New England Power*.
>
> 554 F.2d at 1133 (emphasis in original; footnote omitted).

The services for which OSM proposes to collect a fee—namely, the processing of applications for surface coal mining and reclamation permits, mining plans, applications for coal exploration permits, and mid-term permit review—

vary considerably in the content from recipient-to-recipient.

Involved may be large western or smaller eastern mines; surface and/or underground operations; an environmental impact statement or assessment; independent, joint or cooperative Federal-State responsibility; and numerous other variables. In view of these variables it would be difficult for OSM to calculate in advance the cost basis of a fixed fee schedule with the specificity addressed by *National Association of Broadcasters.*

Actual cost as the basis for permit application fees is expressly provided for by § 507(a) of SMCRA, which states that such fees "shall not exceed the actual or anticipated cost" of the permit process.

The charging of actual cost by the Bureau of Land Management under the authority of the Mineral Leasing Act and the IOAA has been upheld by the courts. *Sohio Transportation Co.* v. *United States*, No. 134–82L (Ct. Cl., filed June 12, 1984); *Nevada Power Co.* v. *Watt*, 711 F.2d 913 (10th Cir. 1983); *Alumet* v. *Andrus*, 607 F.2d 911 (10th Cir. 1979).

And even where a particular item of actual cost has been disallowed, the practice itself of charging actual cost has not been invalidated. *Public Service Co. of Colorado* v. *Andrus*, 433 F. Supp. 144 (D. Colo. 1977).

From the standpoint of the recipient of a service, the process of actual cost reimbursement provides several advantages as compared to a fixed fee schedule. A fixed fee schedule is necessarily based on an average of the estimated cost of providing a service to a large number of recipients. Not only is there a potential that this estimate might exceed the true cost, but also that the cost of servicing a particular recipient might be significantly less than the average—in either instance leading to an effective overcharge.

With actual cost reimbursement, however, each recipient is charged only for the documented cost of providing the service. Moreover, the recipient can, and has an incentive to, cooperate in reducing the cost incurred by the agency. And after billing the recipient can examine the actual cost the agency has documented, and for any item which appears to lack justification seek additional review. For these reasons the proposed rule is based on actual cost reimbursement, rather than a fixed fee schedule.

*D. What Specific Items or Activities Involved in Providing a Service Should the Fee Cover?*

In providing the services covered by the fee provisions of the proposed rule, OSM incurs many identifiable costs. Among the cost items involved are labor, management, materials, machines, travel, overhead, contracts, and environmental studies and documents, to name only a few. These items involve both direct costs, such as the salary of an employee, and indirect costs, such as those for fringe benefits, office space, heat, light, supervision and other overhead.

And not only does OSM itself incur cost in providing the services covered by the fee provisions of the proposed rule; such costs also are incurred by other organizations within the Department. For example, as recited in 30 CFR 740.4, the decision process for a mining plan involves the Secretary and the Bureau of Land Management, and the SMCRA permitting process may involve the Fish and Wildlife Service or other land management agency within the Department.

Because of the diverse situations in which the proposed rule would operate, it is impossible to predict in advance precisely what cost items might be involved in providing a particular covered service. In implementing the proposed rule OSM intends to recoup, to the maximum extent permitted by law, all of the actual costs both direct and indirect, incurred by the Department in providing each covered service.

One OSM cost that has generated considerable controversy in the past, and therefore merits specific discussion, is that for compliance with § 102(2)(C) of the National Enviromental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C), and particularly for the preparation of an environmental impact statement (EIS). The need for an EIS may significantly increase the cost to OSW of providing a service.

With minor exception the courts consistently have held that the cost of preparing an EIS is recoverable from an applicant or other recipient of a service. *Sohio Transportation Co.* v. *United States*, No. 134–82L (Ct. C1., filed June 12, 1984); *Nevada Power Co.* v. *Watt*, 711 F.2d 913 (10th Cir. 1983); *Alumet* v. *Andrus*, 607 F.2d 911 (10th Cir. 1979); *Mississippi Power & Light Co.* v. *Nuclear Regulatory Comm'n* 601 F.2d 223 (5th Cir. 1979), *cert. denied*, 444 U.S. 1102 (1980); *but see, Public Service Co. of Colorado* v. *Andrus*, 433 F. Supp. 144 (D. Colo. 1977).

Accordingly, for any service covered by the proposed rule OSM proposes also to recoup all costs incurred by the Department in complying with § 102(2)(C) of NEPA, including the cost of preparing an EIS.

*E. What Provision Should Be Made for Small Operators?*

Section 507(a) of SMCHA provides that the application fee for a surface coal mining and reclamation permit "may be *less than*" the actual or anticipated processing cost. (Emphasis added.) The legislative history of SMCHA indicates that one intent of the Congress in drafting this provision was to protect small operators from excessive costs.

In discussing H.R. 13950, a precursor to the enacted bill, the House Committee Report states:

> Section 507(a): Under the old bill the amount of the application fee was to be based as nearly as possible on the costs of adminstering the permit application. *Small operators* were concerned that this might significantly increase the front end costs and put him [sic] at a disadvantage to the larger operator. In H.R. 13950 the language was changed to allow the regulatory authority to charge an applicant for less than the cost of administering the application.
>
> H.R. Rep. 1445, 94th Cong., 2d Sess. 7 (1976) (emphasis added).

Consistent with this expressed intent of the Congress, for small operators who apply for a surface coal mining and reclamation permit the proposed rule would authorize OSM to waive reimbursement of any actual cost in excess of $500. In addition, in keeping with the intent of the Congress the proposed rule would authorize OSM to make a similar waiver in connection with the fees for other services covered by the rule.

*F. Typical Processing Costs.*

The typical costs historically incurred by OSM in processing permit applications and mining plans provide a reasonable estimate of the fees OSM would collect under the proposed rule. Because OSM in the past did not have a detailed accounting system to monitor such costs, the following figures are only approximations based on the best data available. Except for the cost of environmental impact statement (EIS) preparation, the figures include only those costs incurred at the applicable OSM technical center, and do not include those incurred at OSM headquarters in Washington, D.C. or at other OSM offices.

Typical permit application and mining plan processing costs for western mines for the several years that data are available have ranged from $37,000 to

over $110,000, with an average cost of $60,000. Where an EIS was required for a western mine, the processing cost increased by an amount ranging from $75,000 to $200,000. For eastern mines, permit application processing costs for the years that data are available have ranged from $6,000 to $29,000. No figures are available on the cost of EIS preparation for eastern mines. Although no data are available on the cost of processing applications for the renewal of, revision of, or transfer assignment or sale of rights in existing permits, OSM anticipates that these costs typically would be lower than those for processing applications for original permits.

OSM experience as the regulatory authority in Tennessee indicates that over the five-year life of a permit the cost of inspecting an eastern mine approximates $70,000. OSM experience in Oklahoma suggests that the cost of inspecting a western mine for a comparable period may exceed $75,000. Because enforcement actions vary greatly from permit-to-permit, it is not possible to make a meaningful estimate of typical enforcement costs.

## III. Discussion of Proposed Rule

### *A. Proposed Implementation Date*

After promulgation of the final rule, OSM proposes to bill the recipients of covered services for all costs incurred by the Department in providing such services beginning today, the publication date of the proposed rule. This implementation date would apply regardless of when OSM began to provide the service, or at what stage OSM was in the review and decision process. Although proposal of this rule does not of itself impose a payment obligation, persons are put on actual notice that the final rule may include payment obligations for costs incurred by the Department from today's date.

Comments are requested on two possible alternative implementation dates. The first alternative would be to make the final rule apply to costs incurred by the Department from 30 days following the promulgation of the final rule. Such a final rule would result in the collection of fewer costs than the other alternatives.

A second alternative, which could be adopted nationwide or, perhaps, only in Tennessee and on Indian lands, would be for the Department to bill for costs incurred subsequent to October 1, 1984. The October 1, 1984, implementation date would be selected for three reasons: First, it is the date on which OSM implemented the cost accounting procedures necessary for determining the actual cost of providing a service. Second, it is the beginning of a new fiscal year, and thus a logical benchmark for accounting purposes. And third, it marks the beginning of the Federal programs for Tennessee and Indian lands. The preambles to those programs put applicants on notice that costs incurred subsequent to October 1, 1984 could be recovered in a permit fee.

### *B. Overview*

The proposed rule includes five independent cost reimbursement regulations, and in addition a series of comprehensive procedures that in varying degree would supplement each of them. The five independent regulations would require an applicant for or holder of a surface coal mining and reclamation permit, an operator/lessee who submits a mining plan for review and approval, or an applicant for a coal exploration permit to reimburse OSM for the actual cost incurred by the Department in processing the application or mining plan, or performing a mid-term permit review.

Proposed 30 CFR 736.25(a) would apply to an applicant for a permit under a Federal program for a State; § 736.25(b) to a permittee under a Federal program; § 740.13(a)(4) to a permittee on Federal lands; § 740.13(b) to an applicant for a permit on Federal lands; § 746.12 to an operator/lessee who submits a mining plan; § 750.11(e) to a permittee on Indian lands; § 750.12(a) to an applicant for a permit on Indian lands; and § 772.12(a)(2) to an applicant for a coal exploration permit.

The comprehensive cost reimbursement procedures would establish uniform requirements for reimbursement of OSM under each of the five independent regulations. They also would include procedures governing reimbursement of OSM under any one or more of the five independent regulations.

These comprehensive procedures would be codified at 30 CFR 701.12, and would include: General requirements; authority for OSM to waive reimbursement by a small operator of any actual cost exceeding $500; and fee calculation and payment procedures, including provision for installment payments by an applicant for a permit to conduct surface coal mining and reclamation operations.

OSM has considered allowing an applicant to seek full or partial waiver of a fee upon satisfactory showing that payment of the full fee would cause undue hardship. OSM solicits (1) comment on whether and how such provision should be included, and (2) suggested criteria to ensure its reasonable, fair, and consistent application.

The organization of the proposed rule is intended to achieve maximum uniformity with minimum repetition. Although the five independent regulations would apply to different types of services, and would operate in somewhat different statutory and regulatory contexts, each would impose essentially the same requirement—namely, that the recipient of a service reimburse OSM for the actual cost incurred by the Department in providing the service. In view of these similarities, OSM tentatively has concluded that the use of comprehensive provisions of general applicability is preferable to the promulgation of five totally self-contained fee provisions. For consistency, any specific procedures applicable to a particular service also would be grouped with the comprehensive provisions.

Each of the five independent fee regulations would be codified in the part of 30 CFR Chapter VII which governs the service for which the fee is charged. The comprehensive provisions would be codified in existing 30 CFR Part 701, along with the general introductory material for the permanent regulatory program under SMCRA.

Where the proposed rule refers to the "Applicant," it is understood that the status of the applicant would change during the fee collection process, and that the applicant may, for example, become a permittee. For purposes of this rule, the term "applicant" should be read to include any subsequent status an applicant may acquire in the permitting process.

To avoid unnecessary repetition of the phrase "mining plan or mining plan modification," the phrase "mining plan" is used throughout the proposed rule to apply to both original mining plans and mining plan modifications.

### *C. Section-by-Section Analysis*

#### Part 701—Permanent Regulatory Program

*Section 701.12 Cost reimbursement procedures.*

Section 701.12 would establish comprehensive procedures governing reimbursment of OSM for the actual cost incurred by the Department in providing a service covered by the proposed rule, including the processing of an application for a surface coal mining and reclamation permit, an application for a permit to conduct coal exploration and a mining plan, and the mid-term review of a surface coal mining and reclamation permit.

*Section 701.12(a) General requirements.*

Section 701.12(a) would include both general fee requirements applicable to all operators, and provision for OSM to waive reimbursement by small operators of any actual cost in excess of $500.

Except as provided in paragraph (a)(2) for a small operator, § 701.12(a)(1) would require the recipient of a service covered by the proposed rule to reimburse OSM as provided elsewhere in §701.12 for the actual cost incurred by the Department in providing the service.

Under § 701.12(a)(2), upon the request of any person required to reimburse OSM under paragraph (a)(1), and a satisfactory showing that he or she is eligible under 30 CFR 795.6 as a small operator, OSM would be authorized to waive reimbursement of that part of the actual cost incurred by the Department in providing the service which exceeds $500.

The $500 maximum amount was selected to discourage frivolous applications, and to insure that small operators bear at least a portion of the cost of providing a service. This maximum amount would apply to all services covered by the proposed rule.

A person who desired a waiver under § 701.12(a)(2) would have to request the waiver and demonstrate to OSM that he or she is eligible under 30 CFR 795.6 as a small operator. Section 795.6 is the provision that governs eligibility for the Small Operator Assistance Program established under 507(c) of SMCRA. It generally requires that a person's production from all locations during any consecutive 12-month period during the permit term will not exceed 100,000 tons of coal.

Notwithstanding the real or apparent status of the applicant or operator/lessee as a small operator, OSM would have complete discretion to charge the full fee. This would enable OSM to consider any unique circumstances and deny a waiver in appropriate cases.

OSM solicits public comment on whether $500 in an appropriate maximum amount to charge small operators, or whether the maximum fee should be reduced or increased to some other amount.

*Section 701.12(b) Calculation and billing of fee.*

Section 701.12(b) would specify the procedures by which OSM would calculate the actual cost of providing a service and bill the recipient. This section would require OSM to take the following steps:

OSM would be required to keep a complete, accurate, detailed account of the actual cost incurred by the Department in providing the service, including but not limited to the direct and indirect cost of any labor, management, materials, machines, travel, overhead, contract, environmental study or document, or other necessary or appropriate item of cost. This list of potential cost items is not meant to be inclusive, but merely represents some typical costs the Department may incur in providing a covered service.

After providing the service, OSM would subtract from the actual cost incurred by the Department any advance payment made by the recipient of the service under subsequent paragraph (c)(1)(i), and either bill the recipient for the actual balance due, or refund any overpayment. Under this section, OSM could bill the recipient for work completed at any point in the review and decision process, and would not have to postpone billing until a final decision was made. In addition, OSM would be required to prepare, and submit to the recipient of the service along with the bill or refund, a detailed account of the actual cost incurred by the Department.

In drafting the proposed rule, OSM considered several alternatives ways to schedule advance fee payments. Among them were advance payment of a specified amount, advance payment of the entire estimated amount of the fee, advance payment of part of the estimated amount of the fee, and no payment until after the service was provided. The proposed rule incorporates the first of these alternatives.

The proposed postponement of payment of most of the fee until after OSM provides all or part of the service would relieve the recipient from potentially burdensome advance payment. It also would give OSM added incentive to provide the service in a timely manner. The proposed rule would apply in the same way to both pending and new applications and mining plans. Thus, after reviewing a pending application or mining plan, OSM would bill the applicant or operator/lessee under proposed § 701.12(b)(2) for the actual balance due for costs incurred beginning on the implementation date of this rule.

*Section 701.12(c) Payment procedures.*

*When payments due.* Under § 701.12(c)(1)(i) any person who requests that OSM provide a service covered by this section would be required to submit with the request an advance payment of $1,500. A person who requests a waiver as a small operator would be required to submit a reduced amount of $500, subject however to the payment of an additional $1,000 if the waiver was denied. Where OSM is required by law to provide a service without a specific request, such as for mid-term permit review, an advance payment would not be required. A person who applies for a surface coal mining and reclamation permit and submits a mining for the same operation plan would have to submit only one advance payment.

Under § 701.12(6)(1)(ii), the recipient of a service covered by this section would be required to pay any amount billed by OSM under § 701.12 within 30 days of the OSM billing date. OSM solicits comment on whether more time, such as 60 or 90 days, should be allowed for payment. OSM would be given authority to withhold the authorization sought by the recipient of the service until after payment was made of the amount billed. In addition to these payment requirements, an applicant authorized by OSM to pay in installments would be required to pay them by the deadlines recited in the installment payment provisions of § 701.12(c)(3).

*Form of payment.* Under § 701.12(c)(2) any payment made under § 701.12 would have to be in the form of a check, draft or money order payable to OSM.

*Installment payments.* Section 507(a) of SMCRA provides that "[t]he regulatory authority may develop procedures so as to enable the cost of the fee to be paid over the term of the [surface coal mining and reclamation] permit." Accordingly, for a surface coal mining and reclamation permit § 701.12(c)(3) would authorize payment of the application fee in annual installments.

OSM solicits comment on an alternative payment procedure that would not provide for installment payments, but instead would require full payment within a specified time (*e.g.*, 90 days of billing).

The installment payment provisions of § 701.12(c)(3) would apply to the application fee for a surface coal mining and reclamation permit and to the fee for processing a mining plan. It would not apply to the application fee for a coal exploration permit or to the fee for mid-term permit review. It would not affect the requirement for an advance payment of $1,500, or in the case of a small operator $500, but would apply only to payment of the remaining actual balance due.

Payments would be spread over the five-year life of the permit, with a 20

percent down payment and the remainder of the actual balance due payable in four installments due at succeeding one year intervals. Since the use of installment payments would in effect constitute a loan, the applicant would be required to pay interest to OSM on the unpaid installment balance.

Upon request, and a satisfactory showing that the applicant met either of two specified criteria, OSM would be required to authorize the applicant to pay the bill for the actual balance due under paragraph (b)(2)(ii) of this section in installments. The criteria are either that the actual balance due exceeds 4% of the capital (other than that for mobile equipment) needed to open the mine, or the coal reserves for the proposed mine are less than one million tons. OSM has excluded the cost of mobile equipment from the first criterion because the use of such equipment typically is not limited to a single mine.

An applicant who desired to pay installments would have to submit to OSM prior to the date when payment was due a request to pay in installments, and a satisfactory showing that the proposed mine meets either of the specified criteria. The applicant could submit the request either before or after receiving the OSM bill for the actual balance due. Regardless of when the request was submitted, however, the applicant would be required to make all payments by the specified deadlines.

An applicant who requested authorization to pay in installments would have to make a down payment of 20 percent of the actual balance due within 30 days of the OSM billing date. If OSM authorized payment in installments, the applicant would pay the remainder of the actual balance due as specified in § 701.12(c)(3)(iv). If OSM disallowed payment in installments, the applicant would have to pay the remainder of the actual balance due, plus interest as specified in § 701.12(c)(5)(iii), within 30 days of the date of the OSM notice of denial. Such interest would run from the date payment originally was due until the date payment actually was made. The provisions for a down payment of 20% and the payment of interest if authorization is denied are intended to forestall requests for installment payments by unqualified applicants for the purpose of postponing payment.

Where an applicant was authorized to pay installments, the remainder of the actual balance due, plus interest, would be due in four equal annual installments. The first installment, plus interest, would be due within 30 days of the first anniversary of the initial OSM billing date. The second, third and fourth installments, plus interest, would be due within 30 days of the corresponding numbered anniversaries of the initial OSM billing date.

With each installment the applicant would be required to pay interest on the unpaid installment balance from the date of the previous installment payment to the date of the current payment. The rate of interest charged would be the investment rate prevailing for 52 week U.S. Treasury Bills at the last Treasury auction prior to the date of the previous payment.

The rate of interest is tied to the auction preceding the date of the previous payment so that the applicant would know the applicable rate in advance of the period for which interest is charged. An applicant would be allowed to pay any installment or part thereof, plus accured interest, in advance, and thereby avoid incurring future interest charges on the prepaid amount.

*Fee nonrefundable.* Except as provided for small operators, or in the case of an overchange or overpayment, § 701.12(c)(4) of the proposed rule would prohibit OSM from waiving or refunding payment of any part of the fee. The recipient of a service would be required to pay the entire fee regardless of any mitigating circumstances.

Because the proposed fees would be based on the actual costs incurred by the Department in providing a service, and not on any specific outcome of the review and decision process, OSM tentatively has concluded that it is reasonable for the recipient of the service to bear these costs regardless of the outcome of the review and decision process. Once the Department had incurred a cost in providing a service, the recipient would be liable for reimbursing OSM when billed for that cost.

The recipient of a service would have to make any payment required by this section by the date it is due, even if the request for the service is withdrawn, the authorization sought is denied, operations under any resulting authorization are terminated, or any other condition arises.

*Failure to Pay.* To enforce the payment provisions of the proposed rule, OSM tentatively has concluded that it would be appropriate to provide for sanctions against a recipient of a service who fails to pay any part of the fee when due. Three mechanisms for this purpose are included in the proposed rule.

One would make the failure to pay any part of the fee when due a violation of the permit. The second would authorize OSM to take various remedial steps where the recipient of a service failed to make any required payment. The third would require the payment of interest on any amount in arrears.

In addition, where the recipient of a service failed to make a payment as required by this section, OSM, as appropriate could delay the processing of the request, deny the authorization sought, withhold notice of its decision on the request, or take other appropriate action.

Finally, except as provided in paragraph (c)(3) for installment payments, any person who failed to make a payment required by this section when due would have to pay interest on the unpaid balance at the investment rate prevailing for 52 week U.S. Treasury bills at the last Treasury auction prior to the date on which payment is due.

OSM could consider any current failure to pay a fee as required by the proposed rule a "violation of th[e] Act" under section 510(c) of SMCRA, and thus as grounds for denying issuance of a surface coal mining and reclamation permit. As part of the permitting process, OSM would determine whether the applicant was in arrears with payments for any previous fee, and in appropriate circumstances would deny permit issuance until payment was made.

*Excess payment.* Section 701.12(c)(6) would require OSM to notify the recipient of a service of any overcharge billed under proposed § 701.12, and of the corrected balance due. It also would require OSM to refund any overpayment. Where the recipient of a service had not yet paid the applicable bill, notice of an overcharge would not extend the time for payment, and the corrected balance would be due within 30 days of the original billing date. Where the bill already was paid, OSM would refund the overpayment.

*Petition for Review.* Section 701.12(d) would establish procedures by which the recipient of a service, after making all current payments due under proposed § 701.12, could petition the Director of OSM to review the actual costs billed by OSM, and to refund any overcharge.

The requirement for payment before a petition is filed is intended to prevent use of the review process as a means for postponing or otherwise avoiding payment. This payment requirement would apply to all current payments due, and all installments when due, but would not require the prepayment of future installments.

A petitioner would have to identify each specific item of cost that is

challenged, and would have the burden of proving that the amount charged exceeded the actual cost incurred by the Department in providing the service. If dissatisfied with the Director's decision on review, the petitioner could appeal to the Department's Office of Hearings and Appeals under 43 CFR Part 4.

The following discussion describes the various programs covered by this rule:

**Part 736—Federal Program For a State**

*Section 736.25 Permit fee.*

Section 736.25(a) would require any person who submits to OSM an application for a permit to conduct surface coal mining and reclamation operations pursuant to a Federal program, including the renewal of, revision of, or transfer, assignment or sale of rights in an existing permit, to reimburse OSM for the actual cost incurred by the Department in processing the application, as provided in proposed § 701.12.

Section 736.25(b) would require any person who holds a surface coal mining and reclamation permit issued pursuant to a Federal program to reimburse OSM as provided in proposed § 701.12 for the actual cost incurred by the Department in performing a mid-term permit review.

**Part 740—General Requirements for Surface Coal Mining and Reclamation Operations on Federal Lands**

*Section 740.13 Permits.*

Section 740.13(a)(4) would require any person who holds a surface coal mining and reclamation permit subject to this part, for which OSM is the regulatory authority, to reimburse OSM as provided in proposed § 701.12 for the actual cost incurred by the Department in performing a mid-term permit review.

Section 740.13(b)(1) would include three different fee payment provisions covering applicants for surface coal mining and reclamation permits for operations on Federal lands. The provision that applied in a given instance would depend on whether OSM or a State was the regulatory authority, and whether a State-Federal cooperative agreement required OSM concurrence with, or other OSM action related to, a State permitting decision.

Section 740.13(b) would apply to any person who submits an application for a permit to conduct surface coal mining and reclamation operations on lands subject to 30 CFR Part 740, including the renewal of, revision of, or transfer, assignment or sale of rights in an existing permit.

Notwithstanding the provisions of 30 CFR 740.11, where OSM is the regulatory authority the applicant would have to reimburse OSM for the actual cost incurred by the Department in processing the application, as provided in proposed § 701.12. Section 740.11, which provides that upon approval or promulgation of a regulatory program for a State, the State program applies to surface coal mining and reclamation operations on Federal lands, no longer would govern determination of the applicable fee criteria in such circumstances. Only in this limited context, however, would the proposed rule supersede § 740.11.

Where a State is the regulatory authority, the applicant would have to pay an application fee to the State as provided by the permit fee criteria of the State program.

Where OSM concurrence with, or other OSM action related to, the permitting decision of a State regulatory authority was required under a State-Federal cooperative agreement, the applicant would have to reimburse OSM for the actual cost incurred by the Department in making the decision on concurrence or taking the other action. Other OSM actions covered by proposed § 740.13(b)(iii) would include, for example, compatibility findings under § 522(e)(2) of SMCRA.

**Part 746—Review and Approval of Mining Plans**

*Section 746.12 Mining Plan Review Fee.*

Section 746.12 would require any operator/lessee who submits a mining plan or mining plan modification for review and approval under 30 CFR Part 746 to reimburse OSM for the actual cost incurred by the Department in processing the mining plan, as provided in proposed § 701.12. OSM would recover mining plan precessing costs even where, under a Federal-State cooperative agreement, a State would issue the surface mining and reclamation permit and collect the permit application fee.

Where OSM is the regulatory authority and there is an overlap in the steps required for processing a permit application and a mining plan, OSM would recover any overlapping costs only one time. However, where a State is the regulatory authority for processing a permit application, but OSM processes the mining plan, OSM might be required by law to duplicate some of the steps involved in the permitting process, with a corresponding overlap in the State and OSM fees. *See In Re: Permanent Surface Mining Litigation*, No. 79–1144 (D. D.C. July 6, 1984). In this latter case OSM would bill the operator/lessee for the full actual cost of processing the mining plan.

**Part 750—Requirements for Surface Coal Mining and Reclamation Operations on Indian Lands**

*Section 750.11 Permits.*

Section 750.11(e) would require any person who holds a surface coal mining and reclamation permit subject to this part to reimburse OSM as provided in § 701.12 of this chapter for the actual cost incurred by the Department in performing a mid-term permit review.

*Section 750.12 Permit Applications.*

Section 750.12(a) would require any person who submits to OSM an application for a permit to conduct surface coal mining and reclamation operations on Indian lands, including the renewal of, revision of, or transfer, assignment or sale of rights in an existing permit, to reimburse OSM for the actual cost incurred by the Department in processing the application, as provided in proposed § 701.12.

**Part 772—Requirements for Coal Exploration**

*Section 772.12 Permit requirements for exploration removing more than 250 tons of coal.*

Section 772.12(a) would add to the existing application requirements for a coal exploration permit a new requirement that would apply where OSM is the regulatory authority. Before conducting any exploration, any person who intends to conduct coal exploration outside a permit area where more than 250 tons of coal would be removed, or which would take place on lands designated as unsuitable for surface mining under 30 CFR Subchapter F, would have to reimburse OSM for the actual cost incurred by the Department in processing the application, as provided in proposed § 701.12.

**IV. Procedural Matters**

*Federal Paperwork Reduction Act*

The proposed rule contains information collection requirements that are being sent for review to the Office of Management and Budget under 44 U.S.C. 3507.

*Executive Order 12291*

The Department has examined the proposed rule acording to the criteria of Executive Order 12291 (Febuary 17, 1981) and has determined that it is not major and does not require a regulatory impact analysis.

Out of the approximately 6,000 active mining operations in the United States, the majority are governed by State programs, and not directly affected by the rule. Most of the operations in the minority potentially affected by the proposed rule already have surface mining and reclamation permits, and approved mining plans where applicable, so for this minority of operations the rule would apply only to the typically less costly renewal of, revision of, or transfer, assignment or sale of rights in existing permits. Since permit renewal is required only at five-year intervals, the potential number of renewal applications in a given year is only one-fifth of the total number of permits outstanding. Adding to these the permits for new operations, and for coal exploration, and the processing of mining plans, for the anticipated number of applications and mining plans processed annually by OSM the anticipated fees are expected to fall below the criteria established by the Executive Order.

Against this background of limited activity, the Department has concluded that the proposed rule would not have an annual effect on the economy of $100 million or more, or result in a substantial increase in costs or prices for the Federal government, consumers, individual industries, State or local government agencies, or geographic regions.

*Regulatory Flexibility Act*

The Department also has determined, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, that the proposed rule would not have a significant economic impact on a substantial number of small entities. In view of the proposed $500 ceiling on fees charged to small operators, the proposed rule would have only minimal economic impact on affected small businesses and self-employed operators.

*National Environmental Policy Act*

To the extent the proposed rule applies to permit application fees in Federal Program States or on Federal lands it constitutes the promulgation of a Federal program or the implementation of a Federal lands program, which are exempt under section 702(d) of SMCRA, 30 U.S.C. 1292(d), from compliance with section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C).

To the extent the proposed rule applies to other than permit application fees in Federal Program States or on Federal lands, OSM has prepared a draft environmental assessment (EA) and has made an interim finding that it would not significantly affect the quality of the human environment. The draft EA is on file in the OSM Administrative Record at the address listed previously (see "**ADDRESSES**"). A final EA will be completed and a final finding made on the significance of any resulting impacts prior to issuance of the final rule.

*Principal Drafters*

This proposal was drafted principally by Albert Kashinski of the Interior Department, Office of the Solicitor and Murray Newton of the Office of Surface Mining.

**List of Subjects in 30 CFR Parts 701, 736, 740, 746, 750 and 772**

Coal mining, Surface mining, Underground mining.

Accordingly, it is proposed to amend 30 CFR Parts 701, 736, 740, 746, 750 and 772 as follows:

Dated: February 15, 1985.

**J. Steven Griles,**

*Deputy Assistant Secretary for Land and Minerals Management.*

## PART 701—PERMANENT REGULATORY PROGRAM

1. The authority citation for Part 701 is revised to read as follows:

**Authority:** Pub. L. 95-87 (30 U.S.C. 1201 *et seq.*), unless otherwise noted. Sec. 701.12 also issued under sec. 9701, Pub. L. 97-258, 96 Stat. 1051 (31 U.S.C. 9701).

2. Section 701.12 is added to Part 701 as follows:

**§ 701.12 Cost reimbursement procedures.**

(a) *General requirements*—(1) *All operators.* Any person who is required by this chapter to reimburse OSM for the actual cost incurred by the Department in providing a service, including the processing of an application for a surface coal mining and reclamation permit, the processing of an application for a coal exploration permit, the review of a mining plan, and the mid-term review of a surface coal mining and reclamation permit, shall do so as provided in this section.

(2) *Small Operators.* Upon the request of any person who is required to reimburse OSM as provided in paragraph (a)(1) of this section, and a satisfactory showing that he or she is eligible under § 795.6 of this chapter as a small operator, OSM may waive reimbursement of that part of the actual cost incurred by the Department in providing the service which exceeds $500.

(b) *Calculation and billing of fee.* In providing a service covered by this section, OSM shall—

(1) Keep a complete, accurate, detailed account of the actual cost incurred by the Department in providing the service, including but not limited to the direct and indirect cost of any labor, management, materials, machines, travel, overhead, contract, environmental study or document, or other necessary or appropriate item of cost; and

(2) After providing the service—

(i) Subtract from the actual cost accounted for under paragraph (b)(1) of this section any advance payment made under paragraph (c)(1)(i) of this section;

(ii) Either bill the recipient of the service for the actual balance due, or refund any overpayment; and

(iii) Prepare, and submit to the recipient of the service along with the bill or refund, a detailed account of the actual cost incurred by the Department in providing the service.

(c) *Payment procedures.*—(1) *When payments due.* (i) Except as provided in this paragraph, any person who requests that OSM provide a service covered by this section shall submit with such request an advance payment of $1,500. A person who requests a waiver under paragraph (a)(2) of this section shall submit an advance payment of $500, subject to payment of an additional $1,000 if the waiver is denied. A person who applies for a surface coal mining and reclamation permit and submits a mining plan for the same operation may submit a single advance payment to cover both reviews.

(ii) The recipient of a service covered by this section shall pay any amount billed by OSM under this section within 30 days of the billing date and, at OSM's discretion, prior to the issuance of any authorization sought. An applicant who is authorized by OSM to pay installments shall make installment payments by the dates specified in paragraph (c)(3) of this section.

(2) *Form of payment.* Any payment required by this section shall be made in the form of a check, draft or money order payable to OSM.

(3) *Installment payments.* (i) Upon request, OSM shall authorize an applicant for a surface coal mining and reclamation permit or an operator/lessee who submits a mining plan to pay the bill for the actual balance due under paragraph (b)(2)(ii) of this section in installments if the applicant makes a satisfactory showing that either—

(A) The actual balance due exceeds 4% of the capital (other than that for mobile equipment) needed to open the mine; or

(B) The size of the coal reserves for the proposed mine is less than one million tons.

(ii) Any applicant for a surface coal mining and reclamation permit or operator/lessee who desires to pay the actual balance due under paragraph (b)(2)(ii) of this section in installments shall submit to OSM prior to the date when payment is due—

(A) A request to pay in installments; and

(B) A satisfactory showing that the proposed mine meets either of the criteria specified in paragraph (c)(3)(i) of this section.

(iii)(A) Any applicant who requests authorization to pay installments shall make a down payment of 20% of the actual balance due within 30 days of the OSM billing date.

(B) If OSM authorizes payment in installments, the applicant shall make payments as specified in paragraph (c)(3)(iv) of this section.

(C) If OSM denies payment in installments, the applicant shall pay the remainder of the actual balance due, plus interest as specified in paragraph (c)(5)(iii) of this section, within 30 days of the date of the OSM notice of denial. Such interest shall run from the date payment originally was due until the date payment is made.

(iv) An applicant who is authorized by OSM to pay installments shall—

(A) Pay the remainder of the actual balance due, plus interest, in four equal annual installments;

(B) Pay the first installment, plus interest, within 30 days of the first anniversary of the initial OSM billing date;

(C) Pay the second, third and fourth installments, plus interest, within 30 days of the corresponding numbered anniversaries of the initial OSM billing date; and

(D) With each installment, pay interest on the unpaid installment balance from the date of the previous installment payment to the date of the current payment at the investment rate prevailing for 52-week U.S. Treasury Bills at the last Treasury auction prior to the date of the previous payment.

(v) An applicant who is authorized to pay installments may pay any installment or part thereof, plus accrued interest, in advance.

(4) *Fee nonrefundable.* (i) OSM shall not waive or refund payment of any amount that is due or paid under this section unless OSM—

(A) Waives reimbursement of any actual cost that exceeds $500 under paragraph (a)(2) of this section; or

(B) Finds that the recipient of a service either was overcharged or made an overpayment.

(ii) Any person who requests that OSM provide a service covered by this section shall make any required payment by the date it is due, even if the request for the service is withdrawn, the authorization sought is denied, operations under any resulting authorization are terminated, or any other condition arises.

(5) *Failure to pay.* (i) Any permit resulting from an application for which the payment of a fee is governed by this section shall include the condition that failure to pay any part of the fee when due is a violation of the permit.

(ii) Where any person fails to make a payment as required by this section, OSM may delay the processing of the request, deny the authorization sought, withhold notice of its decision on the request, or take other appropriate action.

(iii) Except as provided in paragraph (c)(3) for installment payments, any person who fails to make a payment required by this section when due shall pay interest on the unpaid balance at the investment rate prevailing for 52-week U.S. Treasury bills at the last Treasury auction prior to the date on which payment is due.

(6) *Overcharge or overpayment.* OSM shall—

(i) Upon finding that a bill submitted under this section includes an overcharge, notify the recipient of the service of the overcharge, and of the corrected balance due; and

(ii) Refund any overpayment made by the recipient of a service under this section.

(d) *Petition for review.* (1) After making all current payments due under this section, a recipient of a service covered by this section may petition the Director to review the actual cost billed by OSM under this section, and to refund any overcharge.

(2) A petitioner shall identify each specific item of cost that is challenged, and shall have the burden of proving that the amount charged by OSM exceeded the actual cost incurred by the Department in providing the service.

(3) A petitioner may appeal the decision of the Director to the U.S. Department of the Interior, Office of Hearings and Appeals under 43 CFR Part 4.

## PART 736—FEDERAL PROGRAM FOR A STATE

3. The authority citation for Part 736 is revised to read as follows:

**Authority:** Secs. 501, 503–519, 521, 522, 525, and 705, Pub. L. 95–87 (30 U.S.C. 1251, 1253–1269, 1271, 1272, 1275 and 1295).

4. Section 736.25 is added to Part 736 as follows:

**§ 736.25 Permit fees.**

(a) Any person who submits an application to OSM for a permit to conduct surface coal mining and reclamation operations pursuant to a Federal program, including the renewal of, revision of, or transfer, assignment or sale of rights in an existing permit, shall reimburse OSM as provided in § 701.12 of this chapter for the actual cost incurred by the Department in processing the application.

(b) Any person who holds a surface coal mining and reclamation permit issued pursuant to a Federal program shall reimburse OSM as provided in § 701.12 of this chapter for the actual cost incurred by the Department in performing a mid-term permit review.

## PART 740—GENERAL REQUIREMENTS FOR SURFACE COAL MINING AND RECLAMATION OPERATIONS ON FEDERAL LANDS

5. The authority citation for Part 740 reads as follows:

**Authority:** 30 U.S.C. 1201 *et seq.* and 30 U.S.C. 181 *et seq.* Secs. 740.13(a)(4) and 740.13(b)(1)(iii) also issued under sec. 9701, Pub. L. 97–258, 96 Stat. 1051 (31 U.S.C. 9701).

6. In § 740.13, paragraph (a)(4) is added, and paragraph (b)(1) is revised to read as follows:

**§ 740.13 Permits.**

(a) * * *

(4) Any person who holds a surface coal mining and reclamation permit subject to this part, for which OSM is the regulatory authority, shall reimburse OSM as provided in § 701.12 of this chapter for the actual incurred by the Department in performing a mid-term permit review.

(b) *Permit application package.* (1) Any person who submits an application for a permit to conduct surface coal mining and reclamation operations on lands subject to this part, including the renewal of, revision of, or transfer, assignment or sale of rights in an existing permit, shall—

(i) Notwithstanding the provisions of § 740.11 of this chapter, where OSM is the regulatory authority reimburse OSM as provided in § 701.12 of this chapter for the actual cost incurred by the Department in processing the application;

(ii) Where a State is the regulatory authority, pay an application fee to the

State regulatory authority as provided by the State program.

(iii) Where OSM concurrence with, or other OSM action related to, the permitting decision of a State regulatory authority is required under a State-Federal cooperative agreement, reimburse OSM for the actual cost incurred by the Department in making a decision on concurrence or taking the other action.

* * * * *

## PART 746—REVIEW AND APPROVAL OF MINING PLANS

7. The authority citation for Part 746 is revised to read as follows:

**Authority:** 30 U.S.C. 1201 *et seq. and 30 U.S.C. 181 et seq.* Sec. 746.12 also issued under sec. 9701, Pub. L. 97-258, 96 Stat. 1051 (31 U.S.C. 9701).

8. Section 746.12 is added to Part 746 as follows:

### § 746.12 Mining plan review fee.

Any operator/lessee who submits a mining plan, including a mining plan modification, for review and decision under this part shall reimburse OSM as provided in § 701.12 of this chapter for the actual cost incurred by the Department in processing the mining plan.

## PART 750—REQUIREMENTS FOR SURFACE COAL MINING AND RECLAMATION OPERATIONS ON INDIAN LANDS

9. The authority citation for Part 750 is revised to read as follows:

**Authority:** Pub. L. 95-87 (30 U.S.C. 1201-1328); 5 U.S.C. 301; Secs. 750.11 and 750.12 also issued under sec. 9701, Pub. L. 97-258, 96 Stat. 1051 (31 U.S.C. 9701).

10. In § 750.11, paragraph (e) is added as follows:

### § 750.11 Permits

* * * * *

(e) Any person who holds a surface coal mining and reclamation permit subject to this part shall reimburse OSM as provided in 701.12 of this chapter for the actual cost incurred by the Department in performing a mid-term permit review.

11. In 750.12, paragraph (a) is revised to read as follows:

### § 750.12 Permit fees.

(a) Any person who submits to OSM an application for a permit to conduct surface coal mining and reclamation operations on Indian lands, including the renewal of, revision of, or transfer, assignment or sale of rights in an existing permit, shall reimburse OSM as provided in § 701.12 of this chapter for the actual cost incurred by the Department in processing the application.

* * * * *

## PART 772—REQUIREMENTS FOR COAL EXPLORATION

12. The authority citation for Part 772 is revised to read as follows:

**Authority:** Pub. L. 95-87 (30 U.S.C. 1201 *et seq.*). Sec. 772.12(a)(2) also issued under sec. 9701, Pub. L. 97-258, 96 Stat. 1051 (31 U.S.C. 9701).

13. In § 772.12, paragraph (a) is revised to read as follows:

### § 772.12 Permit requirements for exploration removing more than 250 tons of coal.

(a) *Exploration permit.* Any person who intends to conduct coal exploration outside a permit area during which more than 250 tons of coal will be removed or which will take place on lands designated as unsuitable for surface mining under Subchapter F of this chapter, before conducting the exploration shall—

(1) Submit to the regulatory authority an application for a coal exploration permit;

(2) Obtain written approval from the regulatory authority in an exploration permit; and

(3) Where OSM is the regulatory authority, reimburse OSM as provided in § 701.12 of this chapter for the actual cost incurred by the Department in processing the application.

* * * * *

[FR Doc. 85-4239 Filed 2-21-85; 8:45 am]

BILLING CODE 4310-05-M

federal register

Friday
February 22, 1985

Part IV

# Department of Labor

**Employment Standards Administration, Wage and Hour Division**

**Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions, Notice**

## 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 its 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 5.1 (including the statutes listed at 36 FR 306 (1970) following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determinations 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, 48 FR 19533 (1983) and of Secretary of Labor's Orders 9–83, 48 FR 35736 (1983), and 6–84, 49 FR 32473 (1984). 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 the 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 Part 1 and 5. Accordingly, the applicable decision together with any modification 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 5.1 (including the statutes listed at 36 FR 306 (1970) 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, 48 FR 19533 (1983) and of Secretary of Labor's Order 6–84, 49 FR 32473 (1984). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded 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 in 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 persons 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 Program Operations, Division of 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.

#### Modification 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.

| | |
|---|---|
| Colorado: CO84–5113 | July 15, 1983. |
| Connecticut: CT84–3016 | June 8, 1984. |
| Hawaii: HI84–5019 | July 20, 1984. |
| Iowa: IA84–4042 | June 15, 1984. |
| Michigan: MI83–2008 | Feb. 11, 1983. |
| Minnesota: | |
| MN84–5015 | May 25, 1984. |
| MN85–5000 | Jan. 11, 1985. |
| Missouri: MO75–4070 | Mar. 28, 1975. |
| Montana: MT84–5041 | Dec. 14, 1984. |
| New York: NY85–3009 | Feb. 1, 1985. |
| North Dakota: ND81–5131 | July 6, 1981. |
| Pennsylvania: | |
| PA82–3012 | Mar. 5, 1982. |
| PA83–3051 | Nov. 25, 1984. |
| PA84–3002 | Feb. 10, 1984. |
| PA84–3015 | June 1, 1984. |
| PA82–3010 | Mar. 15, 1982. |

#### Supersedeas Decisions to General Wage Determination Decisions

The number 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 number of the decisions being superseded.

| | |
|---|---|
| Alabama: AL83–1059 (AL85–1003) | Aug. 19, 1983. |
| Illinois: IL83–2036 (IL85–5011) | Apr. 15, 1983. |
| Texas: TX82–4065 (TX85–4003) | Dec. 17, 1982. |

Signed at Washington, D.C. this 15th day of February 1985.

**James L. Valin,**

*Assistant Administrator.*

BILLING CODE 4510-27-M

MODIFICATIONS P. 1

DECISION NO. CO83-5113 - MOD. #12
(48 FR 32541 July 15, 1983)

Adams, Arapahoe, Boulder Clear Creek, Denver, Douglas, Eagle, Elbert, Gilpin, Grand, Jefferson, Lake, Larimer, Morgan, Park, Summit and Weld Counties, Colorado

OMIT:
Carpenters as originally issued & previously modified

ADD:
Carpenters:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| Adams, Arapahoe, Boulder, Denver and Jefferson Counties | $12.59 | $3.12 |
| Remaining Counties | 10.34 | 3.12 |

DECISION #CT84-3016 - MOD #11
(49 FR 23980-June 8, 1984)
Statewide, Connecticut

CHANGE:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| PAINTERS | | |
| Area 4 & 5 | | |
| Painters, Brush, Roller and Tapers | $16.55 | $3.05 |
| Paperhangers | 17.05 | 3.05 |
| Riggers | 17.60 | 3.05 |
| Tanks, Towers, Swing Stage, Boatswain Chair, Riding Steel and Hazardous work of a similar nature | 18.60 | 3.05 |
| Sandblasters & Spraymen | 20.60 | 3.05 |

DECISION NUMBER HI84-3019 - MOD. #2
(49 FR 29518 - July 20, 1984)
Statewide, Hawaii

Change:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| Elevator Constructors: | | |
| Mechanics | $20.56 | $3.29+a |
| Helpers | 14.39 | 3.29+a |
| Helpers (Prob.) | 10.28 | |
| Plumbers; Pipefitters; & Steamfitters | 17.00 | 7.75 |
| Sheet Metal Workers | 17.00 | 8.40 |
| Soft Floor Layers | 17.50 | 6.05 |

Footnote:
c. Asphalt Paving Group only: Employee who has completed two but less than 10 yrs.' service with employer - 2 wks.' paid vac.; 10 but less than 15 yrs.' service - 3 wks.' paid vac.; & 15 or more yrs.' service - 4 wks.' paid vac.

DECISION #IA84-6042-Mod.#2
(49 FR 24855 - 6/15/84)
WOODBURY COUNTY, IOWA

CHANGE:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| Electricians | $14.64 | $2.07+ 3-3/4% |
| Line Construction: | | |
| Group 1 | 16.74 | 1.25+b +7-1/2% |
| Group 2 | 13.89 | " |
| Group 3 | 13.39 | " |
| Group 4 | 11.13 | " |
| Group 5 | 11.05 | " |
| Group 6 | 10.71 | " |
| Group 7 | 12.89 | " |
| Sheet Metal Workers | 11.65 | 2.45 |

MODIFICATIONS P. 2

DECISION NUMBER MN84-3015 - MOD. #2
(49 FR 22184 - May 25, 1984)
Aitkin, Becker,...Wright and Yellow Medicine Counties, Minnesota

Change:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| Boilermakers | $17.345 | $3.25 |
| Bricklayers; Stonemasons: | | |
| Area 3 | 14.06 | 1.10 |
| Area 4 | 16.88 | 2.94 |
| Area 5 | 14.06 | 1.10 |
| Area 11 | 14.06 | 1.10 |
| Carpenters; Millwrights; Piledrivermen; & Soft Floor Layers: | | |
| Area 8: | | |
| Carpenters; Piledrivermen | 15.86 | 3.87 |
| Area 12: | | |
| Carpenters; Soft Floor Layers | 14.50 | 2.60 |
| Area 13: | | |
| Carpenters; Soft Floor Layers | 13.15 | 3.60 |
| Area 19: | | |
| Carpenters; Millwrights; & Piledrivermen | 14.93 | 1.10 |
| Cement Masons; Plasterers: | | |
| Area 4 | 13.30 | 1.10 |
| Area 8 | 13.30 | 1.10 |
| Area 15 | 13.30 | 1.10 |
| Area 18 | 14.95 | .75 |
| Electricians: | | |
| Area 4: | | |
| Electrical Installations over $75,000.00 | 15.75 | 13.5% +1.32 |
| Electrical Installations under $75,000.00 | 13.31 | 13.5% +1.32 |
| Area 6: | | |
| Electrical Installations over $75,000.00 | 15.75 | 13.5% +1.32 |
| Electrical Installations under $75,000.00 | 12.53 | 13.5% +1.32 |
| Area 9: | | |
| Electrical Installations over $75,000.00 | 15.75 | 13.5% +1.32 |
| Electrical Installations under $75,000.00 | 12.58 | 13.5% +1.32 |
| Elevator Constructors: | | |
| Chisago & Isanti Cos.: | | |
| Mechanic | $17.935 | $3.00 +a+b |
| Helpers | 70%JR | 3.00 +a+b |
| Helpers (Prob.) | 50%JR | |
| Glaziers: | | |
| Area 1 | 16.44 | 2.79 |
| Area 2 | 16.25 | 2.64 |
| Area 4 | 11.80 | 2 |
| Ironworkers: | | |
| Area 3 | 14.63 | 3.14 |
| Marble Setters | 16.40 | 2.94 |
| Painters: | | |
| Area 7: | | |
| Brush; Roller; Wallpaper | 16.06 | 2.68 |
| Sandblast; Spray; Steel | 16.81 | 2.68 |
| Finishers & Tapers | 17.01 | 1.72 |
| Sanders | 12.76 | 1.72 |
| Area 8: | | |
| Brush | 14.41 | 1.93 |
| Paperhangers; Spray; Steel & Taping | 15.21 | 1.93 |
| Pipefitters; Plumbers; & Steamfitters: | | |
| Area 4: | | |
| Pipefitters; Steamfitters | 16.72 | 5.39 |
| Plumbers | 16.53 | 5.58 |
| Area 6 | 16.23 | 2.27 |
| Area 8: | | |
| Plumbers | 14.95 | 7.14+c |
| Area 9 | 15.76 | 3.90 |
| Roofers: | | |
| Area 3 | 10.19 | 1.52 |
| Area 6 | 12.82 | 1.32 |
| Sheet Metal Workers: | | |
| Area 9: | | |
| Light Commercial ($175,000 and less H.V.A.C.) Contract | 12.35 | 1.96+d |
| All Other Work | 15.79 | 2.05+d |
| Terrazzo Workers | 17.61 | 1.83 |
| Omit: | | |
| Electricians: | | |
| Area 3: | | |
| Electricians | 15.93 | 3½% |
| Cable Splicers | 16.48 | 3½% |
| Pipefitters; Plumbers; & Steamfitters: | | |
| Area 2 | 15.62 | 2.54 |
| Roofers: | | |
| Area 7: | | |
| Roofers | 13.78 | 3.30 |
| 2nd Roofers | 13.53 | 3.30 |
| Kettlemen | 13.33 | 3.30 |

MODIFICATIONS P. 3

DECISION NUMBER MT84-5015 (Cont'd)

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| Unit (Cont'd): | | |
| Sheet Metal Workers: | | |
| Area 7 | $14.32 | $2.36+d |
| Add: | | |
| Electricians: | | |
| Area 3: | | |
| Commercial: | | |
| Electrical Installations above $14,000.00: | | |
| Electricians | 14.04 | 32½% |
| Cable Splicers | 14.59 | 32½% |
| Electrical Installations less than $14,000.00: | | |
| Electricians | 11.54 | 32½% |
| Cable Splicers | 12.09 | 32½% |
| Industrial: | | |
| Electricians | 15.93 | 32½% |
| Cable Splicers | 16.48 | 32½% |
| Area 5: | | |
| Sound Communications Installers | 14.30 | 17 5/8% |
| Pipefitters; Plumbers; & Steamfitters: | | |
| Area 2: | | |
| Commercial | 14.86 | 3.36 |
| Industrial | 15.88 | 3.36 |
| Roofers: | | |
| Area 7 | 14.58 | 1.92 |
| Sheet Metal Workers: | | |
| Area 3: | | |
| Over $250,000.00 H.V.A.C. Contract | 15.26 | 3.22 |
| Under $250,000.00 H.V.A.C. Contract | 12.00 | 3.15 |
| Footnotes: | | |
| f. 1 week's paid vacation - 1 year's service; 2 weeks' paid vacation - 3 years' service; & 3 weeks' paid vacation - 12 years' service | | |
| g. 6 Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; & Christmas Day | | |
| h. 1 week's paid vacation - 1 year's service | | |

DECISION NUMBER MT85-5000 - MOD. #2
(50 FR 1678 - January 11, 1985)

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| Anoka, Benton, Carlton, Chisago, Cook, Dakota, Hennepin, Lake, Ramsey, St. Louis, Scott, Sherburne, Stearns, Washington, Winona, & Wright Counties, Minnesota | | |
| Change: | | |
| Well Drillers: | | |
| Construction or Repair of Water Wells & Apurtenances: | | |
| Area 1: | | |
| Driller - Pumpman | $13.45 | .50+b+c+d |
| General - Tender; Driver or Service Man | 10.99 | .50+b+c+d |
| Mechanic - Welder | 12.46 | .50+b+c+d |
| Area 2: | | |
| Driller - Pumpman | 13.45 | .50+b+c+d |
| Tender | 9.54 | .50+b+c+d |
| Mechanic - Welder | 11.66 | .50+b+c+d |
| Driver - Serviceman | 10.24 | .50+b+c+d |
| Footnotes: | | |
| b. One year's service - one week's paid vacation; three years' service - two weeks' paid vacation; ten years' service - three weeks' paid vacation; & eighteen years' service - four weeks' paid vacation | | |
| c. 8 Paid Holidays: New Year's Day; Memorial Day; Fourth of July; Labor Day; Thanksgiving Day; Christmas Day; The day before or the day after Christmas & 1 floating day | | |
| Add: | | |
| Footnote: | | |
| d. Up to 3 days' pay for Funeral Leave | | |

MODIFICATIONS P. 4

DECISION #MO75-4070-MOD#1
(40 FR 14225-March 28, 1975)

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| Atchinson, Doniphan, Leavenworth & Wyandotte Cos., Kansas; Andrew, Atchison, Boone, Buchanan, Callaway, Carroll, Charlton, Clay, Cole, Cooper, Franklin, Gasconade, Holt, Howard, Jackson, Lafayette, Moniteau, Montgomery, Osage, Platte, Ray, Saline, St. Charles, St. Louis, & Warren Cos., Missouri; Nemaha & Richardson Cos., Nebraska | | |
| CHANGE: | | |
| Description of work to read as follows: | | |
| Maintenance Dredging (excluding self-propelled hopper dredges) | | |

DECISION NO. MI83-2008 - MOD. #10
(48 FR 6456 - February 11, 1983)

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| Alger, Baraga, Chippewa, etc., Counties, Michigan | | |
| CHANGE: | | |
| Electricians: | | |
| Alger & Marquette Cos.: | | |
| Contracts $75,000 or less: | | |
| Electricians | $12 75 | $2.43+3% |
| Cable Splicers | 14.75 | 2.43+3% |
| Contracts over $75,000: | | |
| Electricians | 15.44 | 2.45+3% |
| Cable Splicers | 17.44 | 2.45+3% |

DECISION NO. MT84-5041 - MOD #3
(49 FR 48883 - December 14, 1984)

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| Statewide, Montana | | |
| ADD: | | |
| LINE CONSTRUCTION: Flathead, Lake and Lincoln Counties: | | |
| All work for power utilities, all highway lighting, street lighting and motor traffic controlling. | | |
| Lineman | $17.15 | $ .95+3-1/2% |
| Cable Splicers | 19.09 | .95+3-1/2% |
| Pole Sprayer | 15.24 | .95+3-1/2% |
| Line Equipment Operators | 14.62 | .95+3-1/2% |
| Jackhammer, Compressorman | 11.89 | .95+3-1/2% |
| Groundman "A" | 10.81 | .95+3-1/2% |
| Tree Trimmer | 15.18 | .95+3-1/2% |
| Powerman | 12.67 | .95+3-1/2% |
| Head Groundman and Groundman "B" are not applicable | | |
| Statewide, except Flathead, Lake, and Lincoln Counties: | | |
| Lineman, Pole Sprayer | 16.48 | 1.75+3-1/2% |
| Cable Splicers | 17.61 | 1.75+3-1/2% |
| Line Equipment Operators' Powderman | 14.59 | 1.75+3-1/2% |
| Groundman | 11.86 | 1.75+3-1/2% |

MODIFICATIONS P. 6

MODIFICATIONS P. 5

DECISION NO. NY85-3009 - MOD. #1
(50 FR 4846 - February 1, 1985)

EXCLUDE FROM COVERAGE OF DECISION:

Self-propelled hopper dredges

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|

DECISION NO. ND81-5131 - Mod. #12
(46 FR 35008 - July 6, 1981)
Burleigh, Cass, Grand Forks, Morton, Richland, Steele, Traill, Walsh and Ward Counties, North Dakota

Change:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| CARPENTERS: | | |
| Area 4: | | |
| Carpenters | $11.75 | 1.02 |
| Piledrivers | 12.30 | 1.02 |
| SHEET METAL WORKERS: | | |
| Commercial HVAC contract over $175,000.00 | 15.79 | 2.57 |
| Commercial HVAC contract under $175,000.00 | 12.35 | 2.38 |

DECISION NO. PA82-3012 - MOD. #13
(47 FR 9681 - March 5, 1982)
Columbia, Montour, and Snyder Counties, Pennsylvania

CHANGE:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| PLUMBERS & STEAMFITTERS | 17.85 | 2.42 |

DECISION NO. PA83-3051 - MOD. #6
(48 FR 53264 - November 25, 1984)
Franklin County, Pennsylvania

CHANGE:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| PLUMBERS | 17.85 | 2.42 |

DECISION NO. PA84-3002 - MOD. #7
(49 FR 5295 - February 10, 1984)
Adams & York Counties, Pennsylvania

CHANGE:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| PLUMBERS & STEAMFITTERS | 17.85 | 2.42 |

DECISION NO. PA84-3015 - MOD. #5
(49 FR 22976 - June 1, 1984)
Cumberland, Dauphin, Perry, Juniata, New Cumberland Depot in York County, Pennsylvania

CHANGE:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| PLUMBERS | 17.85 | 2.42 |
| STEAMFITTERS | 17.85 | 2.42 |

MODIFICATIONS P. 6

DECISION NO. PA82-3010 - MOD. #15
(47 FR 9684 - March 15, 1982)
Clinton, Centre, Huntingdon, Fulton & Mifflin Counties, Pennsylvania

CHANGE:

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| ASBESTOS WORKERS | | |
| Clinton County | 16.33 | 2.66 |
| ELECTRICIANS: | | |
| Fulton, Hintingdon, and Remainder of Centre Co. | 17.72 | 3.45+ 3% |
| GLAZIERS: | | |
| Centre, Fulton, Huntingdon, Mifflin Counties | 15.73 | 5.45 |
| LABORERS: | | |
| Clinton, Centre, Fulton, Huntingdon & Mifflin Counties | | |
| Unskilled Laborers | 11.65 | 2.79 |
| Plasterers Tenders | 11.72 | 2.79 |
| LINE CONSTRUCTION | | |
| Clinton County | | |
| Lineman, Dynamite man, heavy equipment op. | 15.99 | .80+3 3/8% |
| Winch truck operator | 11.29 | .80+3 3/8% |
| Groundman | 10.00 | .80+3 3/8% |
| Mifflin County | | |
| Lineman | 15.06 | .80+3 3/8% |
| Winch truck op. | 10.54 | .80+3 3/8% |
| Groundman | 9.04 | .80+3 3/8% |
| MILLWRIGHTS | 15.22 | 43½% |
| PAINTERS: | | |
| Clinton County | | |
| Brush | 12.30 | 2.70 |
| Tapers | 12.96 | 2.70 |
| Structural Steel | 13.96 | 2.70 |
| PLUMBERS & STEAMFITTERS: | | |
| Centre, Mifflin & Fulton Counties | 17.85 | 2.42 |
| ROOFERS | | |
| Composition, Damp, and Waterproof | 17.34 | 4.10 |

SUPERSEDEAS DECISION

STATES: ALABAMA, ARKANSAS, FLORIDA (West of the Aucilla River), GEORGIA (West of the Aucilla and Ocumlgee Rivers within the boundaries of the Mobile District of the Corps of Engineers), KENTUCKY, LOUISIANA, MISSISSIPPI, TENNESSEE, and TEXAS.
DECISION NUMBER: AL85-1003 DATE: DATE OF PUBLICATION
Supersedes Decision Number AL83-1059 dated August 19, 1983 in 48 FR 37799.
DESCRIPTION OF WORK: DREDGING PROJECTS (EXCLUDING SELF-PROPELLED HOPPER DREDGES) along the Gulf of Mexico Coast Area including the Mississippi River and its tributaries to the Ohio River.

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| DREDGES 16" & OVER: | | |
| Leverman | $ 6.10 | |
| Dredge Tender Operator | 5.14 | |
| First Assistant Engineer | 6.06 | |
| Second Assistant Engineer | 5.50 | |
| Third Assistant Engineer | 5.06 | |
| Deckhand | 3.88 | |
| Shoreman | 3.90 | |
| Fireman | 4.40 | |
| Oiler | 4.00 | |
| Truck Driver | 3.90 | |
| Welder | 5.47 | |
| DREDGES UNDER 16": | | |
| Leverman | 4.25 | |
| Dredge Tender Operator | 3.60 | |
| Deckhand | 3.35 | |
| Oiler | 3.50 | |
| Welder | 3.80 | |

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| HYDRAULIC DREDGING: | | |
| First Cook | $ 3.90 | |
| Second Cook | 3.65 | |
| Cook's Helper - Mess Boy | 3.35 | |
| Janitor - Cabin Boy | 3.85 | |
| Handyman | 4.33 | |
| DERRICK OPERATOR | 5.38 | |
| DOZER OPERATOR | 5.53 | |
| MARSH BUGGY DRAGLINE: | | |
| Operator | 6.70 | |
| Oiler | 6.33 | |

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)).

SUPERSEDEAS DECISION

STATE: ILLINOIS
DECISION NUMBER: IL85-5011 COUNTIES: *SEE BELOW
Supersedes Decision Number IL83-2036, dated April 15, 1983, in 48 FR 16404 DATE: Date of Publication
DESCRIPTION OF WORK: Heavy and Highway Projects including Dredging.

* ADAMS, BROWN, CASS, CHAMPAIGN, CHRISTIAN, CLARK, COLES, CUMBERLAND, DEWITT, DOUGLAS, EDGAR, LOGAN, MACON, MENARD, MORGAN, MOULTRIE, PIATT, PIKE, SANGAMON, SCHUYLER, SCOTT, SHELBY & VERMILION

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| CARPENTERS & PILEDRIVERMEN: | | |
| Area 1 | $16.09 | $2.50 |
| Area 2 | 15.58 | 3.03 |
| Area 3: | | |
| Carpenters | 16.31 | 2.54 |
| Piledrivermen | 16.81 | 2.54 |
| Area 4 | 15.98 | 2.42 |
| Area 5: | | |
| Carpenters | 16.71 | 1.91 |
| Piledrivermen | 17.22 | 1.91 |
| Area 6: | | |
| Carpenters | 16.20 | 3.07 |
| Piledrivermen | 16.70 | 3.07 |
| Area 7 | 15.77 | 2.32 |
| Area 8: | | |
| Carpenters | 15.67 | 2.66 |
| Piledrivermen | 16.47 | 2.66 |
| Area 9: | | |
| Carpenters | 15.58 | 2.62 |
| Piledrivermen | 16.08 | 2.62 |
| Area 10: | | |
| Carpenters | 16.14 | 2.91 |
| Piledrivermen | 16.64 | 2.91 |
| CEMENT MASONS: | | |
| Area 1 | 15.65 | 1.50 |
| Area 2 | 16.40 | .80 |
| Area 3 | 15.55 | 1.775 |
| Area 4 | 15.55 | 1.775 |
| Area 5 | 17.15 | |
| Area 6 | 15.09 | 2.06 |
| Area 7 | 16.30 | .85 |
| Area 8 | 16.015 | 1.00 |
| Area 9 | 15.65 | 2.75 |
| Area 10 | 14.60 | |
| Area 11 | 16.79 | 1.42 |
| ELECTRICIANS: | | |
| Area 1: | | |
| Electricians | 17.32 | 2.50 |
| Cable Splicers | 19.05 | 2.56 |
| Area 2 | 17.32 | 2.29 |
| Area 3 | 17.35 | 2.61 |
| Area 4 | 17.30 | 2.38 |
| Area 5 | 17.85 | 2.14 |
| Area 6 | 17.33 | 2.32 |
| Area 7: | | |
| Electricians | 17.32 | 2.50 |
| Cable Splicers | 19.05 | 2.56 |
| Area 8 | 17.57 | 1.72 |

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| IRONWORKERS: | | |
| Area 1 | 16.53 | 2.48 |
| Area 2 | 16.25 | 2.15 |
| Area 3 | 15.00 | 3.03 |
| Area 4 | 15.25 | 4.05 |
| LINE CONSTRUCTION: | | |
| Area 1: | | |
| Lineman | 18.10 | 1.00+4% |
| Groundmen Equip. Op. Class 1 | 16.89 | 1.00+4% |
| Groundmen Truck Driver with Winch | 12.85 | 1.00+4% |
| Groundmen Truck Driver without winch | 12.10 | 1.00+4% |
| Groundmen | 11.54 | 1.00+4% |
| Area 2: | | |
| Lineman | 18.26 | 1.00+13% |
| Groundmen Equip Op. Class 1 | 15.59 | 1.00+13% |
| Groundmen Equip Op. Class 2 | 13.96 | 1.00+13% |
| Groundmen | 11.60 | 1.00+13% |
| PAINTERS: | | |
| Area 1: | | |
| Brush | 11.00 | |
| Spray | 13.00 | |
| Area 1: | | |
| Brush | 14.50 | 2.20+a |
| Spray | 15.25 | 2.20+a |
| Area 3 | 16.57 | 1.14 |
| Area 4: | | |
| Brush & Roller: | | |
| 0-30 ft | 15.40 | 1.00 |
| Over 30 ft to 300 ft | 16.20 | 1.00 |
| Over 300 ft | 17.20 | 1.00 |
| Blasting & Spraying: | | |
| 0-30 ft | 16.20 | 1.00 |
| over 30 ft to 300 ft | 16.90 | 1.00 |
| Over 300 ft | 17.90 | 1.00 |
| Area 5: | | |
| Brush, Roller | 14.80 | 1.65 |
| Spray | 15.55 | 1.65 |
| Radio & TV Towers; Steeples; & Structures over 50 ft | 15.80 | 1.65 |
| Area 6: | | |
| Brush | 15.35 | 2.38 |
| Bridge Work & Spray | 16.20 | 2.38 |
| Area 7: | | |
| Industrial | 14.97 | 1.30 |
| Bridges | 15.22 | 1.30 |

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| PAINTERS (Cont'd): | | |
| Area 5: | | |
| Brush | 16.00 | |
| Sandblast; Spray | 17.00 | |
| LABORERS: | | |
| Area 1: | | |
| Unskilled | 14.66 | 1.70 |
| Semi-Skilled | 14.86 | 1.70 |
| Skilled | 15.01 | 1.70 |
| Area 2: | | |
| Unskilled | 14.36 | 2.00 |
| Semi-Skilled | 14.56 | 2.00 |
| Skilled | 14.71 | 2.00 |
| Area 3: | | |
| Unskilled | 15.70 | 1.60 |
| Semi-Skilled | 15.90 | 1.60 |
| Skilled | 16.05 | 1.60 |
| Area 4: | | |
| Unskilled | 13.91 | 2.45 |
| Semi-Skilled | 14.11 | 2.45 |
| Skilled | 13.26 | 2.45 |
| Area 5: | | |
| Unskilled | 15.00 | 2.10 |
| Semi-Skilled | 15.20 | 2.10 |
| Skilled | 15.35 | 2.10 |
| Area 6: | | |
| Unskilled | 15.35 | 1.75 |
| Semi-Skilled | 15.55 | 1.75 |
| Skilled | 15.70 | 1.75 |
| Area 7: | | |
| Unskilled | 14.41 | 2.45 |
| Semi-Skilled | 14.61 | 2.45 |
| Skilled | 14.76 | 2.45 |
| Area 8: | | |
| Unskilled | 14.65 | 2.45 |
| Semi-Skilled | 14.85 | 2.45 |
| Skilled | 15.00 | 2.45 |
| Area 9: | | |
| Unskilled | 13.86 | 2.50 |
| Semi-Skilled | 14.06 | 2.50 |
| Skilled | 14.21 | 2.50 |
| Area 10: | | |
| Unskilled | 14.85 | 2.25 |
| Semi-Skilled | 15.05 | 2.25 |
| Skilled | 15.20 | 2.25 |
| Area 11: | | |
| Unskilled | 14.30 | 2.95 |
| Semi-Skilled | 14.50 | 2.95 |
| Skilled | 14.65 | 2.95 |

| | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| POWER EQUIPMENT OPERATORS: | | |
| Area 1: | | |
| Group 1 | 16.95 | 1.83 |
| Group 2 | 15.30 | 1.83 |
| Group 3 | 13.20 | 1.83 |
| Area 2: | | |
| Group 1 | 17.45 | 2.60 |
| Group 2 | 17.35 | 2.60 |
| Group 3 | 17.15 | 2.60 |
| Group 4 | 9.50 | 2.60 |
| Area 3: | | |
| Group 1 | 17.29 | 2.35 |
| Group 2 | 16.14 | 2.35 |
| Group 3 | 14.43 | 2.35 |
| TRUCK DRIVERS: | | |
| Area 1: | | |
| Group 1 | 14.275 | 1.90+a |
| Group 2 | 14.475 | 1.90+a |
| Group 3 | 14.875 | 1.90+a |
| Group 4 | 15.125 | 1.90+a |
| Area 1: | | |
| Group 1 | 14.875 | 1.90+a |
| Group 2 | 15.275 | 1.90+a |
| Group 3 | 15.475 | 1.90+a |
| Group 4 | 15.725 | 1.90+a |
| DREDGING: | | |
| Mason County: | | |
| Group 1 | 13.07 | 1.30 |
| Group 2 | 12.87 | 1.30 |
| Group 3 | 12.495 | 1.30 |
| Group 4 | 12.22 | 1.30 |
| Group 5 | 11.61 | 1.30 |



FOOTNOTES:
a. $25.00 Per Year
b. $55.00 Per Week

AREA DESCRIPTIONS

CARPENTERS & PILEDRIVERMEN:
AREA 1: Adams Co.
AREA 2: Brown, Cass, Morgan, Pike, Schuyler & Scott Cos.
AREA 3: Champaign, Douglas (N. of US Rte. #36), & Piatt (NE ¼) Cos.
AREA 4: Christian, Menard, & Sangamon (Except Illiopolis) Cos.
AREA 5: Clark, Coles, Cumberland, Douglas (US Rte. #36 & S. thereof), Edgar, Moultrie (Exclu. area N. of Rte. #133), & Shelby (Exclu. Moweaqua & N. thereof) Cos.
AREA 6: DeWitt Co.
AREA 7: Logan Co.
AREA 8: Macon, Moultrie (N. of Rte. #133), Piatt(SW ¼), Sangamon (Illiopolis) & Shelby (Moweaqua & N. thereof) Cos.
AREA 9: Mason Co.
AREA 10: Vermilion Co.
CEMENT MASONS:
Area 1: Adams, Brown, and Pike Cos.
Area 2: Cass, Christian, Menard, and Sangamon Cos.
Area 3: Champaign, Clark, Douglas (N½), Edgar, and Shelby (excluding Moweaqua)
Area 4: DeWitt (Clinton and S.), Macon, Moultrie (NE corner including Lovington, Bethany, Piatt (S. of Monticello), and Shelby (Incl. Moweaqua).
Area 5: Logan Co.
Area 6: Morgan Co.
Area 7: Schuyler
Area 8: Vermilion Co.
Area 9: Mason Co.
Area 10: Coles, Cumberland, Douglas (S ½), Moultrie (W. ½), Shelby (Eastern)
Area 11: DeWitt (N. of Clinton)
ELECTRICIANS:
AREA 1: Adams, Brown, Pike, & Schuyler Cos.
AREA 2: Cass, Logan, Mason (Lynchburg, Bath, Kilbourne, Crane Creek, Salt Creek, & Mason), Menard, Morgan, Sangamon & Scott Cos.
AREA 3: Champaign, DeWitt (Santa Anna Twp.), Douglas (N ½), & Piatt (Blue Ridge, Sangamon & Monticello Twps.) Cos.
AREA 4: Clark & Edgar Cos.
AREA 5: Christian, Coles, Cumberland, DeWitt (Harp, Wapella, Barnett, Clintonia, DeWitt, Turnbridge, Texas, Creek & Nixon Twps.), Douglas (Arcola, Burbon, Garrett Twps. & that portion of Tuscola lying W. of the city of Tuscola & the Illinois Central RR Tracks), Macon, Moultrie, Piatt (Goose Creek, Willow Branch, Cerro Gordo, Bement & Unity Twps.), & Shelby Cos.
AREA 6: DeWitt (Waynesville, Wilson & Rutledge Twps.) Co.
AREA 7: Mason (Exclu. Lynchburg, Bath, Kilbourne, Crane Creek, Salt Creek, & Mason) Co.
AREA 8: Vermilion Co.
IRONWORKERS:
AREA 1: Adams (Kingston & Vic.), Brown, Cass, Christian, DeWitt (W ½), Logan, Macon (Except portion E. of Decatur), Mason, Menard, Morgan, Pike, Sangamon, Schuyler (E ½), Scott & Shelby (W ½) Cos.
AREA 2: Adams (Except Kingston & Vic.) & Schuyler ((W ½) Cos.
AREA 3: Champaign, Coles, Cumberland, DeWitt (E ½), Douglas, Edgar, Macon (E. of Decatur), Moultrie, Piatt, Shelby (E ½), & Vermilion Cos.
AREA 4: Clark Co.

AREA DESCRIPTIONS

LINE CONSTRUCTION:
AREA 1: Adams, Brown, Cass, Champaign, Christian, Coles (E. Oakland, Humboldt, Morgan, S. Okaw, & Seven Hickory Twps.), DeWitt, Douglas, Edgar, Logan, Macon, Mason, Menard, Morgan, Moultrie (Except Whitley Twp.), Piatt, Pike, Sangamon, Schuyler, Scott, Shelby (W. of Holland, Prairie, Richland, & Windsor Twps.), & Vermilion (Except work performed on Illinois Power Company & REA Co-op properties) Cos.
AREA 2: Clark, Coles (S ½), Cumberland, Moultrie (Whitley Twp.), Shelby (Except W. of Holland, Prairie, Richland, & Windsor Twps.) Cos.

PAINTERS:
AREA 1: Adams Co.
AREA 2: Brown, Cass, Christian, Logan, Menard, Morgan, Sangamon, & Scott Cos.
AREA 3: Champaign, Coles, Cumberland, & Douglas Cos.
AREA 4: Clark & Edgar Cos.
AREA 5: DeWitt, Macon, Moultrie, Piatt, & Shelby Cos.
AREA 6: Mason & Schuyler Cos.
AREA 7: Pike Co.
AREA 8: Vermilion Co.

LABORERS:
AREA 1: Adams Co.
AREA 2: Brown, Cass, Mason, Morgan, Pike, Schuyler, & Scott Cos.
AREA 3: Champaign, DeWitt, & Piatt (N ½) Cos.
AREA 4: Christian Co.
AREA 5: Clark, Douglas, Edgar, Moultrie (E ½), & Piatt (S ½) Cos.
AREA 6: Coles & Cumberland Cos.
AREA 7: Logan & Menard (S ½) Cos.
AREA 8: Macon & Moultrie (W ½) Cos.
AREA 9: Menard (N ½) & Sangamon Cos.
AREA 10: Shelby Co.
AREA 11: Vermilion Co.

POWER EQUIPMENT OPERATORS:
AREA 1: Adams, Brown, Cass, Christian, DeWitt, Logan, Macon, Menard, Morgan, Piatt, Pike, Sangamon, Schuyler, Scott & Shelby Cos.
AREA 2: Champaign, Clark, Coles, Cumberland, Douglas, Edgar, Moultrie, & Vermilion Cos.
AREA 3: Mason Co.

TRUCK DRIVERS:
AREA 1: Adams, Brown, Cass, Champaign, Christian, Clark, Coles, Cumberland, DeWitt, Douglas, Edgar, Logan, Macon, Menard, Morgan, Moultrie, Piatt, Pike, Sangamon, Schuyler, Scott, Shelby & Vermilion Cos.
AREA 2: Mason Co.

LABORERS CLASSIFICATIONS:
UNSKILLED - Common Laborers
SEMI-SKILLED - Asphalt Rakers; Asphalt Saw Operators; Blade Grade Operators; Cement Handlers; Chain Saw Operators; Concrete Saw Operators; Dumping Dry Cement From Dump & Batch Trucks; Form Setters; Handling of Creosote Lumber & Line; Hopper Men; Mechanical Form Tampers; Powder Men; Powdermen & Dynamite Men ($1.00 premium); Power Tool Operators; Priming & Wrapping of Gas Lines; Puddlers; Rubbing of Concrete; Sewer or Conduit, Tunnel Miners, Top Men, Muckers, & Bottom Men ($.25 premium); Sewer Tile & Pipe Layers; Shoring & Bracing in Sewer & Tunnels; & Spotters & Dumpmen or on Levees, Fills, or Grades
SKILLED - Air Spades; Brick Tenders; Gunnite Nozzlemen; & Jackhammers



POWER EQUIPMENT OPERATORS CLASSIFICATIONS (AREA 1)

Group 1: Asphalt plant engineer; Asphalt screed man; Apsco concrete spreader; Asphalt paver; Asphalt roller on bituminous concrete; Athey loader; Backfiller; Crane type backhoe; Cableway; Cherry picker; Clam shell; CMI & similar type Autograde formless paver, Autograde placer & finisher; Concrete breaker; Concrete plant operator; Concrete pump; Cranes; Derricks; Derrick Boats; Draglines; Earth auger boring machine; Elevating grader; Engineer on dredge; Gravel processing machine; Head equipment greaser; High lift or fork lift; Hoist with 2 drums or 2 or more loadlines; Locomotive; Mechanics; Motor grader or auto patrol; Operator or leverman on dredge; Power boat operator; Pug mill operator (asphalt plant); Orange peels; Overhead crane; Paving mixer; Piledriver; Pipe wrapping & painting machine; Push dozers or push cat; Rock crusher; Ross carrier or similar; Scoops; Skimmers 2 cu yd capacity & under; Sheep foot roller (self-propelled); Shovels; Skimmer scoops; Test hole drilling machine; Tower crane; Tower machines; Tower mixers; Track type loader; Track type fork lift or high lift; Track jacks & tampers; Tractors; Sideboom; Trenching machine; Ditching mathhine; Tunnel lugger; Wheel type end loader; Winch cat; Scoops (all or tournapull)

Group 2: Asphalt boosters & heaters; Asphalt distributors; Asphalt plant fireman; Building elevator; Bull float or flexplane; Concrete finishing machine; Concrete saw, self-propelled; Concrete spreader machine; Gravel or stone spreader, power operated; Automatic hoist; Hoist with one drum and one load line; Oiler on 2 paving mixers when used in tandem boom or winch trucks; Post hole digger, mechanical; Road or street sweeper-self propelled; Scissors hoist; Seaman tiller; Straw machine; Vibratory compactor; Well drilling machine; Mud jacks

Group 3: Air compressor* (incl. track or self-propelled); Bulk cement batching plant; Conveyor*; Concrete mixer (except plant, paver, tower); Fireman; Generator* Greaser; Light plant*; Mechanical heater*; Oiler; Power form grader; Power sub-grader; Pug mill when used for other than asphalt operation; Roller (except bituminous concrete); Tractor with power attachments regardless of size or type; Truck crane oiler & driver (one man); Vibratory hammer; Water pump* Welding machine*( one 300 amp or over);
*Combinations of one to five of any air compressors, conveyors, welding machines, water pumps, light plants or generators shall be in batteries or within 300 ft.

POWER EQUIPMENT OPERATORS CLASSIFICATIONS (AREA 2)

Group 1: Master Mechanic

Group 2: Utility operator

Group 3: Power crane; Dragline; Derrick; Shovel; Gradall; Mechanics; Concrete mixer with skip; Tournamixers; Two drum machine; One drum hoist with tower or boom; Cableway; Tower machine; Motor patrol; Boom tractor; Boom or winch truck; Winch or hydraulic boom truck; Truck crane; Tournapull; Tractor operating scoops; Bulldozer; Push tractor; Asphalt planer; Finishing machine on asphalt; Large rollers on earth; Rollers on asphalt mix; Ross carriers or similar machine; Gravel processing machine; Asphalt plant engineer; Paver operator; Farm tractor with 1/2 yd bucket and or backhoe attachment; Dredging equipment or dredge engineer or dredge operator; Central mix plant engineer; CMI or similar type machine; Concrete pump Truck or skid mounted; Tower crane; Engine or rock crusher plant; Concrete plant engineer; Ditching machine with dual attachment; Tractor mounted loader; Cherry picker; Hydro crane; Standard or Dinkey locomotives; Scoopmobiles; Euclid loader; Soil cement machine; Back filler; Elevating machine; Power blade; Drilling machine incl. well testing, caissons, shaft or any similar type drilling machine; Motor driven paint machine; Pipe cleaning machine; Pipewrapping machine; Pipe bending machine; Apsco paver; Boring machine; head equipment greaser; Barber Greene loader; Formless paver; Well point system; Concrete spreader; Hydra ax; Resco concrete saw; Marine scoops; Brush mulcher; Brush burner; Mesh placer; Tree mover; Helicopter crew (3); Piledriver-skid or crawler;

POWER EQUIPMENT OPERATORS CLASSIFICATIONS AREA 2 (CONT'D)

Group 3 (cont'd): Stump remover; Root rake; Tug boat operator; Refrigerating machine; Freezing operator; Chair cart - self-propelled; Hydra seeder; Straw blower; Power sub grader; Bull float; Finishing machine; Self-propelled pavement breaker (backhoe attached); Lull or similar type machine; Two air compressors; compressors hooked in manifold; Overhead crane; Chip spreader; Mud cat; Sull-air; Tractor highlift; Tournadozer; Tube float; Spray machine; Curing machine; Concrete or asphalt milling machine.

POWER EQUIPMENT OPERATORS CLASSIFICATIONS (AREA 3)

Group 1: Cranes, Hydro crane; Shovels; Crane type backfiller; Tower cranes-Mobile & crawler & stationary; Derrick & hoist (3 drum); Draglines; Drott Yumbo & similar types considered as cranes; Backhoe; Derrick boats; Pile driver and skid rigs; Clam shell; Locomotive - cranes; Road pavers - single drum -Dual drum -tri batcher; Motor patrol & power blades - Dunnore - Elevating & similar types; Mechanics; Central concrete mixing plant operator; Asphalt batch plant operator and plant engineer; Gradall; Caisson rigs; Skimmer scoop - Koehring scooper; Dredges; Hoptoe; All cherry pickers; Work boat; Ross carrier; Helicopter; Dozer; Tournadozer; Tournapulls, all and similar types; Multiple unit earth movers; 25c/hr for each scoop over one; Scoops; pushcats; Endloaders; Asphalt surfacing machine; Slip form paver; Rock crusher; Heavy equipment greaser (top greaser on spread); CMI, auto grade, CMI belt placer & 3 track & similar types; Side booms; Starting engineer on pipeline; Asphalt heater & planer combination; Wheel tractors with dozer, hoe or endloader; FWD and similar types; Blaw knox spreader & similar types; Trench machines; Pump Crete, Belt Crete, Squeeze Crete, screw type pumps & gypsum (operator will clean); Formless finishing machines; Flaherty spreader or similar types; Screedman on laydown machine; Vermeer concrete saw; Premium rate on Crane & Derrick Booms - 1c/hr per foot over 80 ft including jib, $1.00/hr over scale when positioned 50 ft or more adjecent ground level or water level.

Group 2: Bulker & pump; Power launches; Boring machine & pipe jacking machine; Dinkeys; P-H one pass soil cement machines and similar types; Wheel tractor; Back fillers; Euclid-loader; Fork lifts; Jeep with ditching machine or other attachments; Tuneluger; Automatic cement & gravel batching plants; Mobile drills - soil testing & similar types; Pugmill with pump; All one & two drum hoists; Dewatering system; Straw blower; Hydro seeder; Boring machine; Hydro boom; Bump grinders-self propelled; Assistant heavy equipment greaser; Apsco spreader; Tractors - track type w/o power units pulling rollers; Rollers on asphalt, brick, or macadam; Concrete breakers; Concrete spreaders; Cement strippers; Cement finishing machines & CMI texture & reel curing machines; Vibro-tampers & similar types self-propelled; Mechanical bull floats; Mixers over three bags to 27E; Winch & boom trucks; Tractor pulling power blade or elevating grader; Porter rex rail; Clary screed; Mule pulling rollers; Pugmill w/o pump; Barber Greene or similar loaders; Track type tractor with power unit; Fireman; Spray machine on paving; Curb machine; Paved ditch machine; Power broom; Self-propelled conveyors; Power subgrader; Oil distributor; Straight Tractor; Truck crane oiler; Truck type oilers; 3-4 pieces small equipment; oiler and 1 piece small equipment

Group 3: Trac Air machine w/o attachments; Herman Nelson Heater, Dravo Wartec, Silent Glo & Similar (1 engineer will operate 1-5, 2 operators more than 5; Self-propelled concrete saws; Rollers, 5 ton & under on earth & gravel; Form grader; 1 or 2 Pumps, 1 or 2 light plants, 1 or 2 air compressors, 1 Or 2 conveyors, 1 or 2 generators, 1 or 2 welding machines, 1 or 2 mixers 3 bags & under; Bulk cement plant; Oilers



TRUCK DRIVERS CLASSIFICATIONS:

GROUP 1: Drivers on 2 Axles hauling less than 9 tons; Air Compressor & Welding Machine incl. those pulled by separate units; Fork Lifts up to 6,000 lbs. cap.; Mechanic Tenders; Pick-ups when hauling materials, tools, or men to and from and on the job site; & Truck Driver Tenders

GROUP 2: 2 or 3 Axles hauling more than 9 tons, but hauling less than 16 tons; A-Frame Winches; Fork Lifts over 6,000 lbs. cap.; 4-Axle Combination units; Hydrolifts or similar equipment when used for transportation purposes; & Winches

GROUP 3: 2, 3 or 4 Axles hauling 16 tons or more; Dispatcher; 5-Axles or more combination units; Mechanics & Working Foreman; & Water Pulls

GROUP 4: Drivers on Oil Distributors; & Drivers on Semi-Lowboys when moving equipment

DREDGING CLASSIFICATIONS:

GROUP 1 - Operators on Hydraulic Dipper or Clamshell Dredges,, Engineers and Repairmen, Operators on Work Boats
GROUP 2 - Power Winches 1-2-3 Drums
GROUP 3 - Security Engineer
GROUP 4 - Cranemen on Dipper Dredges, Operators on Launches or Power Boats
GROUP 5 - Firemen & 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)).

SUPERSEDEAS DECISION

STATE: TEXAS
DECISION NO.: TX85-4003
Supersedeas Decision No. TX82-4065, dated December 17, 1982, in 47 FR 56604.
DESCRIPTION OF WORK: Building Projects (does not include single family homes and apartments up to and including 4 stories).

COUNTIES: Bell, Coryell & McLennan
DATE: Date of Publication

| BUILDING CONSTRUCTION | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| ACOUSTICAL CEILING INSTALLERS | $ 9.05 | |
| AIR CONDITIONING & HEATING MECHANICS | 8.90 | |
| ASBESTOS WORKERS/MECHANICAL INSULATORS: | | |
| Bell & Coryell Cos. | 14.54 | 53.24 |
| McLennan Co. | 16.71 | 2.54 |
| BRICKLAYERS: Bell & Coryell Cos. | 15.25 | 1.80 |
| McLennan Co. | 12.21 | |
| CARPENTERS | 10.91 | |
| CEMENT MASONS | 10.00 | |
| DRYWALL INSTALLERS | 11.98 | |
| ELECTRICIANS: | | |
| McLennan, Bell (that part which is nearer to Waco than Austin but excluding that part of Ft. Hood, the boundary of which is presently located approx. 2 miles inside the Bell Co. line & the City of Killeen) & Coryell (except that part of Ft. Hood south of Cowhouse Creek): | | |
| Electricians | 13.90 | 1.00+ 8.5% |
| Cable Splicers | 14.90 | 1.00+ 8.5% |
| Bell (not to exceed more than two miles into the county from the southeast boundary line of Coryell Co., Gray Field & the City of Killeen & that part which is nearer to Austin than Waco) & Coryell (to include that part of Ft. Hood south of Cowhouse Creek): | | |
| Electricians & Cable Splicers | 15.90 | 1.00+ 8-8/10% |
| ELEVATOR CONSTRUCTORS: | | |
| Mechanics | 16.175 | 3.00+a |
| Helpers | 70%ER | 3.00+a |
| Helpers (Prob.) | 50%ER | |
| GLAZIERS | 9.20 | |
| INSULATION INSTALLERS (Batt & Blown) | 5.73 | |
| IRONWORKERS: | | |
| Bell & Coryell Cos.: | | |
| Structural & ornamental | 11.28 | |
| Reinforcing | 11.50 | |
| McLennan Co. | 15.00 | 2.97 |
| LABORERS: | | |
| Unskilled | 5.13 | |
| Mason Tenders | 7.00 | |
| Plasterers' Tenders | 6.89 | |
| LATHERS | 13.38 | |
| PAINTERS | 8.47 | |
| PLASTERERS | 12.78 | |
| PLUMBERS & PIPEFITTERS: | | |
| McLennan Co. | 13.41 | 1.19 |
| Outside McLennan Co. but within 45 miles of the McLennan Co. Courthouse including the towns of Temple & Belton | 13.91 | 1.19 |
| Over 45 miles from McLennan Co. Courthouse | 15.41 | 1.19 |
| ROOFERS | 8.44 | |
| SHEET METAL WORKERS | 12.01 | |
| SOFT FLOOR LAYERS | 8.47 | |
| TILE SETTERS | 11.63 | |
| TRUCK DRIVERS | 6.69 | |
| POWER EQUIPMENT OPERATORS: | | |
| Backhoes | 7.75 | |
| Blade Operators | 9.05 | |
| Cranes | 10.43 | |
| Drillers | 10.35 | |
| Loaders | 7.66 | |
| 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 labor standards contract clause (29 CFR 5.5(a)(1)(ii)).

DECISION NO.: TX85-4003 Page 2

| FOOTNOTE FOR ELEVATOR CONSTRUCTORS: | Basic Hourly Rates | Fringe Benefits |
|---|---|---|
| a - Employer contributes 8% of basic hourly rate for over 5 yrs. service & 6% of basic hourly rate for 6 mos. to 5 yrs. service as Vacation Pay Credit. Following Paid Holidays: New Years' Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, the Friday after Thanksgiving Day and Christmas Day. | | |
| INCIDENTAL PAVING & UTILITIES | | |
| ASPHALT HEATER OPERATOR | $ 6.25 | |
| ASPHALT RAKER | 5.75 | |
| CARPENTER | 7.45 | |
| CARPENTER HELPER | 5.90 | |
| CONCRETE FINISHER (Structures) | 6.95 | |
| CONCRETE FINISHER HELPER (Structures) | 5.60 | |
| CONCRETE RUBBER | 5.70 | |
| FORM BUILDER (Structures) | 6.70 | |
| FORM BUILDER HELPER (Structures) | 6.00 | |
| FORM SETTER (Paving & Curb) | 6.00 | |
| FORM SETTER (Structures) | 6.90 | |
| FORM SETTER HELPER (Structures) | 5.55 | |
| LABORER, Common | 4.70 | |
| LABORER, UTILITY | 5.30 | |
| MECHANIC | 7.95 | |
| MECHANIC HELPER | 6.10 | |
| SERVICER | 6.15 | |
| PIPELAYER (McLennan Co.) | 5.75 | |
| PIPELAYER HELPER (McLennan Co.) | 4.70 | |
| PIPELAYER (Conc. & Clay) Bell & Coryell Cos. | 5.75 | |
| PIPELAYER HELPER (Conc. & Clay) Bell & Coryell Co. | 4.70 | |
| PLUMBERS (Bell & Coryell Cos.): | | |
| Within 45 miles of the McLennan Co. Courthouse including the towns of Temple & Belton | 13.91 | 1.19 |
| Over 45 miles from McLennan Co. Courthouse | 15.41 | 1.19 |
| REINFORCING STEEL SETTER (Structures) | $ 6.60 | |
| REINFORCING STEEL SETTER HELPER | 5.30 | |
| SIGN ERECTOR | 5.00 | |
| POWER EQUIPMENT OPERATORS: | | |
| Asphalt Distributor | 6.85 | |
| Asphalt Paving Machine | 5.95 | |
| Brown or Sweeper Operator | 6.25 | |
| Bulldozer 150 HP & Less | 6.00 | |
| Bulldozer Over 150 HP | 7.10 | |
| Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (Less than 1½ CY) | 7.10 | |
| Crane, Clamshell, Backhoe, Derrick, Dragline, Shovel (1½ CY & Over) | 8.05 | |
| Foundation Drill Operator (Truck Mounted) | 8.65 | |
| Foundation Drill Operator Helper | 6.25 | |
| Front End Loader (2½ CY & Less) | 6.40 | |
| Front End Loader (Over 2½ CY) | 7.45 | |
| Motor Grader Operator, Fine Grade | 8.30 | |
| Motor Grader Operator | 7.55 | |
| Roller, Steel Wheel (Plant-Mix Pavement) | 5.40 | |
| Roller, Steel Wheel (Other-Flat Wheel or Tamping) | 5.80 | |
| Roller, Pneumatic (Self-Propelled) | 5.70 | |
| Scrapers (17 CY & Less) | 6.00 | |
| Scrapers (Over 17 CY) | 6.65 | |
| Side Boom | 5.80 | |
| Tractor (Crawler Type) 150 HP & Less | 5.00 | |
| Tractor (Crawler Type) Over 150 HP | 5.25 | |
| Tractor (Pneumatic) 80 HP & Less | 5.00 | |
| Tractor (Pneumatic) Over 80 HP | 6.35 | |
| Traveling Mixer | 5.50 | |
| TRUCK DRIVERS: | | |
| Single Axle, Light | 5.40 | |
| Tandem Axle or Semi-Trailer | 5.50 | |
| WELDER | 6.45 | |

[FR Doc. 85-4278 Filed 2-21-85; 8:45 am]

BILLING CODE 4510-27-C

federal register

Friday
February 22, 1985

Part V

# Department of Defense

Department of the Army

32 CFR Part 544

Civilian Marksmanship; National Marksmanship Matches and Other Excellence-in-Competition Matches; Final Rule and Proposed Rule

**DEPARTMENT OF DEFENSE**

**Department of the Army**

**32 CFR Part 544**

**Civilian Marksmanship; National Marksmanship Matches and Other Excellence-in-Competition Matches; Removal of Regulations**

**AGENCY:** Department of the Army, DOD.

**ACTION:** Final rule: Removal of regulations.

**SUMMARY:** This document removes a rule on National marksmanship matches that was inadvertently submitted and published on October 11, 1984 (49 FR 39946). We regret that action and withdraw the earlier rule.

**EFFECTIVE DATE:** February 22, 1985.

**ADDRESS:** Director of Civilian Marksmanship, Attention: Lieutenant William Creech, 20 Massachusetts Avenue, NW, Room 1205—Pulaski Building, Washington, DC 20314–0100.

**FOR FURTHER INFORMATION CONTACT:** John Roach, DA Liaison Officer with the Federal Register at (202) 653–1865.

**PART 544—[REMOVED]**

Therefore we are removing Part 544 of Title 32 of the Code of the Federal Regulations.

**John O. Roach, II,**

*Army Liaison Officer with the Federal Register.*

[FR Doc. 85–4581 Filed 2–21–85; 10:12 am]

BILLING CODE 3710-08-M

## DEPARTMENT OF DEFENSE

### Department of the Army

### 32 CFR Part 544

### National Marksmanship Matches and Other Excellence-in-Competition (EIC) Matches

**AGENCY:** National Board for the Promotion of Rifle Practice, Department of the Army, DOD.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed regulation on the rules and regulations for National Marksmanship Matches and other Excellence-in-Competition [EIC] matches has been revised. It gives responsibilities for the National Matches, eligibility criteria and categories for the competitors, and the program for the National Trophy Matches. It also describes the awards for the National Matches. This regulation has been revised to change the staff organization of the National Matches, show new eligibility requirements and programs for the National Trophy Matches, and introduce new awards.

**DATES:** Comments must be received by March 25, 1985.

**ADDRESS:** Director of Civilian Marksmanship, Attention: Lieutenant William Creech, 20 Massachusetts Avenue, NW, Room 1205—Pulaski Building, Washington, DC 20314–0100.

**FOR FURTHER INFORMATION CONTACT:** LTC William Creech at (202) 272–0810 at the above address.

**SUPPLEMENTARY INFORMATION:** This regulation promotes the maintenance of national defense through the promotion of nationally held rifle and pistol matches. An earlier draft of the rule was inadvertently submitted and published on October 11, 1984 (49 FR 39946). We regret that action and in another document published in this issue are removing the earlier rule. We are submitting this proposed rule for comment with the intent to publish a final rule.

#### Executive Order 12291

It has been determined that this document is not a major rule and does not require a regulatory impact analysis under Executive Order 12291 because the rule is administrative and has no economic effect on the public.

#### Regulatory Flexibility Act

The Department has also determined that this document will not have a significant economic effect on a substantial number of small entities and does not require a flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. 601 etc. seq.).

#### Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C 3507.

#### List of Subjects in 32 CFR Part 544

Armed forces, national defense, Awards, Nonprofit organizations.

Acordingly, a new Part 544 is added to read as follows:

## PART 544—CIVILIAN MARKSMANSHIP

**Subpart A—General**

Sec.
544.1 Purpose.
544.2 References.
544.3 Explanation of abbreviations and terms.
544.4 The intent of the National Matches.
544.5 Composition of the National Matches.
544.6 National Match Staff.
544.7 Armed Forces involvement.
544.8 Role of the NRA.
544.9 Places and dates.
544.10 Fees.
544.11 Substances and travel allowances.

**Subpart B-Responsibilities**

544.12 Secretary of the Army (SA).
544.13 President, National Board for the Promotion of Rifle Practice (NBPRP).
544.14 Director of Civilian Marksmanship (DCM).
544.15 Executive Officer, National Matches (XO, NM).
544.16 Executive Officer, Civilian Marksmanship Program (Support) (XO, CMP (SPT)).
544.17 National Match Support Coordinator (NMSC).
544.18 Match Directors.
544.19 Range Director.
544.20 Statistical Director.
544.21 Director, Small Arms Firing Schools (SAFS).
544.22 The Commanding General, US Army Material Command (CG, AMC).
544.23 Chief of Public Affairs (CPA).
544.24 Chief, National Matches Support Detachment (NMSD).
544.25 Ordnance Safety Officer (OSO).
544.26 Commanding General, US Army Forces Command (CG, FORSCOM).
544.27 Commanding General, US Army Training and Doctrine Command (CG, TRADOC).
544.28 Commanding General, US Army Comunications-Electronics Command (CG, CECOM).
544.29 Adjutant General, Ohio National Guard.

**Subpart C—Competitor Eligibility, Requirements, Categories, and Teams**

544.30 Eligibility for the matches.
544.31 Requirements for competitors in individual matches.
544.32 Requirements for military competitors.
544.33 Requirements for certain civilian competitors.
544.34 Competitor categories for National Trophy Matches.
544.35 Team member eligibility requirements.
544.36 Authorized teams in National Trophy Matches.
544.37 Requirements for new shooters in National Trophy Team Matches.

**Subpart D—General Rules for National Trophy Matches**

General Match Rules

544.38 National Trophy and EIC match rules.
544.39 Entries.
544.40 Directives competitors must follow.
544.41 Coaching.
544.42 Elimination of terms or individuals.
544.43 Penalties.
544.44 Competitors varifying their scores.
544.45 Referees, scoring, and challenge procedures.
544.46 Protests.
544.47 Bulletins.

Team Match Rules

544.48 Team composition.
544.49 Team squadding.
544.50 Station and duties of team coaches.
544.51 Station of team captain.

Types of Firearms, Ammunition, and Other Equipment

544.52 Description of arms to be used.
544.53 Rifles and pistols available.
544.54 Checking firing characteristics.
544.55 Use of the same firearm by more than one competitor.
544.56 Disabled firearms.
544.57 Ammunition.
544.58 Targets.
544.59 Field glasses and telescopes.

Firing

544.60 Safety precautions.
544.61 Organization of firing areas.
544.62 Station of competitors.
544.63 Target assignments and operations in rifle matches.
544.64 Slow target operation in rifle matches.
544.65 Practice firing.
544.66 Firing procedure and punctuality.
544.67 Firing positions.
544.68 Loading and reloading a rifle in rapid fire.
544.69 Unauthorized firing.
544.70 Time limits and extensions.
544.71 Sighting shots.
544.72 Competitors serving as range officials.

**Subpart E—Program for the National Trophy Matches**

544.73 The President's Pistol Match.
544.74 National Trophy Individual Pistol Match.
544.75 National Trophy Pistol Team Match.
544.76 The President's Rifle Match.
544.77 National Individual Trophy Rifle Match.
544.78 National Trophy Rifle Team Match.
544.79 National Trophy Infantry Team.

**Subpart F—Awards**

544.80 General.
544.81 Participation requirements for certain National Trophy Match awards.
544.82 Awards for the President's Pistol Match.
544.83 Awards for the National Trophy Individual Pistol Match.
544.84 Awards for the National Trophy Pistol Team Match.
544.85 Additional National Trophy Pistol Match awards.
544.86 Awards for the President's Rifle Match.
544.87 Awards for the National Trophy Individual Rifle Match.
544.88 Awards for the National Trophy Rifle Team Match.
544.89 Additional National Trophy Rifle Match awards.
544.90 Awards for the National Trophy Infantry Team Match.
544.91 Special medals in National Trophy Individual Pistol and Rifle Matches.
544.92 Place medals in National Trophy team matches.
544.93 Placed medals in individual EIC matches.
544.94 Distinguished designation and badge awards.
544.95 EIC badges.
544.96 Marksmanship qualification awards.
544.97 Scores allowed for club qualification firing

Appendix A—Related Publications
Appendix B—Trophies of the National Board for the Promotion of Rifle Practice
Glossary

**Authority:** 10 U.S.C. 4307 through 4313.

## Subpart A—General

### § 544.1 Purpose.

This regulation prescribes the policies, procedures, and responsibilities for the National Matches and other excellence-in-competition (EIC) matches.

### § 544.2 References.

Related publications are listed in appendix A.

### § 544.3 Explanation of abbreviations and terms.

Abbreviations and special terms used in this regulation are explained in the glossary.

### § 544.4 The intent of the National Matches.

(a) The national Matches and included competitions are part of the Civilian Marksmanship Program (CMP). Sections 4307 through 4313, title 10, United States Code (U.S.C.), establish the CMP to be conducted under rules approved by the Secretary of the Army (SA).

(b) As part of the CMP, these matches are intended to promote the national defense. The CMP provides and encourages voluntary marksmanship training for persons who are not reached by training programs of the Armed Forces and who might be called into service in an emergency. The National Matches enhance this training by offering open competition at the highest national level. Further, the statutes in § 544.4(a) above provide that marksmanship competitions sponsored by the National Rifle Association (NRA) may be held in connection with the National Matches.

(c) The Services have established individual rifle and pistol matches at major command levels in which civilians may participate. The Services will conduct these matches according to the parts of this regulation that apply.

(d) Upon approval by the Director of Civilian Marksmanship (DCM), recognized civilian rifle and pistol clubs and State rifle and pistol associations may conduct similar matches in conjunction with NRA Regional and State Championships. The intention of all of these matches is to promote civilian marksmanship training.

### § 544.5 Composition of the National Matches.

The National Matches are composed of (a) through (e) of this section.

(a) *Small Arms Firing Schools (SAFS).* The SAFS give instruction in the service rifle and pistol, particularly the current service rifle with which civilians may not be familiar. The SAFS, also introduce the latest approved training concepts for these arms. The Army will conduct the schools and provide the Director, SAFS. The Director, SAFS, may request Armed Forces shooting teams participating in the National Matches to provide qualified persons to serve as assistant instructors and coaches. The SA will prescribe the curriculum based on the recommendation of the National Board for the Promotion of Rifle Practice (NBPRP). The Director, SAFS, will give a certificate of satisfactory completion to those who meet the qualifications set by the NBPRP.

(b) *National Trophy Matches.* The National Trophy Matches are listed below.

(1) The President's Pistol Match.
(2) National Trophy Individual Pistol Match.
(3) National Trophy Pistol Team Match.
(4) The President's Rifle Match.
(5) National Trophy Individual Rifle Match.
(6) National Trophy Rifle Team Match.
(7) National Trophy Infantry Team Match.

(c) *NRA National Rifle and Pistol Championships.* The NRA National Rifle and Pistol Championships are conducted according to the NRA's rules and regulations. These championships are listed below.

(1) National Pistol Championships.
(2) National Smallbore Rifle Position Championships.
(3) National Smallbore Rifle Prone Championships.
(4) National Highpower Rifle Championships.

(d) *Additional events.* The National Matches also include events sponsored by the SA or sponsored by the NRA and arranged in coordination with the SA, such as the NRA Junior Smallbore Camp and Whistler Boy Smallbore and Highpower Matches.

(e) *Ceremonies.* As approved by the DXM (who is also the National Matches Installation Commander (NMIC)), the appropriate opening, closing, award, and other ceremonies are conducted as official parts of the National Matches.

### § 544.6 National Match Staff.

(a) The organization of the National Match Staff is shown in figure 1–1.

(b) The specific duties of the National Match Staff are set by the DCM/NMIC and the NRA National Match Coordinator.

(c) Key members of the National Match Staff are listed below. Their responsibilities are explained in the paragraphs cited after their titles.

(1) DCM/NMIC (§ 544.3).
(2) Executive Officer, National Matches (XO, NM)/Deputy Installation Commander (Operations/Services) (DNMIC (Ops/Svcs)) (§ 544.14 2–4).
(3) Executive Officer, Civilian Marksmanship Program (Support) (XO, CMP (SPT)) (§ 544.15).
(4) NRA National Matches Coordinator (§ 544.81–8).
(5) Match Directors (§ 544.17).
(6) Deputy Match Directors (§ 544.8).
(7) Range Director (§ 544.18).
(8) Statistical Director (§ 544.19).
(9) Director, SAFS (§ 544.20).
(10) National Matches Support Coodinator (§ 544.6).
(11) Chief, National Matches Support Detachment (NMSD) (§ 544.23).
(12) Ohio Army National Guard Facilities Manager (§ 544.23).
(13) Billeting Officer (§ 544.28).
(14) US Army Reserve Command and Liaison Group Commander (§ 544.26).
(15) Active Army Food Service Advisor (§ 544.26).

### § 544.7 Armed Forces involvement.

The US military services will support the National Matches as follows:

(a) The Army will conduct the SAFS.

(b) As approved by the SA and subject to the availability of resources.

the Army will also supply the personnel, equipment, and supplies needed to conduct the National Matches.

(c) Subject to the availability of resources, all Services will furnish personnel as requested by the DCM and approved by their respective departments. The number of personnel furnished should be proportional to the number of competitors that the particular Service furnished in the most recent National Matches.

**§ 544.8 Role of the NRA.**

(a) The NRA sponsors and regulates the conduct of the NRA National Rifle and Pistol Championships. The NRA advises the NBPRP on NRA participation in the National Matches. It also coordinates with the DCM and the XO, NM, on National Match matters.

(b) Unless the SA determines otherwise, the NRA will be invited to assist in the conduct of the National Matches. The NRA assists the DCM/NMIC in the conduct of the schools related to the matches and provides, administers, and funds the NRA Match Coordinator, Match Director, Deputy Match Director, Range Director, Range Engineer, and Statistical Director and staff. (Their responsibilities are outlined in Subpart B.) The NRA also provides other personnel needed to conduct the shooting events and NRA-sponsored schools.

(c) The NRA National Match Coordinator is the principal representative of the NRA at the National Matches and conducts the NRA-sponsored events of the matches. When the NRA is requested to conduct the shooting events related to the National Matches, the NRA National Coordinator will also—

(1) Conduct the National Trophy Matches.

(2) Coordinate match operations with the DCM/NMIC.

(d) The NRA Match Director will follow § 544.18.

(e) The NRA Deputy Match Directors will assist their NRA Match Director in conducting specific shooting events, groups of events, or championships.

**§ 544.9 Places and dates.**

The National Matches will be held each year at Camp Perry, Ohio, or at other places. The DCM will recommend the places and dates for the matches, and the SA will approve and publish them in advance. The National Matches Program, approved by the DCM and NRA, gives additional details on the matches.

**§ 544.10 Fees.**

When approved by the DCM, nominal administrative fees may be charged for the National Trophy Matches, the SAFS, and EIC matches approved by the DCM. The NRA prescribes fees for its NRA National Championships and its other events.

**§ 544.11 Subsistence and travel allowances.**

Civilian competitors at the National Matches may be reimbursed for subsistence and travel expenses at rates set forth in Invitational Travel Orders. The payment of subsistence and travel allowances for civilian competitors is authorized by section 4313, title 10, United States Code (USC), and Joint Travel Regulations (JTR), Volume 2, para C-6002-6. General qualifications and criteria for reimbursement are as follows:

(a) Civilian competitors must be members of DCM-enrolled clubs or State Associations. Competitors must have Invitational Travel Orders issued by the Office of the Secretary of the Army.

(b) The rate of payment for travel (mileage) will be announced in the Invitational Travel Orders. The rate of payment for the mileage allowance will be based on travel from the place of residence, as stated in orders, to the National Matches and return regardless of the actual location of the competitor when travel commences. The mileage will be determined from the Official Table of Distance (AR 55-60).

(c) The authorized subsistence and mileage allowance rates payable to civilian competitors may not exceed the amount paid to military members and Federal Government employees under the JTR.

(d) Subsistence is not payable to competitors while they are traveling to and from the National Matches.

(e) Subsistence will be prorated, meal by meal, on the days of arrival and departure. Subsistence for full days is authorized when a competitor is present for an event during and entire day, from 0001 hours through 2400 hours (midnight to midnight). The rate of reimbursement for each meal will be published in the Invitational Travel Orders for each competitor and will be used for proration of entitlement to the authorized subsistence allowance.

(f) Constructive payment of allowances for the return trip may be made before departure from the national Matches. Payment will be made only for return to place of residence, without regard to the actual destination of the competitor.

(g) Competitors may travel by any method desired; however, reimbursement will be based on the mileage rate for travel by privately owned vehicle.

(h) If a competitor provides a substantiating document (such as an airline ticket) and claims reimbursement for travel by air or other mode, reimbursement will be made for the mode of travel claimed by will not exceed the amount which would have been payable for travel by privately owned vehicle.

(i) Each competitor is entitled to reimbursement for mileage for the residence to the National Matches and return, regardless of the ownership of the vehicles used or the number of occupants.

(j) All substantiating documents (receipts) accompanying travel claims must be originals.

(k) Firearms for marksmanship or rifle practice are authorized to be carried incident to travel performed by DCM-sponsored competitors.

(l) Payment of entry fees and other administrative fees will be authorized only to the extent they are indicated in Initational Travel Orders.

(m) Collection for meals in Government-sponsored or Government-affiliated messes will be made at the time of consumption of each meal.

(n) Civilian competitors or support personnel, traveling under Invitational Travel Orders published by Office of the Secretary of the Army, are not required to pay surcharges in Government-sponsored or Government-affiliated messes.

## Subpart B—Responsibilities

**§ 544.12 Secretary of the Army (SA).**

The SA shall conduct the National Matches each year. The SA may delegate this authority to the President, NBPRP.

**§ 544.13 President, National Board for the Promotion of Rifle Practice (NBPRP).**

The President, NBPRP, will—

(a) Act for the SA in the conduct of the National Matches.

(b) Advise the SA on the conduct of the National Matches.

(c) Receive advice of the NBPRP concerning the conduct of the National Matches.

(d) Provide guidance to the DCM governing the conduct of National Matches and approve the annual National Matches plan and expenditures.

**§ 544.14 Director of Civilian Marksmanship (DCM).**

The DCM, a statutory official, will—

(a) Direct and implement the National Matches as approved by the President, NBPRP, for the SA.

(b) Serve as the NMIC according to AR 600–20.

(c) When the National Match Staff (§ 544.6) is assembled for duty at the site of the National Matches, the NMIC will assign duties to the National Match Staff and be responsible to the President, NBPRP, for all National Match matters. However, when the NRA is requested to conduct the National Matches, the NMIC will not conduct the shooting events. Further, the NMIC will supervise personnel involved in conducting base operations associated with the National Matches. This supervision does not include courts martial jurisdiction.

**§ 544.15 Executive Officer, National Matches (XO,NM).**

The XO, NM, Will—

(a) Perform the year-round planning and operations needed to conduct the National Matches. This responsibility includes recommending support requirements.

(b) Serve as the Deputy National Matches Installation Commander (Operations and Services) (DNMIC (Ops/Svcs)).

**§ 544.16 Executive Officer, Civilian Marksmanship Program (Support) (XO,CMP (SPT)).**

The XO, CMP (SPT) will—

(a) Provide technical assistance and operational advice to all DCM-affiliated clubs and State associations that participate in the National Matches.

(b) Provide communications, supply and billeting (logistics) ammunition, and the ordnance safety officer (OSO) support to the NRA National Match Coordinator as required and directed.

(c) Insure the NBPRP trophies, medals, brassards, and prizes are available.

(d) Arrange for NBPRP awards ceremonies and receptions. Coordinate combined ceremonies.

(e) Supervise the in and out processing of DCM-supported State association and club teams.

**§ 544.17 National Match Support Coordinator (NMSC).**

The NMSC will be designated by the Commanding General, US Army Forces Command (CG, FORSCOM). The NMSC will—

(a) Coordinate the activities of the National Match Support Detachment during the National Matches.

(b) Assist the XO, NM/DNMIC (Ops/Svcs) with year-round planning and coordination for the National Matches.

(c) Attend meetings, conferences, and briefings concerning logistics support for the National Matches.

**§ 544.18 Match Directors.**

The Match Directors for Pistol, Samllbore rifle, and Highpower rifle will conduct specific shooting events, groups of events, or championships. When the Army conducts the matches, the March Directors are responsible to the DCM/NMIC. When the NRA conducts the shooting events of the National Matches, the Match Directors are responsible to the NRA National Match Coordinator § 544.8(c)).

**§ 544.19 Range Director.**

The Range Director is responsible to the respective Deputy Match Director.

The Range Director will prepare, maintain, and operate the firing ranges. Operating the ranges includes controlling and directing all personnel, competitors, and spectators on the ranges. Normally, the Range Director is assisted by and is responsible for the functions of the following officials and others as designated:

(a) Range Safety Officer.

(b) Range Communications Officer (normally provided from the military).

(c) Range Engineer Officer.

(d) Chief Range Officer (usually one for each range).

(e) Chief Pit Officer (usually one each operating rifle range).

**§ 544.20 Statistical Director.**

The Statistical Director is responsible to the March Director and will perform the statistical operations. These operations include—

(a) Insuring that entries are correct.

(b) Checking the eligibility of competitors and teams. The Statistical Director will work with the Range Director in assigning these people to relays and targets.

(c) Verifying scores.

(d) Listing participants in order of excellence.

(e) Publishing match results in official bulletins.

**§ 544.21 Director, Small Arms Firing Schools (SAFS).**

The Director, SAFS, will organize and conduct the SAFS.

**§ 544.22 The Commanding General, US Army Material Command (CG, AMC).**

CG, AMC, will act as the procurement agent for small arms and related equipment use to support the National Matches. Also, CG, AMC, will budget for and provide—

(a) The personnel, supplies, and equipment needed for the onsite repair of service-type small arms. Such repair will be provided only if required and authorized.

(b) Technical assistance and advice regarding National Match arms, ammunition, target materiel, and related equipment.

(c) Limited logistical support as required.

(d) The OSO (§ 544.25).

**§ 544.23 Chief of Public Affairs (CPA).**

(a) The CPA will—

(1) Arrange for appropriate public affairs support to the National Matches and other Excellence-in-Competition (EIC) matches. Such support will be provided within available resources.

(2) Designate a qualified individual to serve as the National Matches Public Affairs Officer (NMPAO) for a period not to exceed three week before and one week after the competitions.

(b) The NMPAO will work with the public information activities conducted by the Service and directed by the NMIC.

**§ 544.24 Chief, National Matches Support Detachment (NMSD).**

The Chief, NMSD, will, through the NMSC, act as the logistics coordinator for the National Matches, supervise all National Match supply activities, and coordinate service activities. The Chief, NMSD, will—

(a) Procure, control, and issue Army-furnished supplies and equipment.

(b) Provide repair and utilities activities.

(c) Issue and/or sell ammunition or arms that are provided by the DXM and that are required and authorized.

(d) Coordinate logistical matters between National Match activities and match support organizations.

**§ 544.25 Ordnance Safety Officer (OSO).**

The OSO will—

(a) Investigate the circumstances leading to any weapon or ammunition malfunction that results in an accident or creates a hazardous condition at the match site.

(b) Determine the probable cause of a malfunction and insure the problem has been resolved before the weapon or ammunition is return to the firing line.

(c) Report to the Match Director, in writing, about an incident or malfunction that called for his or her services.

**§ 544.26 Commanding General, US Army Forces Command (CG, FORSCOM).**

The CG, FORSCOM, will—

(a) Appoint the NMSC.

(b) Budget for and provide personnel and other support and services as

required by the National Matches Support and Operations Plan.

**§ 544.27 Commanding General, US Army Training and Doctrine Command (CG, TRADOC).**

The CG, TRADOC, will budget for and provide services and equipment in the areas of communications, facilities engineering, food service, medicine, maintenance, supply, transportation, procurement and contracting, and other areas as may be required by the National Matches Support and Operations Plan. The CG, TRADOC, will also provide comptroller assistance as required.

**§ 544.28 Commanding General, US Army Communications-Electronics Command (CG, CECOM).**

THE CG, CECOM, will budget for and provide selected items of signal equipment as set forth in the National Matches Support and Operations Plan.

**§ 544.29 Adjutant General, Ohio National Guard.**

(a) Per existing leases and contracts, the Adjutant General, Ohio National Guard, will provide personnel, services, facilities, and equipment to the maximum extent possible to support and conduct the National Matches.

(b) Additional support that may be requested that is not provided for elsewhere, may be provided for when concurred in by the Adjutant General, Ohio National Guard, and approved by the National Guard Bureau as appropriate.

## Subpart C—Competitor Eligibility, Requirements, Categories, and Teams

**§ 544.30 Eligibility for the matches.**

(a) The National Trophy matches are open to all US citizen 16 years of age or older, any other persons subject to induction in the US Armed Forces, and all members of the US Armed Forces, both Regular and Reserve Components. The minimum age may be waived. (Requests for waivers, with justification, must be submitted to the DCM before the opening date of the National Matches.)

(b) Other EIC matches noted in § 544.31 are open as described in § 544.30(a) of this section. However, there are restrictions for these matches. These restrictions are described in §§ 544.31 (c) and (d) and 544.94. Further restrictions for Service personnel are described in the regulations of their own Service. The match sponsor may waive the minimum age requirement. Request for waiver will be submitted to the sponsor as explained in the match program. These requests must include a justification. For example, an acceptable justification is that the person is classified by the NRA as a Sharpshooter or higher or has completed an EIC match with the arm concerned.

(c) Competitors designated Distinguished with the arm concerned may enter the National Trophy Matches and other EIC matches. Non-Distinguished competitors cannot enter any EIC match on a noncredit basis (such as entering for practice).

(d) Non-Distinguished military competitors may not enter EIC matches at NRA Regional or State championship matches if these competitors have earned, with the arm concerned, the maximum credit points their Service allows for such matches.

(e) The SAFS are open to all US citizens, any other persons subject to induction in the US Armed Forces, and all members of the US Armed Forces, both Regular and Reserve Components. To attend the SAFS, a person must not necessarily compete in the National Matches. For pistol instruction, a person must be 16 years old or older; for rifle instruction, 12 years old or older.

**§ 544.31 Requirements for competitors in individual matches.**

(a) All competitors must state on their entry forms whether their status is Distinguished or non-Distinguished.

(b) For the National Trophy Matches, non-Distinguished military competitors must advise the DCM when, per their Service's regulations, they cannot be credited with points earned in National Trophy Matches. Competitors must advise the DCM before the matches and in writing.

**§ 544.32 Requirements for military competitors.**

Military competitors (Regular and Reserve Components) who compete in the National Matches and whose transportation or other expenses connected with the matches are paid, wholly or in part, from appropriated or non-appropriated funds (NAF) must meet special requirements. (Examples of NAF are funds for exchanges, recreation, and morale.) These competitors will—

(a) Participate in the appropriate SAFS.

(b) Enter and complete the appropriate National Trophy Individual Match and President's Match if eligible under this regulation, unless eliminated from the match.

(c) Enter and complete the appropriate National Trophy Team Matches if eligible under this regulation and selected by the team captain, unless eliminated from the match.

(d) Fire a service rifle (authorized by § 554.52 at ranges of 200 through 600 yards in both the NRA and the National Trophy Rifle Matches, unless exempted in the current match program. These military competitors may also use other rifles at greater ranges.

**§ 544.33 Requirements for certain civilian competitors.**

Civilian competitors in the National Trophy Matches whose transportation or other expenses connected with these matches are paid, wholly or in part, by the DCM must meet special requirements. These competitors will—

(a) Attend the appropriate SAFS.

(b) Enter and complete the appropriate National Trophy Individual Match and President's Match, unless eliminated according to § 544.42.

(c) Enter and complete the appropriate National Trophy Team Matches if eliminated according to § 544.42.

**§ 544.34 Competitor categories for National Trophy Matches.**

Competitors may register and participate in only one of the following categories:

(a) *Regular Service.* (1) This category consists of—

(i) Regular Service personnel on active duty.

(ii) National Guard and Reserve personnel on extended active duty with active forces of 90 days or more with a Regular Service status under Title 10 USC.

(2) This category does not include enrolled undergraduates of the Service academies.

(b) *Reserve.* This category consist of members of any Reserve branch of the US Armed Forces who are not on extended active duty as in § 554.34(a) of this section above. It includes Fleet Reserve but excludes Fleet Marine Corps Reserve. This category also excludes Army or Air National Guard and ROTC. If also qualified under § 544.84 (e) and (f)(3), Reserve members may instead register and participate in one of those categories.

(c) *National Guard.* This category consists of members of the Army or Air National Guard who are not on extended active duty as in § 544.34(a)(i)(ii) of this section. If also qualified under §§ 544.34 (e) or (f)(3), National Guard members may instead register and participate in one of those categories.

(d) *Service Academy and Reserve Officers Training Center (ROTC).* (1) This category consists of enrolled undergraduate members of—

(i) The Service academies of the Armed Forces.

(ii) Any high school or college Army, Navy, or Air Force ROTC unit.

(2) If also qualified under § 544.34(f)(3) of this section. Service Academy and ROTC members may instead register and participate in that category.

(e) *Police.* This category is defined in NRA Rule 2.4. If also qualified in the Reserve, National Guard, or Civilian categories, police may instead register and particapte in one of those categories.

(f) *Civilian.* This category consists of competitors listed in § 544.34(f)(1) through § 544.34(f)(3). Reserve or National Guard category personnel who elect to compete as civilians under § 544.34(f)(3) may not revert to a Reserve or National Guard category later, unless the proper authority orders them to active duty for a purpose other than marksmanship competition. The penalty for noncompliance will be determined by the DCM.

(1) Individuals who are not in the Regular Service, Reserve, National Guard, Service Academy and ROTC, or Police categories.

(2) Retired service (Regular, Reserve, or National Guard) and Fleet Marine Corps Reserve personnel. However, if qualified in the Police category, they may instead register and participate as police.

(3) Members of the Reserve, National Guard, Service Academy and ROTC, or Police categories who, during the current calendar year.

(i) Have not competed with the arm concerned in any of the Reserve, National Guard, Service Academy and ROTC, or Police categories.

(ii) Received support for any competition in the form of arms, ammunition, or travel expenses, wholly or in part, from organizations in the Reserve, National Guard, and Service Academy and ROTC categories. Do not include as support the arms or ammunition provided for a specific competition (such as National Trophy or other EIC matches) when such items are available to all competitors within the calendar year.

(g) *Junior.* This category consists of civilians who will not reach 20 years old by the end of the calendar year. Juniors may compete on Civilian teams if they are eligible. Individuals who have National Guard, Reserve, or Regular Service status may not compete as juniors.

**§ 544.35 Team member eligibility.**

For teams to be eligible to compete, the following requirements must be met:

(a) No person may be a team captain, firing member, or alternate member of a team unless he or she is qualified in the category the team represents. (Categories are listed in § 544.34) This rule does not apply to police on State Civilian teams as authorized in § 544.35(f)(1). Nor does it apply to qualified juniors on Civilian teams.

(b) Individuals must be bona fide members of the organization and category represented for at least 30 days before the opening date of the matches.

(c) Members of State Civilian, State Junior, State fraternal-type Police organization, or club teams must be bona fide residents of the State that the team represents or in which the club is located. Further, they must have lived in that State for at least 30 days before the opening date of the matches.

**§ 544.36 Authorized teams in National Trophy Team Matches.**

The categories of teams that may enter the National Trophy Team Matches and the number that may in each category are listed below.

(a) *Regular Service.* Two teams may represent each Service (the Army, Navy, Marine Corps, Air Force, and Coast Guard).

(b) *Reserve.* Two teams may represent the Reserve branch of each Service (the Army, Navy, Air Force, Marine Corps, and Coast Guard).

(c) *National Guard.* Two teams may represent the National Guard at large. Such teams may be composed of both Army National Guard and Air National Guard personnel.

(d) *Service Academy and ROTC.* One team from each Service academy may participate in the match. One team from each Army ROTC region, Naval Base Command, and Air Force ROTC Liaison Area within the continental United States (CONUS) may participate. ROTC members from units outside CONUS will compete on ROTC teams as authorized by the DCM.

(e) *Police.* One or more teams may represent each bona fide organized Federal, State, county, or municipal agency having law enforcement police powers. Also, one or more teams may represent a State, Commonwealth, Territory, or District of Columbia police organization of a fraternal nature. Fraternal organizations may enter only if they are organized according to AR 920–20 and affiliated with the DCM, or they are organized as a club and in good standing under the rules of the NRA. However, the entry of more than one team per fraternal organization will be subject to the availability of range facilities.

(f) *Civilian and Junior.* (1) One or more State Civilian Teams and one or more State Junior teams may represent the DXM-affiliated State association of each State, Commonwealth, Territory, and the District of Columbia. However, the entry of more than one team per organization will be subject to the availability or range facilities. Also, only one State Civilian team and State Junior team may be supported by the DCM through payment of travel and subsistence expenses on a cost sharing basis. Each State Civilian team in the National Trophy Pistol Team Match may include two police officers; however, the officers must not be members of a police organization that enters a team in the same match.

(2) One or more Civilian teams and one or more Junior teams may represent a club. The club must be organized according to AR 920–20 and in good standing on the rolls of the DCM, or it must be organized and in good standing under the rules of the NRA. The entry of more than one team per club will be subject to the availability of range facilities.

**§ 544.37 Requirements for new shooters in National Trophy Team Matches.**

(a) *Regular Service, Reserve, and National Guard Teams.* Pistol teams will have at least one firing member who has never fired before as a member of any team that has competed in the particular event. Rifle teams will have at least two such firing members.

(b) *Civilian and Police teams.* These teams will have at least one firing member who has never fired before as a member of any team that has competed in the particular event.

(c) *Service Academy, ROTC, and Junior teams.* There are no requirements for new shooters on these teams. Having fired as a member of a Service Academy ROTC or Junior team or as a junior member of a Civilian team is not considered previous participation. It will not disqualify a competitor from being a member of teams in §§ 544.37(a) and 544.37(b) of this part.

## Subpart D—General Rules for National Trophy Matches

### General Match Rules

**§ 544.38 National Trophy and EIC match rules.**

(a) NRA rules will apply unless changed by this regulation or as stated in § 544.38(b).

(b) The XO, NM, or the corresponding official in another EIC match, may alter, the NRA rules for a particular match only if such action is needed to complete

the match successfully. If any alterations are made, the XO, NM, or the corresponding official must immediately report the details in writing to the President, NBPRP (ATTN: DCM).

**§ 544.39 Entries.**

(a) Individual entries will be made in advance as prescribed in the match program. Post entries will be accepted if the established post entry fee is paid, range space is available, and the acceptance of the post entry will not interfere with match operations. The following individual entry forms may be obtained by request to the Statistical Director or the DCM. Forms that require personal information must be accompanied by a Privacy Act statement (AR 340–21, para 4–3 and 5 U.S.C. 552a(e)(3)).

(1) DA Form 1342 (Entry and Score Card for Individual Pistol Match) or a substitute form approved by the DCM.

(2) DA Form 1344 (Entry and Score Card for Individual Rifle Match) or a substitute form approved by the DCM.

(b) Team match entries will be made by team captains using official forms provided by the Statistical Director. Team captains will—

(1) Enter the following data on the team entry form.

(i) The full official name and address of the organization their team represents. Civilian, Junior, and Police teams will be recognized as representing a particular State, Commonwealth, Territory, the District of Columbia, or DCM or NRA-Affiliated organization only if attested to on the form by an official of the organization represented.

(ii) The category under which the team will enter according to § 544.34.

(iii) Further identification of the organization's team name (such as "Blue," "Jones," or the like) if the organization enters more than one team.

(iv) The designations of team officials and other members.

(v) Each member's correct first name, middle initial, last name, home address, and if applicable, the member's grade and official military mailing address.

(vi) A statement by the team captain that the team is certified under this regulation.

(2) Submit entry forms at the match site as prescribed in the match program. Entries by mail will not be accepted.

(c) Incomplete or inaccurate entry forms or the use of the wrong form may cause the entries to be refused or the individual or team entrant to be disqualified.

(d) Entries will be accepted on a first-come, first-served basis until range capacity is filled.

**§ 544.40 Directives competitors must follow.**

(a) The competitor must know and comply with this regulation, the Official Match Program, and the NRA rules and Match bulletins that apply.

(b) In team matches, the team captain will insure that team members comply with § 544.40(a) of this part.

**§ 544.41 Coaching.**

Coaching is not permitted in individual matches, it is permitted only in team matches. Usually, coaching is permitted only with the team, but there are exceptions to this rule:

(a) Service members will coach teams of their respective Service, and only Service members may coach Service Academy and ROTC teams. They may also coach Police, Civilian, and Junior teams.

(b) Upon request by a Civilian, Junior, or Police team, the XO, NM, will assign a coach from among qualified and available Service personnel.

**§ 544.42 Elimination of teams or individuals.**

The XO, NM, or the corresponding official in matches may establish standards by which individuals and teams of the lowest standing may be eliminated after the first stage of a match is completed.

**§ 544.43 Penalties.**

(a) Any person interfering with or annoying a competitor on the firing line will be warned by a range official to stop. If the offender does not stop, he or she will be disqualified from that match and ordered off the range immediately.

(b) If the XO, NM, finds a competitor guilty of any of the offenses below, the competitor may be disqualified from competing further in the current National Trophy Matches. Further, the competitor may be denied any award won during the current matches. However, these penalties will be imposed only if the competitor is found guilty. The offenses are—

(1) Violating range safety regulations or the safety precautions prescribed in this regulation.

(2) Firing under an assumed name.

(3) Firing under a name other than the one on the entry form.

(4) Firing more than once for the same award.

(5) Falsifying scores or being an accessory to falsifying scores.

(6) Offering any person a bribe relating to a match.

(7) Evading the conditions prescribed for a match.

(8) Refusing to obey the instructions of a match official.

(9) Disorderly conduct.

(10) Being guilty of conduct that the XO, NM, considers a discredit to the National Matches, their sponsors, or the intended purposes of the matches.

**§ 544.44 Competitors verifying their scores.**

The competitor in individual matches and the team captain in team matches must verify the score card. Verification includes checking the names on the card, the value of each shot, and all other data and then signing the card. The signature acknowledges the card is correct. Should a competitor or team captain sign an incorrect score card or leave the firing line without signing the card, no challenge or protest concerning data recorded on the card will be allowed. If the competitor or team captain wants to protest data recorded on the card, he or she will write the word "Protested" above the signature and follow the procedure prescribed in § 544.46.

**§ 544.45 Referees, scoring, and challenge procedures.**

NRA rules cover the use of referees and scoring and challenge procedures. Exceptions are listed below.

(a) The Match Director will appoint an Official Referee and Assistant Referees are required, including Scoring Referees for Pistol matches.

(b) If a competitor (in individual matches) or a team captain (in team matches) is not satisfied with the score announced by the scorer, the competitor or team captain may challenge it. They must pay a challenge fee (§ 544.45(c) below) to have the Referee settle the disputed score. The Referee's decision will be final. For pistol matches, the decision of the Scoring Referee is final. For rifle matches, the decision of the Pit Officer is final.

(c) The XO, NM, will establish the challenge fee. When the Referee's decision is not in favor of the competitor or team member, the challenge fee will be delivered to the XO, NM, for deposit into the National Match Fund. If the decision is in favor of the competitor, the challenge fee will be returned.

**§ 544.46 Protests.**

(a) Competitors (individual matches) or team captains (in team matches) may protest any decision or injustice that they believe unfairly affects the competition. Protests may be in such areas as competitor or team eligibility, the conditions of firing (including the conditions under which another competitor is permitted to fire), or the equipment allowed. However, competitors or team captains may not

protest the score of a target. In this case, they must challenge the score according to § 544.45.

(b) A protest must be made when the incident occurs and according to the steps below. Failure to comply with these steps may void a protest.

(1) State the complaint orally to the Chief Range Officer or to the Statistical Director, as appropriate, for a decision. If not satisfied with the decision, then follow § 544.46(b)(2).

(2) State the complaint orally to the Official Referee for a decision. If not satisfied with that decision, carry out § 544.46(b)(3) within 2 hours after completing the match.

(3) File a formal, written protest with the Official Referee. State all the facts the protest is based on. As quickly as possible, the Official Referee must send this protest to the National Trophy Match Protest Committee. The Official Referee will include his or her own statement concerning the alleged facts, any other facts considered pertinent to the case, and copies of related documents such as entry forms and score cards.

(c) The National Trophy Match Protest Committee will sit at the match site. The committee will consist of three or more members appointed by the Match Director. The Match Director will not appoint competitors or team or match officials participating in the match being protested. The decision of the committee will be final.

### § 544.47 Bulletins.

Preliminary bulletins showing award winners will be published at the match site. Complete, final official bulletins showing the scores for all competitors, including all firing members of teams, will be published by the Statistical Director in coordination with the DCM/NMIC. The bulletins will be published as soon as possible after the matches are completed.

## Team Match Rules

### § 544.48 Team composition.

Each team will include the number of firing members required by the match conditions to fire for score. A team may include up to two alternate firing members who are eligible to fire as substitutes. (Follow NRA Rule 12.4 when using substitutes.) Each team will have a designated team captain and may have a designated team coach. (Sec. 544.41 on when coaches are allowed and who may serve as a coach.) The captain and coach may be firing members or alternates if eligible, and must be listed as such on the team entry form. (§§ 544.37 and 544.38 discuss new shooter requirements and team member eligibility.)

### § 544.49 Team squadding.

(a) All teams will be assigned the same number of targets.

(b) In rifle team matches, slow fire will be conducted with two firers assigned to a single target. This is known as pair firing. If firing points are too narrow to permit this procedure, each team may be assigned one or more adjoining firing points, provided all teams fire concurrently. When enough targets are available, each team may be assigned more than one target. However, in this case, each team must be assigned the same number of targets.

(c) When two competitors are assigned to a single target (pair firing), they will fire alternately. The competitor on the right will fire first. A shot fired out of turn will be scored as a miss. A range official may require a left-handed competitor to be on the left of a pair.

(d) Team captains may place team members on assigned targets in any order they choose. They may change the order of a team member firing between stages, in each case notify the scorer.

### § 544.50 Station and duties of team coaches.

(a) In the slow fire stages of rifle matches, the team coach's station will be between the pair on the firing line. If only one member is firing, the station will be directly behind the member. In rapid fire stages, the station will be directly behind the member firing.

(b) In pistol team matches, one coach is allowed for each target assigned the team. When the team is on the firing line, the team coach's station will be directly behind the team member or members firing. The team captain may act as a coach on the second target.

(c) In pair firing, the positions of the coach or competitors may not be shifted to form a windshield for a firer.

(d) When the team is on the firing line, coaches will be confined to the prescribed station and to the activities normally expected of a coach. Coaches may assist team members by calling shots, checking time and scores, ordering sight changes, and so on. However, coaches may not physically assist in loading, making sight changes, or in assuming positions. Also, they must control their voices and actions so as not to disturb other competitors. In communicating with the team, coaches will not use electrical or mechanical means.

### § 544.51 Stations of team captain.

When a team is on the firing line, the team captain and one assistant may be stationed in front of the ready line and slightly behind the coach. The captain is positioned there to observe team operations and the scorekeeping. The team captain may not assist in coaching unless occupying the coach's station. The captain may talk with the coach if it does not distract firers on the firing line. The captain may not talk to the firer.

## Types of Firearms, Ammunition, and Other Equipment

### § 544.52 Description of arms to be used.

(a) US rifle, caliber .30 M1 as issued by the US Army, a commercial rifle of the same type and caliber, or either rifle if chambered for 7.62mm. The requirements for those rifles are listed below.

(1) The trigger pull must be at least 4½ pounds.

(2) A standard issue type wood or synthetic material stock and standard issue type leather or web sling must be used.

(3) Sling cuffs and sling pads are not permitted. Hooks, buttons, straps, or other similar devices fastened to the shooting coat for the purpose of holding the sling in place are prohibited.

(4) The gas system must be fully operational.

(5) The front and rear sights must be of US Army design for this rifle, but the dimensions of the rear sight aperture and front sight blade may vary.

(6) External alterations to the assembled arm are not allowed.

(7) These rifles may be modified internally to improve functioning and accuracy. A special match barrel may be installed. Synthetic materials may be applied to the interior of the stock to improve the bedding. Modifications must not interfere with the functioning of the rifle and safety devices as manufactured. Also modifications must not change the configuration or appearance of the assembled arm.

(b) U.S. rifle caliber 7.62mm M14 series. Competitors may use the caliber 7.62mm M14 series as issued by the U.S. Army or a commercial rifle of the same type and caliber. The requirements for these rifles are listed below.

(1) The trigger pull must be at least 4½ pounds.

(2) A standard issue type wood or synthetic material stock must be used. The stock must not be more than 2 inches wide at a point immediately to the rear of the front band and not more than 2.5 inches wide at the front and rear of the receiver. The width at the receiver may be carried through to the butt plate The stock must have a

continuous taper from receiver to front band.

(3) A standard issue type leather or web sling must be used. Sling cuffs and sling pads are not permitted. Hooks, buttons, straps, or other similar devices fastened to the shooting coat for the purpose of holding the sling in place are prohibited.

(4) The gas system must be fully operational. To improve operation, the gas cylinder plug may be altered by making an axial hole that is approximately 1/64th inch in diameter in the center of the plug.

(5) The front and rear sights must be of US Army design for this rifle, but the rear sight aperture and front sight blade may vary in dimensions.

(6) The rifle must be adjusted so that automatic fire is impossible without removing the stock and changing or altering parts.

(7) The standard 20 or 30 round box magazine must be attached during the firing of all courses and in all positions.

(8) The hinged butt plate will be used only in the folded position.

(9) External alterations to the assembled arm are not allowed.

(10) The rifle may be modified internally to improve functioning and accuracy. A special match barrel may be installed. Synthetic materials may be applied to the interior of the stock to improve the bedding. Modifications must not interfere with the proper functioning of the rifle or safety devices as manufactured. Modifications must not change the configuration or appearance of the assembled arm.

(c) U.S. rifle, caliber 5.56mm M16 series. Competitors may use the caliber 5.56mm M16 series as issued by the U.S. Armed Forces or a commercial rifle of the same type and caliber. (The U.S. rifle caliber 5.56mm M16 AZ or its commercial equivalents are not authorized under this regulation.) The requirements for these rifles are listed below.

(1) A bipod or grenade launcher will not be used.

(2) The trigger pull must be at least 5 pounds.

(3) A standard issue type stock, pistol grip, handguard, and web sling must be used.

(4) The rifle must be modified so that automatic fire is impossible without removing, replacing, or altering parts.

(5) The standard 20 or 30 round box magazine must be attached during the firing of all courses and in all positions.

(6) The gas system must be fully operational.

(7) External alterations to any part of the assembled arm are not allowed. However, an external device may be attached to prevent selector level movement to the auto position.

(8) The front and rear sights must be the standard design for this rifle as issued by the U.S. Armed Forces.

(9) Hooks, buttons, straps, or other similar devices fastened to the shooting coat for the purpose of holding the sling in place are prohibited.

(d) U.S. pistol, caliber .45M1911 or M1911A1. Competitors may use the caliber .45M1911 or M1911A1 as issued by the U.S. Armed Forces or a commercial pistol of the same type and caliber. The requirements for these pistols are listed below.

(1) A standard issue stock of wood or synthetic material, a similar stock of commercial manufacture, or another comparable design that does not interfere with the functional or maintenance features of the pistol must be used. The stock must be functionally identical for right or left hand use. It must not—

(i) Be more than 1½ inches thick between the right and left side extremities.

(ii) Cover the mainspring housing.

(iii) Prevent holstering in the standard service holster.

(2) The trigger pull must be at least 4 pounds.

(3) The pistol will have open sights only. The front sight must be nonadjustable. The rear sight may be adjustable and must have an open "U" or rectangular notch. The distance between sights, measured from the apex of the front sight to the rear face of the rear sight, must not be more than 7¼ inches.

(4) The forestrap of the grip may be checkered or stippled.

(5) The mainspring housing may be either the straight or the arched type, and may be checkered or stippled.

(6) Trigger shoes and trigger stops, internal or external, may be used.

(7) External finishes may be blued, parkerized, or bright. All other external alterations, additions, or changes to the appearance or configuration of the assembled arm are prohibited, except that the ejection part may be lowered to aid in ejection.

(8) The pistol may be modified internally to improve functioning and accuracy. (For example, a special match barrel may be fitted.) However, the modifications may not interfere with the proper functioning or safety devices of the arm as issued by the U.S. Armed Forces. All safety features must operate properly.

**§ 544.53 Rifles and pistols available.**

Under rules announced by the DCM, National Match-grade rifles M14 and M1 and pistols M1911 series will be made available at the National Matches for temporary loan to participants.

**§ 544.54 Checking firearm characteristics.**

The competitor will insure that his or her firearm is safe and meets the requirements of § 544.52. At any time, the XO, NM, may direct the weighing of triggers with official test weights and may check other functions and component parts.

**§ 544.55 Use of the same firearm by more that one competitor.**

More than one competitor may use the same firearm in a match if squadding permits, but special squadding permits, but special squadding for this purpose is not authorized.

**§ 544.56 Disabled firearm.**

Within 30 minutes of the time the appropriate range official declares a firearm disabled, the competitor must repair or replace the firearm and report with it to a range official. A replacement firearm, if authorized, must be of the same type and caliber as the disabled firearm.

**§ 544.57 Ammunition.**

Range personnel will issue Government special match, match-grade, or service-grade service ammunition at the firing line. A single lot will be used if feasible, but more than one lot may be used if curcumstances require. Competitors will fire only this ammunition and none other. Competitors will be disqualified if ammunition issued to them is altered in any way. Competitors will also be disqualified if any other ammunition is found about their person or equipment while they are on the firing line. However, if the match sponsor does not make 5.56mm ammunition available, competitors using the M–16 series rifle or commercial equivalent will use their own safe ammunition.

**§ 544.58 Targets.**

The following targets will be used:

(a) Pistol targets. (1) For firing at 50 yards, use the Standard American 50-yard pistol target with the x, 10, 9, and 8 rings black (NRA B–6 target).

(2) For firing at 25 yards, use the Standard American 25-yard, rapid fire pistol target. Use the same dimensions as § 544.5(a)(1) of this section, but with only the x, 10, and 9, rings black (NRA B–8 target)

(b) Rifle targets (except in the National Trophy Infantry Team Match). (1) For firing at 200 yards or meters, use the standard US Army, short range (200 to 300 yards or meters), competitive rifle

target with the x, 10, and 9 rings black (NRA SR target).

(2) For firing at 300 yards or meters, use the same target and distance as in 544.5(b)(1) of this section, except the aiming black is enlarged to include the 8 ring (NRC SR-3 target).

(3) For firing at 500 yards or meters, use the standard US Army target, midrange (500 yards or meters), competitive rifle target with the x, 10, 9, and 8 rings black (NRA MR target).

(4) For firing at 600 yards or meters, use the standard US Army target, midrange (600 yards or meters), competitive rifle target with the x, 10, 9, 8, and 7 rings black (NRA MR-1 target).

(c) For the National Trophy Infantry Team Match, use the targets described in §544.80(c)(4).

**§ 544.59 Field glasses, and binoculars.**

In the Infantry Match, the team captain and coach will not be permitted to use field glasses or binoculars of greater power or objective lens diameter than 10 x 50. Binoculars will be provided on the firing line for teams requiring them. The team captain and coach may use a telescope behind the assembly line for the purpose of reading the wind before the start of their team relay. These telescopes will not be used for coaching after the targets have appeared for the team and may not be displaced forward of the assembly line.

**Firing**

**§ 544.60 Safety precautions.**

(a) Arms will be loaded only at a firing point and only when directed by a range official for authorizing firing.

(b) Unless competitors are at a firing point and the range official has given the order to load, they must keep—

(1) The magazines must be removed from the firearm.

(2) The slides or bolts locked back.

(3) The safeties of rifles on.

(c) During and until their arms are unloaded, competitors will—

(1) Keep their pistols at the raised (or ready) pistol position or hold them on the bench and pointed downrange at the target.

(2) Keep their rifles pointed downrange at the target.

**§ 544.61 Organization of firing areas.**

The firing areas on each range will be organized into a firing line, a ready line, and an assembly line.

**§ 544.62 Station of competitors.**

Each competitor will remain on or behind the assembly line until the competitior's assigned relay is called to the ready line or firing line. Without the Range Director's permission, only the following people will be allowed forward of the assembly line:

(a) The officials of the matches.

(b) NBPRP members.

(c) Team officials.

(d) Competitors on the ready line and on the firing line.

(e) Scorers.

(f) Others on duty.

**§ 544.63 Target assignments and operations in the rifle matches.**

(a) The Satistical Director will assign targets and relays. Competitors may obtain these assignments at times announced by the Statistical Director. Before the matches start, target assignments will be posted at a convenient location.

(b) Each team will assign two target pullers to work in the pits. Target pullers must be physically able and experienced in handling targets for high power rifles. Failure to provide capable target pullers may disqualify the team involved. Both target pullers will go to the target assigned to their team. Before the firing starts, one puller will be reassigned at random by the chief pit officer.

(c) Firing will not be interrupted for changes of pit personnel. Once firing has started, and if other conditions permit, the match will continue until all firing is completed.

**§ 544.64 Slow target operation in rifle matches.**

In individual matches, if a competitor believes a target is operating slowly he or she must complain to a line official. In team matches, the team captain makes the complaint. Complaints must be made before completing a firing stage and in ample time to enable the line official to check the time used. The line official will check the time used. The line official will check the time used by the competitor and by the target operators and make adjustments as needed. When there is no complaint to a line official by the competitor or team captain, it will be assumed the target was operated satisfactorily.

**§ 554.65 Practice firing.**

During the SAFS, the only firing permitted is that scheduled in the school curriculum. At other times, practice firing may be allowed if the match program states that it is allowed at the range and range personnel are available.

**§ 544.66 Firing procedure and punctuality.**

(a) Matches will be fired in relays. The XO, NM, may decide whether to allow infiltration squadding in slow fire stages of rifle matches.

(b) After a relay is called to the firing line, competitors on that relay will be allowed 3 minutes in which to prepare to fire. Competitors will not be allowed to take positions on the firing line after the 3-minute preparation time expires, and they will lose their right to fire if they arrive after that time. They may regain their right to fire only if they present satisfactory evidence to the XO, NM, that the delay was the fault of the range operating personnel.

(c) In team matches, only the first pair of competitors for a team need to be present at the time the firing is scheduled to commence.

**554.67 Firing positions.**

NRA Rule 5.5 on firing positions will apply. The rules for rifles are as follows:

(a) *Standing.* The sling must be attached to the rifle at both standard attachment points, in the parade position. On the M-14 rifle, the sling may rest along either the side or the bottom of the magazine. The sling may not be used for support, except as provided for in the National Trophy Infantry Team Match rules.

(b) *Kneeling.* Use of a kneeling roll or pad is prohibited.

(c) *Using ground cloths or ground pads.* Ground cloths or ground pads may be used if they do not provide artificial support. They may not be used in the National Trophy Infantry Team Match.

**§ 544.68 Loading and reloading the rifle in rapid fire.**

NRA Rule 9.22 applies in all matches except the National Trophy Infantry Team Match. In this match, team captains will direct loading and reloading.

**§ 544.69 Unauthorized firing.**

No firing is allowed except at authorized targets in prescribed practice or competition and under the supervision of assigned officials. Violation of this rule may disqualify the offender for the rest of the matches.

**§ 544.70 Time limits and extensions.**

(a) Time limits are prescribed in NRA Rules, section 8.

(b) The range official may extend the time in the slow fire stages if delays are caused by—

(1) Target malfunctions.

(2) Slow or improper target operation.

(3) Reasons over which the competitor or team has no control.

**§ 544.71 Sighting shots.**

Sighting shots are not allowed in any National Trophy Matches.

**§ 544.72 Competitors serving as range officials.**

In the match program, the Match Director or the Range Director may

require competitors to score, operate, or mark targets or serve as range officials; in team matches, they may require a team of furnish scorers for teams firing on adjacent targets. The XO, NM, may disqualify from further participation a competitor who is detailed to perform such duties and fails to do so satisfactorily.

## Subpart E—Program for the National Trophy Matches

### § 544.73 The President's Pistol Match.

Table 5–1 gives the course of fire for this match.

### § 544.74 National Trophy Individual Pistol Match.

Competitors will use the National Match Pistol Course as the course of fire. Table 5–2 gives this course of fire.

Other EIC individual pistol matches will schedule this course of fire.

### § 544.75 National Pistol Team Match.

(a) *Team composition.* Four members fire for the team's score.

The team will consist of a team captain, team coach, four firing members, and up to two alternates.

(b) *Course of fire.* Each firing member will use the National Match Pistol Course (table 5–2).

### § 544.76 The President's Rifle Match.

Table 5–3 gives the course of fire for the President's Rifle Match.

### § 544.77 National Trophy Individual Rifle Match.

(a) Course A is the National Match Rifle Course. Only Course A will be scheduled in the National Trophy Matches. Table 5–4 gives this course of fire. Other EIC individual rifle matches will consist of the National Match Rifle Course A except as described in b below.

(b) Course B is restricted to the M16-series rifle or commercial rifle of the same type and caliber (§ 544.51). This course may be scheduled for EIC individual rifle matches other than those in the National Trophy Matches. Table 5–5 gives this course of fire.

### § 544.78 National Trophy Rifle Team Match.

(a) *Team composition.* Six members fire for the team's score. The team will consist of a team captain, a team coach, six firing members, and two alternatives.

(b) *Course of fire.* Course A of the National Match Rifle Course will be used for each firing member. Table 5–4 gives this course of fire.

### § 544.79 The National Trophy Infantry Team Match.

(a) *Team composition.* Six members fire for the team's score. The team will consist of a team captain, team coach, six firing members, and two alternates.

(b) *Course of fire.* Table 5–6 gives the course of fire for this match.

(c) *Conditions.* (1) A sling may be used for support in all positions.

(2) On the 600-yard firing line, 384 rounds of ammunition of one caliber will be issued to each team. This ammunition is the team's total for the match. The team captain will divide the ammunition among firing members and stages and decide the number of rounds to be loaded into clips or magazines.

(3) Each team will use eight adjoining targets. Gaps in the target line will separate one team's targets from another.

(4) For firing at 600 and 500 yards, a standard 600-yard target will be pasted on a standard competitive target frame. The face of the target will be reversed to display a solid white background. The Army "E" silhouette target will be pasted on this background and centered horizontally, with the top of the silhouette 13 inches below the top of the frame. For firing at 300 and 200 yards, the Army "F" silhouette target will be pasted over the face of a standard 200-yard target, with the top of the silhouette located at the top of the 8 ring.

(5) Teams will take firing positions on the 600-yard firing line as directed by the team officials. Only the captain, coach, and firing members will be permitted on the firing line during the match. After teams are in firing position with rifles loaded and locked, they may start firing when the targets appear. The targets will be withdrawn after 50 seconds. Between stages, teams will move forward abreast in a line. Their rifles will be unloaded, magazines removed, bolts open, and muzzles elevated and pointed downrange. The firing procedure at each range will be the same as those at 600 yards. Each relay will complete the match before the next relay is called to the 600-yard firing line.

(6) Scoring. (i) All scores will be recorded on the firing line at the end of each stage. Spotters will indicate hits on the silhouettes only.

(ii) Hits on the silhouettes will count 4 points at 600 yards, 3 points at 500 yards, 2 points at 300 yards, and 1 point at 200 yards. Hits outside the silhouettes will not be scored or marked.

TABLE 5–1.—COURSE OF FIRE—THE PRESIDENT'S PISTOL MATCH

| Stage | Distance (yards) | Type of fire | Firing position | Number of shots | Time limit | Scoring |
|---|---|---|---|---|---|---|
| First | 50 | Slow | Standing | 2 strings of 10 shots each | 10 minutes per string | After each string. |
| Second | 25 | Timed | do | 2 strings of 5 shots each | 20 seconds per string | After 1 or 2 strings as announced by the match director. |
| Third | 25 | Rapid | do | do | 10 seconds per string | After 1 or 2 strings as announced by the match director. |

TABLE 5–2.—COURSE OF FIRE—NATIONAL MATCH PISTOL COURSE

| Stage | Distance (yards) | Type of fire | Firing position | Number of shots | Time limit | Scoring |
|---|---|---|---|---|---|---|
| First | 50 | Slow | Standing | 10 | 10 minutes | After 10 shots. |
| Second | 25 | Timed | do | 2 strings, of 5 shots each | 20 seconds per string | After 1 or 2 strings as announced by the match director. |
| Third | 25 | Rapid | do | do | 10 seconds per string | After 1 or 2 strings as announced by the match director. |

TABLE 5-3.—COURSE OF FIRE—THE PRESIDENT'S RIFLE MATCH

| Stage | Distance (yards) | Type of fire | Firing position | Number of shots | Time shot |
|---|---|---|---|---|---|
| First | 200 | Slow | Standing | 10 | 10 minutes. |
| Second | 300 | Rapid | Prone from standing | 10 | 70 seconds. |
| Third | 600 | Slow | Prone | 10 | 10 minutes. |

TABLE 5-4—COURSE OF FIRE, COURSE A—NATIONAL MATCH RIFLE COURSE

| Stage | Distance (yards) | Type of fire | Firing position | Number of shots | Time limit |
|---|---|---|---|---|---|
| First | 200 | Slow | Standing | 10 | 10 minutes. |
| Second | 200 | Rapid | Sitting or kneeling from standing | 10 | 60 seconds. |
| Third | 300 | ....do | Prone form standing | 10 | 70 seconds. |
| Fourth | 600 | Slow | Prone | 20 | 20 minutes. |

TABLE 5-5—COURSE OF FIRE, COURSE B—COMPETITIVE RIFLE COURSE, M-16 RIFLE ONLY

| Stage | Distance (yards or meters) | Type of fire | Firing position | Number of shots | Time limit |
|---|---|---|---|---|---|
| First | 200 | Rapid Fire | Rapid fire—sitting from standing | Radip fire, 10 shots | Rapid fire—50 seconds. |
| Second | 200 | Rapid | Kneeling from standing | 10 | 50 seconds. |
| Third | 200 | Slow | Standing | 10 | 10 minutes. |
| Fourth | 300 | ....do | Prone | 10 | Do. |
| Fifth | 300 | Rapid | Prone from standing | 10 | 50 seconds. |

(iii) A bonus for distribution will be computed. At each range, count the number of silhouette targets that contains six or more hits each. Square that number, then add the square to the total hit score for that range.

(iv) Ties will be broken by the highest team score at the longest range. If the tie cannot be broken by that score, use the highest team score at the next longest range, and so on.

(7) No alibis will be allowed for misfires, disabled pieces, or other failures of range or team equipment or personnel.

(8) Telescopes and field glasses may be used as follows:

(i) Before the start of the team's relay, the team captain and coach may use a telescope behind the assembly line. These telescopes will neither be moved forward of the 600-yard assembly line nor be used for coaching after the team's preparation period starts.

(ii) After the team's preparation starts, the captain and coach may use field glasses. However, the power and objective lens diameter of the glasses must not be more than 10 x 50mm. Field glasses will be provided on the firing line for teams requiring them.

(9) An assistant range officer will be assigned for each team to enforce safety regulations and supervise the scoring.

## Subpart F—Awards

### § 544.80 General.

(a) *All EIC matches.* The providing of awards that are prescribed and earned always depends on whether funds are available.

(b) *National Trophy Matches.* (1) Awards for the National Trophy Matches will normally be given at the time and place of the National Matches.

(i) Permanent trophies will remain in the DCM's custody. They will be engraved with the names of the winners.

(ii) Winners will be awarded plaques or miniatures of the trophies. These plaques and miniatures will be engraved at the DCM's expense and according to the DCM's instructions.

(iii) In certain matches, categories, or award groups, a secretary of the Army Trophy Firearm award will be given to the highest scoring competitor who has never received this award before. No competitor may receive more than one of these awards for a match. This award is subject to restrictions of law.

(iv) Further match awards may be authorized from time to time. Such awards and the conditions for receiving them will be published in the Match Program or in the Match Director's Bulletins.

(2) Correspondence concerning awards for the National Trophy Matches will be addressed to the Director of Civilian Marksmanship, Office of the Secretary of the Army, HQDA (SFDM), Washington, DC 20314-0100.

### § 544.81 Participation requirements for cetain National Trophy Match awards.

In certain National Trophy Matches, awards are given for a named category or special awards group (such as Navy, Women, Infantry, Junior, or Police). These awards will be given only if the required number of competitors from the category or award group fire in the match. The required number are listed below.

(a) *Individual matches.* (1) Winner: At least 5 competitors.

(2) Second place: At least 8 competitors.

(3) Third place: At least 12 competitors.

(b) *Team matches.* (1) Winner: At least 3 teams.

(2) Second place: At least 5 teams.

(3) Third place: At least 7 teams.

### § 544.82 Awards for the President's Pistol Match.

(a) The match winner will be awarded the President's Trophy Plaque, a congratulatory letter from the President of the United States, and a President's Hundred Metalic Brassard.

(b) The match winner may also be awarded a Secretary of the Army Trophy Firearm if the requirements in § 544.80(b)(1)(ii) are met.

(c) The highest scoring 15 percent of all competitors who fire in the match will be designed "The President's Hundred." They will be awarded a "President's Hundred" metallic brassard. Not more than 100 of these awards will be given.

### § 544.83 Awards for the National Trophy Individual Pistol Match.

(a) The match winner will be awarded the Custer Trophy Plaque and a gold medal.

(b) The highest scoring Reserve competitor will award the U.S. Army Reserve Memorial Trophy Plaque.

(c) The highest scoring National Guard competitor will be awarded the National Guard Association Trophy Plaque.

(d) The highest scoring Service Academy and ROTC competitor will be awarded the Intercollegiate Trophy Plaque.

(e) The highest scoring Police competitor will be awarded the Ancient Archer Trophy Plaque.

(f) The highest scoring Civilian competitor will be awarded the Silver Bowl Trophy Plaque.

(g) The highest scoring Junior competitor and Women competitor will be awarded a trophy plaque. These plaques will be named at a later date.

(h) Per § 544.80(b)(1)(iii), a Secretary of the Army Trophy Firearm award may be awarded to the highest scoring competitor in—

(1) The match (match winner).

(2) Each of the Regular Service, Reserve, National Guard, Service Academy and ROTC, Police, Civilian, Junior, and Women competitor categories (if not the match winner).

**§ 544.84 Awards for the National Trophy Pistol Team Match.**

Listed below are the trophy awards following the type of category. Also listed are what second and third place teams and designated competitors will receive.

(a) *Winning team awards—The Gold Cup Trophy.* (1) The winning team will be awarded Gold Cup Trophy Plaques and gold metals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(b) *Reserve Components awards—The U.S. Coast Guard Memorial Trophy.* (1) The highest scoring Reserve Component team will be awarded U.S. Coast Guard Memorial Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(c) Service Academy and ROTC awards-The Alden Partridge Trophy. (1) The highest scoring Service Academy and ROTC team will be awarded Alden Partridge Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(d) Police awards—The American Indian Trophy. (1) The highest scoring Police team will be awarded American Indian Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(e) Civilian awards—The Oglethorpe Trophy.

(1) The highest scoring Civilian team will be awarded Oglethorpe Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(f) Junior awards—(trophy to be named). (1) The highest scoring Junior team will be awarded trophy plaques (to be named at a later date) and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place will be awarded bronze medals.

(g) Awards for highest scoring competitors. (1) The highest scoring competitor will be awarded the Military Police Corps Trophy Plaque.

(2) The highest scoring Army competitor (Regular, Reserve, or Army National Guard) will be awarded the General Mellon Trophy Plaque.

(3) The highest scoring Air Force competitor (Regular, Reserve or Air National Guard) will be awarded the General Carl Spaatz Trophy Plaque.

(h) *Awards for the National Civilian Pistol Team.* The National Civilian Pistol Team will be awarded Elihu Root gold medals. This team will consist of the four highest scoring individual Civilian competitors in this match and the coach and captain of the highest scoring Civilian team.

**§544.85 Additional National Trophy Pistol Match awards.**

The competitors with the highest aggregate score in the National Trophy Individual Pistol Match and the National Trophy Pistol Team Match will receive the following awards:

(a) The Regular Army competitor be awarded the FORSCOM Pistol Trophy Plaque.

(b) The Navy competitor (Regular or Reserve) will be awarded the Fleet Admiral Nimitz Trophy.

(c) The Marine competitor (Regular or Reserve) will be awarded the McMillan Trophy Plaque.

(d) The Civilian competitor will be awarded the Anheuser-Busch Trophy Miniature.

**§ 544.86 Awards for the President's Rifle Match.**

(a) The match winner will be awarded a President's Trophy Plaque, a congratulatory letter from the President of the United States, and a President's Hundred Metallic Brassard.

(b) The match winner may also be awarded a Secretary of the Army Trophy Firearm, subject to the conditions in § 544.81(b)(1)(iii).

(c) The highest scoring 15 percent of all competitors who fire in the match will be awarded the "President's Hundred" metallic brassard. This group will be designated "The President's Hundred." Not more than 100 of these awards will be given.

**§544.87 Awards for the National Trophy Individual Rifle Match.**

The following awards are for Course A.

(a) The match winner will be awarded the Daniel Boone Trophy Plaque and a gold medal.

(b) The highest scoring Reserve competitor will be awarded the Citizen Soldier Trophy Plaque.

(c) The highest scoring National Guard competitor will be awarded the National Guard Association Trophy Plaque.

(d) The highest scoring Service Academy and ROTC competitor will be awarded the Hearst Rifle Trophy Plaque.

(e) The highest scoring Police competitor will be awarded a trophy plaque to be named later.

(f) The highest scoring Civilian competitor will be awarded the Nathan Hale Trophy Plaque.

(g) The highest scoring Junior competitor will be awarded the Golden Eagle Trophy Plaque.

(h) The highest scoring Women competitor will be awarded a trophy plaque to be named later.

(i) The highest scoring Army competitor (Regular, Reserve, or National Guard) will be awarded the Association of the United States Army Trophy Plaque.

(j) The highest scoring Marine competitor (Regular or Reserve) will be awarded the Coast Artillery Trophy Plaque.

(k) The highest scoring Air Force competitor (Regular, Reserve, or National Guard) will be awarded the Lieutenant Paul J. Roberts, Jr. Memorial Trophy Plaque.

(l) The highest scoring Infantry competitor (Regular Army, Army Reserve, or Army National Guard) will be awarded the 25th Infantry Division Trophy Plaque.

(m) Per a Secretary of § 544.80(b)(iii) the Army Trophy Firearm may be awarded to—

(1) The match winner.

(2) The highest scoring competitor in each of the Regular Service, Reserve National Guard, Service Academy and ROTC, Police, Civilian, Junior, and woman categories.

**§ 544.88 Awards for the National Trophy Rifle Team Match.**

Listed below are the trophy awards following the type of category. Also listed are what second and third place teams and designated competitors will receive.

(a) Awards for the winning team—The National Trophy. (1) The winning team will be awarded National Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(b) *Reserve Component awards-The Hilton Trophy.* (1) The highest scoring Reserve Component team will be awarded Hilton Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(c) *Service Academy and ROTC awards.* (1) The highest scoring Service Academy and ROTC team will be awarded NBPRP Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(d) *Civilian awards—The Soldier of Marathon Trophy.* (1) The highest scoring Civilian team will be awarded Solidier of Marathon Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(e) *Junior awards—The Minuteman Trophy.* (1) The highest scoring Junior team will be awarded Minuteman Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(f) *Awards for highest scoring individual competitors.* (1) The highest scoring competitor will be awarded the Pershing Trophy Plaque.

(2) The highest scoring Army competitor (Regular, Reserve, or National Guard) will be awarded the Rattlesnake Trophy Plaque.

(3) The highest scoring Air Force competitor (Regular, Reserve, or National Guard) will be awarded the General Thomas D. White Trophy Plaque.

(g) *Awards for the National Civilian Rifle Team.* The National Civilian Rifle Team will be awarded Elihu Root gold medals. This team will consist of the six highest scoring individual Civilian competitors and the coach and captain of the highest scoring Civilian team.

**§ 544.89 Additional National Trophy Rifle Match awards.**

The competitors with the highest aggregate score in the National Trophy Individual Rifle Match and the National Trophy Rifle Team Match will receive the following awards:

(a) The Regular Army competitor will be awarded the FORSCOM Rifle Trophy Plaque.

(b) The Navy competitor (Regular or Reserve) will be awarded the Admiral Arleigh A. Burke Trophy Plaque.

(c) The Marine competitor (Regular or Reserve) will be awarded the General Shepherd Trophy Plaque.

(d) The Civilian competitor will be awarded the Pietroforte Trophy Plaque.

**§ 544.90 Awards for the National Trophy Infantry Team Match.**

Listed below are the trophy awards following the type of category. Also listed are what second and third place teams and designated competitors will receive.

(a) *Winning team awards—The Infantry Trophy.* (1) The winning team will be awarded Infantry Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(b) *Reserve Component/team awards—The Celtic Chieftain Trophy.* (1) The highest scoring Reserve Component team will be awarded Celtic Chieftain Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(c) *Civilian team awards—The Leatherneck Trophy.* (1) The highest scoring Civilian team will be awarded Leatherneck Trophy Plaques and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

(d) *Junior team awards—Junior Team Trophy.* (1) The highest scoring Junior team will be awarded trophy plaques (to be named at a later date) and gold medals.

(2) The second place team will be awarded silver medals.

(3) The third place team will be awarded bronze medals.

**§ 544.91 Special medals in National Trophy Individual Pistol and Rifle Matches.**

(a) The highest 10 percent of Civilians who fire in the National Trophy Individual Pistol or National Trophy Individual Rifle Match, but who do not receive match awards or the place medals prescribed in 544.95 below, will be given bronze medals. The medal for the pistol match will depict the Silver Bowl Trophy and the medal for the rifle match will depict the Nathan Hale Trophy.

(b) The highest 10 percent of Juniors who fire in the National Trophy Individual Pistol or National Trophy Individual Rifle Match, but who do not receive match awards or the place medals prescribed in § 544.95 below, will be given bronze medals. The medal for the pistol match will depict the Junior Pistol Trophy and the medal for rifle match will depict the Golden Eagle Trophy.

(c) The highest 10 percent of women who fire in the National Trophy Individual Pistol Match or the National Trophy Individual Rifle Match, but who do not receive match awards or the place medals prescribed in § 544.95, will be given bronze medals. The medal for the pistol match will depict the Women's Pistol Trophy and the medal for the rifle will depict the Women's Rifle Trophy.

(d) The highest 10 percent of Police competitors who fire in the National Trophy Individual Pistol Match or the National Trophy Individual Rifle Match, but who do not receive match awards or the place medals prescribed in § 544.95, will be given bronze medals. The medal for the pistol match will depict the Ancient Archer Trophy and the medal for the rifle will depict the Police Rifle Trophy.

**§ 544.92 Place medals in National Trophy team matches.**

Place medals will be given to the captain, coach, and firing members of the highest 15 percent of all teams firing in the match. Medals will be given as follows:

(a) The winning team will be awarded gold medals.

(b) The second place team will be awarded silver medals.

(c) The third place team will be awarded bronze medals.

(d) The remainder of the 15 percent will be awarded bronze medals.

**§ 544.93 Place medals in Individual EIC matches.**

(a) For the EIC matches listed in § 544.94, place medals will be awarded to the highest scoring 10 percent of all

non-Distinguished competitors competing in the match. These medals will be awarded as follows:

(1) The highest one-sixth of the 10 percent will be gold.

(2) The next highest one-third of the 10 percent will be silver.

(3) The remainder of the 10 percent will be bronze.

(b) Competitors who have attained or are qualified for Distinguished designation with the arm concerned will be ranked among the non-Distinguished competitors according to score. Each will be awarded a medal of the same type (gold, silver or bronze) as the non-Distinguished competitor next below him or her.

(1) For rifle, Daniel Boone Trophy medals, will be awarded.

(2) For pistol, General Custer Trophy medals, will be awarded.

**§ 544.94 Distinguished designation and badge awards.**

(a) Competitions in which credits toward Distinguished designation may be earned and for which EIC badges may be awarded are—

(1) The National Trophy Individual Pistol and National Trophy Individual Rifle Matches.

(2) Certain Service matches not open to civilians.

(3) NRA Regional and State Championships.

(b) For credits earned in an EIC match to be recognized, the match must—

(1) Conform to all parts of this regulation that apply.

(2) Include at least 10 non-Distinguished competitors eligible according to this regulation.

(3) Be completed.

(c) The following rules apply to Civilian competitors competing for the Distinguished Designation and Badge award:

(1) In any calendar year, these competitors may compete in not more than four EIC matches for pistol and not more than four for rifle. The matches they may enter are listed below.

(i) The National Trophy Individual Match.

(ii) NRA Regional or State championships. Civilian competitors may not compete in more than three NRA Regional or State championship EIC matches a year.

(iii) A Service-sponsored match. If entry in such a match is possible, the match will constitute as one of the three matches authorized in § 544.94(b) of this section.

(2) The DCM will award credit points toward Distinguished designation to competitors who earn place medals according to § 544.94(b). Points will be awarded as listed below.

(i) For any place medal in a National Trophy Individual Match, 10 points will be awarded. These points will be awarded to civilians only.

(ii) For place medals in other ECI matches listed in § 544.94(a)(1), 10 points will be awarded for gold medals, 8 points will be awarded for silver medals, and 6 points will be awarded for bronze medals.

(3) The DCM will award the Distinguished Badge when a competitor has earned 30 or more credit points with the arm concerned.

(d) Competitors in the Regular Service, Reserve, National Guard, and Service Academy categories can earn credits toward the Distinguished designation and will be awarded the appropriate badges according to the regulations of their Service.

**§ 544.95 EIC badges.**

(a) The DCM will award a bronze EIC badge to Civilian competitors when they first earn credit points toward the Distinguished designation. They must earn their points according to § 544.94. The DCM will award a silver EIC badge to these competitors when they have earned a total of 20 or more credit points.

(b) Competitors in the Regular Service, Reserve, National Guard, and Service Academy categories will be awarded EIC badges according to the regulations of their Service.

**§ 544.96 Marksmanship qualification awards.**

(a) The DCM will award the Basic Marksmanship Qualification Badge to ROTC, Police, Civilian, Junior and Women competitors who fire qualifying scores in the National Trophy Individual Pistol or Rifle Matches. The badge will show qualification as Expert, Sharpshooter, or Marksman. The DCM may also award, separately or along with the badge, a bar that will show whether a rifle or pistol was used. Qualifying scores for these awards are listed below:

(1) Pistol awards—possible 300 points.
(i) Pistol Expert—270 points.
(ii) Pistol Sharpshooter—240 points.
(iii) Pistol Marksman—210 points.
(2) Rifle awards—possible 500 points.
(i) Expert Rifleman—450 points.
(ii) Rifle Sharpshooter—400 points.
(iii) Rifle Marksman—350 points.

(b) The DCM will present these awards after the close of the matches.

**§ 544.97 Scores allowed for club qualification firing.**

To meet the requirements in AR 920-20 on clubs' yearly qualification firing, clubs enrolled by the DCM may count their members' scores from the National Matches and/or EIC matches (§ 544.95).

## Appendix A—Related Publications

Approved courses of fire for civilian marksmanship training for clubs and schools enrolled with the DCM (These courses are available from HQDA(SADM), WASH DC 20314.)

AR 5-9 (Intraservice Support Installation Area Coordination)
AR 140-125 (Marksmanship Training and Competitive Program)
AR 145-1 (Senior ROTC Program: Organization, Administration, and Training)
AR 145-2 (Junior Program and National Defense Cadet Corps: Organization, Administration, Operations, and Support)
AR 340-21 (The Army Privacy Program)
AR 350-6 (Army-Wide Small Arms Competitive Marksmanship)
AR 600-20 (Army Command Policy and Procedures)
AR 600-23 (Nondiscrimination in Federally Assisted Programs)
AR 622-10 (Competition in Small Arms)
AR 672-5-1 (Military Awards)
AR 700-131 (Loan of Army Materiel)
AR 725-1 (Special Authorization and Procedures for Issues, Sales and Loans)
AR 735-5 (Basic Policy and Procedures for Policy Accounting)
AR 735-11 (Accounting for Lost, Damaged and Destroyed Property)
AR 920-15 (National Board for the Promotion of Rifle Practice and Office of Director of Civilian Marksmanship)
AR 920-20 (Promotion of Practice with Rifle Arms)
AR 920-25 (Rifles M14M and M14NM, for Civilian Marksmanship Use)
AR 920-35 (National Match Fund) DODD 1025.1 (DOD Civilian Rifle and Pistol Marksmanship Training Program) (This DODD can be obtained from HQDA (SADM), WASH DC 20314-0100)

NEA Official Rule Books for Pistol and Highpower Rifle (These books can be obtained from the National Rifle Association, 1600 Rhode Island Avenue, NW., Washington, DC 20036).

## Appendix B—Trophies of the National Board for the Promotion of Rifle Practice

*B-1. The President's Pistol Trophy*

This trophy was purchased by the NBPRP in 1981. It consists of a disc of white New England marble on a hardwood base. The Presidential Seal is carved, gilded, and mounted on the disc. This trophy is awarded to the winner of the President's Pistol Match.

*B-2. The General Custer Trophy*

The General Custer Trophy was purchased by the NBPRP in 1926. It is a bronze statuette of General George Armstrong Custer (1828-1876) firing a pistol. The trophy is awarded to the winner of the National Trophy Individual Pistol Match.

*B–3. The US Army Reserve Memorial Trophy*

The US Army Reserve Memorial Trophy was donated to the NBPRP by the US Army Reserve in 1969. The trophy depicts the citizen soldier leaving his civilian occupation to take up arms in defense of his country, and is in memory of those who have given their lives in this duty. It is awarded to the highest scoring Reserve competitor in the National Trophy Individual Pistol Match.

*B–4. The National Guard Association Trophy (Pistol)*

The National Guard Association Trophy (Pistol) was presented to the NBPRP in 1983, replacing the original trophy that was established in 1979. The trophy depicts a helmeted Guardsman in bronze, mounted on a two-tiered walnut base. This trophy is awarded to the highest scoring National Guard competitor in the National Trophy Individual Pistol Match.

*B–5. The Intercollegiate Trophy*

The Intercollegiate Trophy was purchased by the NBPRP in 1958. The trophy is a sterling silver urn, depicting a battle scene in what is believed to be the war between the Romans and Celts in A.D. 43–44. It is awarded to the highest scoring Service Academy or ROTC competitor in the National Trophy Individual Pistol Match.

*B–6. The Ancient Archer Trophy*

The Ancient Archer Trophy was purchased by the NBPRP in 1926. The trophy is made of bronze and depicts an ancient archer stringing his bow. It is awarded to the highest scoring Police competitor in the National Trophy Individual Pistol Match.

*B–7. The Silver Bowl Trophy*

The Silver Bowl Trophy was designed and purchased by the NRA in 1956 and presented to the NBPRP for award that year. It is a large, sterling silver bowl, embossed on the rim and pedestal with floral leaf design. It is awarded to the highest scoring Civilian competitor in the National Trophy Individual Pistol Match.

*B–8. The Gold Cup Trophy*

The Gold Cup Trophy was presented to General John J. Pershing by the Minister of War of the Republic of China as the award for first place in the pistol shooting match among the Allies at Le Mans, France in 1919. It was won by the American Expeditionary Force (AEF) Pistol Team. The team then presented it for annual competition in the National Trophy Individual Pistol Match. The trophy is a helmet-shaped gold cup, engraved and mounted on an ebony base. The Gold Cup Trophy is awarded to the winning team in the National Trophy Individual Pistol Match.

*B–9. The US Coast Guard Memorial Trophy*

The U.S. Coast Guard Memorial Trophy was presented to the NBPRP in 1957 by the Coast Guard. This trophy commemorates Coast Guard personnel who lost their lives while in that Service. It is a replica of the Coast Guard Memorial located in Arlington Cemetery, with statuettes of Coast Guard personnel holding service pistols on either side of the central pyramid. The central pyramid is cast in bronze and heavily plated in silver with an oxidized finish. It is awarded to the highest scoring Reserve Component team in the National Trophy Pistol Team Match.

*B–10. The Alden Partridge Trophy*

The Alden Partridge Trophy was presented to the NBPRP in 1971 by the president of Norwich University, Northfield, Vermont. The trophy is a bronze bust of General Alden Partridge, founder and first president of Norwich University. This university was the first institution of higher learning to include military training as a part of its curriculum and is credited as the founding school of what is now known as the ROTC program. This torphy is awarded to the highest scoring Service Academy or ROTC team in the National Trophy Pistol Team Match.

*B–11. The American Indian Trophy*

The trophy was donated to the NBPRP in 1962 by the YMCA of Greenwich, Connecticut. It is a bronze of Sinte Maze, "Iron Tail," an Oglala Sioux Indian. It is awarded to the highest scoring Police team in the National Pistol Team Match.

*B–12 The Oglethorpe Trophy*

The Oglethorpe Trophy was presented to the NBPRP in 1962 by the River Bend Rifle and Gun Club of Atlanta. The trophy is a sterling silver bowl mounted on a walnut base and was named in honor of the founder and first Governor of Georgia, James Oglethorpe. The trophy is awarded to the highest scoring Civilian team in the National Torphy Pistol Team Match.

*B–13. The Military Police Corps Pistol Trophy*

The Military Police Corps Trophy was presented to the NBPRP in 1956 through private subscription among the officers and enlisted members of the Military Police Corps. This trophy is a specially designed bronze relief depicting the worldwide mission of the Military Police Corps. Crossed pistols are mounted at the apex of the trophy and are exact duplicates of the original pistols used in the design of the Corps insignia. The trophy is awarded to the highest scoring competitor in the National Trophy Pistol Team Match.

*B–14. The General Mellon Trophy*

The General Mellon Trophy was presented to the NBPRP in 1858 by General Richard K. Mellon, Deputy Adjutant General, Commonwealth of Pennsylvania. The Mellon Trophy is a miniature of a giant Kodiak bear in an upright and alert pose. This trophy is awarded to the highest scoring Army Competitor (Regular or Reserve) in the National Trophy Pistol Team Match.

*B–15. The General Carl Spaatz Trophy*

This trophy was presented to the NBPRP in 1961 by the US Air Force in honor of General Carl Spaatz, Chief of Staff of the Air Force from 1947 to 1948. It is a large silver globe mounted on an ebony base and surrounded by four silver eagles. This trophy is awarded to the highest scoring Air Force competitor (Regular, Reserve, or Air National Guard) in the National Trophy Pistol Team Match.

*B–16. The US Army Forces Command Pistol Trophy*

The US Army Forces Command Pistol Trophy was presented to the NBPRP by the Commanding General, US Army Forces Command. The mounted brace of pistols are circa 1900 Colt Army Special caliber. 38 revolvers. The trophy was designed and constructed by artisans of Rock Island Arsenal and is awarded to the Regular Army competitor making the highest aggregate score in the National Individual Pistol Match and National Trophy Pistol Team Match.

*B–17. The Fleet Admiral Nimitz Trophy*

The Fleet Admiral mimitz Trophy was presented to the NBPRP in 1978 by the US Navy through private subscription among the officers and enlisted members of the Navy and Naval Reserve. The trophy is the pistol presented to Fleet Admiral Chester W. Nimitz in 1921 by his classmates at the US Naval Academy. It is awarded to the Navy competitor (Regular or Reserve) making the highest aggregate score in the National Trophy Individual Pistol Match and National Trophy Pistol Team Match.

*B–18. The McMillan Trophy*

The McMillan Trophy was presented by the US Marine Corps to the NBPRP in 1978 for award in the Service pistol competitions sponsored by the NBPRP. The trophy honors Lieutenant Colonel William W. McMillan, an outstanding Marine Corps shooter for over 20 years. It is awarded to the Marine competitor (Regular or Reserve) making the highest aggregate score in the National Trophy Individual Pistol Match and National Trophy Pistol Team Match.

*B–19. The Anheuser-Busch Trophy*

This trophy is a sterling silver bowl, emblazoned with the Anheuser-Busch eagle and mounted on a hardwood base. It is awarded to the Civilian competitor making the highest aggregate score in the National Trophy Individual Pistol Match and the National Trophy Pistol Team Match.

*B–20. The President's Rifle Trophy*

This trophy was purchased by the NBPRP in 1977. It consists of a disc of black New England slate mounted on a hardwood base. On the disc, the Presidential Seal is carved and gilded. The President's Trophy is awarded to the winner of the President's Rifle Match.

*B–21. The Daniel Boone Trophy*

The Daniel Boone Trophy was purchased by the NBPRP in 1925. The trophy is a bronze statue of the marksman Daniel Boone, American pioneer in Kentucky and Missouri (1734–1820), with his rifle. The trophy is awarded to the winner of the National Trophy Individual Rifle Match.

*B–22. The Citizen Soldier Trophy*

The Citizen Soldier Trophy was presented to the NBPRP in 1964 by the Reserve Officers' Association of the United States. The trophy is flanked by miniature replicas of the Liberty Bell. Affixed to the front of the trophy, encompassing a large Reserve Officers' Association seal, are the five insignia of the

Armed Services. The trophy is awarded to the highest scoring Reserve competitor in the National Trophy Individual Rifle Match.

*B-23. The Hearst Rifle Trophy*

The present Hearst Rifle Trophy was donated by Willam Randolph Hearst to The National Matches in 1940. The Hearst Rifle Trophy is a 17 century Spanish flintlock carbine in blunderbuss style, inlaid with ivory and mother of pearl and having a chased lock. This trophy is awarded to the highest scoring Service Academy or ROTC competitor in the National Trophy Individual Rifle Match.

*B-24. The Nathan Hale Trophy*

The Nathan Hale Trophy was presented to the NBPRP by the NRA in 1956. It is a bronze figure created in 1890, of the Revolutionary War hero, Caption Nathan Hale. It is awarded to the highest scoring Civilian in the National Trophy Individual Rifle Match.

*B-25. The Golder Eagle Trophy*

The Golder Eagle Trophy was purchased by the NBPRP in 1963. The trophy is a golden eagle, ascending, with wings elevated and displayed. The eagle is mounted on a walnut base. The trophy is awarded to the highest scoring Junior competitor in the National Trophy Individual Rifle Match.

*B-26. The Association of the United States Army Trophy*

The Association of the US Army Trophy was presented to the NBPRP in 1962 by the Association of the United States Army. The trophy is a 16-inch bronze statuette of a US Army soldier mounted on a wooden base. The trophy is awarded to the highest scoring Army competitor (Regular, Reserve, or National Guard) in the National Trophy Individual Rifle Match.

*B-27. The Coast Artillery Trophy*

The Coast Artillery Trophy was presented to the NBPRP by the Commandant, United States Marine Corps, in 1961. The trophy is a sterling silver cup with figures of Marines in standing and kneeling positions firing a rifle. In 1923, officers and enlisted members of the Coast Artillery Corps presented the trophy to the Marine Corps in appreciation of the Marine Corps Team training the Coast Artillery Team for the National Matches. (This training was from 1910 to 1922.) This trophy is awarded to the highest scoring Marine competitor (Regular or Reserve) in the National Trophy Individual Rifle Match.

*B-28. The Lieutenant Paul J. Roberts, Jr., Memorial Trophy*

The Lieutenant Paul J. Roberts, Jr., Memorial Trophy was presented to the NBPRP in 1958. It is a sterling silver globe, designated by the US Air Forces as a memorial to Lieutenant Paul J. Roberts, Jr., a fighter pilot who was killed during combat in World War II in Germany. The trophy was presented to the NBPRP by his father. It is awarded to the highest scoring Air Force competitor (Regular, Reserve, or National Guard) in the National Trophy Individual Rifle Match.

*B-29. The 25th Infantry Division Trophy*

The 25th Infantry Division Trophy was presented to the NBPRP in 1955 by the 25th Infantry Division Association. It illustrates the World War II area in which the division saw combat and lists the campaigns in which the division participated. This trophy is awarded to the highest scoring Infantry competitor (Regular Army, Army Reserve, or Army National Guard) in the National Trophy Individual Rifle Match.

*B-30. The National Trophy*

The National Trophy was provided by Congress in 1903 in the law that established the National Matches. Commonly referred to as the "Dogs of War Trophy," it is a bronze plaque depicting a warrior of ancient times with four dogs of war on a leash. The trophy is awarded to the winning team in the National Trophy Rifle Team Match.

*B-31. The Hilton Trophy*

The Hilton Trophy was presented to the NRA by the Honorable Henry Hilton of New York in 1878, and the NRA presented the trophy to the NBPRP in 1903. The silver-plated bronze plaque depicts an Indian buffalo hunt. Also on the plaque are figures of eagles, oak boughs, and war trophies. It is awarded to the highest scoring Reserve Component team in the National Trophy Rifle Team Match.

*B-32. The Soldier of Marathon Trophy*

The Soldier of Marathon Trophy is the oldest NBPRP trophy. It has been in shooting competitions since 1875. The NRA presented the trophy to the US Government for competition in the National Trophy Rifle Team Match in 1903. The trophy is a bronze figure of the runner. Pheidippides who, though exhausted and fallen to a reclining position, still holds high the torch he is carrying to announce the Greek victory at Marathon. The trophy is now awarded to the highest scoring Civilian team in the National Trophy Rifle Team Match.

*B-33. The Minuteman Trophy*

The Minuteman Trophy was placed in competition in 1925. The trophy is a bronze statuette of the "Minuteman of Concord." (The original life-sized monument stands in Concord, Massachusetts.) The trophy is awarded to the highest scoring Junior team in the National Trophy Rifle Team Match.

*B-34. The Pershing Trophy*

The Peshing Trophy was presented by General John J. Pershing (1860–1948), Commander of the AEF of World War I, for team competition at the Inter-allied Games in Paris in 1919. Won by the AEF, it was brought to the United States and placed in the custody of the NBPRP with General Pershing's concurrence. The trophy is a bronze figure of a World War I soldier firing the service pistol. It was awarded to the highest scoring individual competitor in the National Trophy Rifle Team Match.

*B-35. The Rattlesnake Trophy*

The Rattlesnake Trophy was purchased by the NBPRP in 1938. This statuette depicts a cowboy and his horse at the moment a rattlesnake strikes at the horse's front feet. It is awarded to the highest scoring Army competitor (Regular, Reserve, or National Guard) in the National Trophy Rifle Team Match.

*B-36. The General Thomas D. White Trophy*

The General Thomas D. White Trophy was presented to the NBPRP in 1960 by the US Air Force in honor of General Thomas D. White, Chief of Staff of the Air Force from 1957 to 1961. The trophy is a large silver bowl mounted on an ebony base. It is awarded to the highest scoring Air Force competitor (Regular, Reserve, or National Guard) in the National Trophy Rifle Team Match.

*B-37. The U.S. Army Forces Command Rifle Trophy*

The US Army Forces Command Rifle Trophy was presented to the NBPRP by the Commanding General, US Army Forces Command. The mounted rifles are circa 1900 Winchester low wall muskets, caliber .22 short, with consecutive serial numbers, the highest of which was the last musket chambered for the .22 short cartridge. The trophy was designed and constructed by artisans of Rock Island for award to the Regular Army competitor making the highest aggregate score in the National Trophy Individual Rifle Team Match and National Trophy Rifle Team Match.

*B-38. The Admiral Arleigh A. Burke Trophy*

The Admiral Arleigh A. Burke Trophy was presented to the NBPRP by the US Navy through private subscription among the officers and enlisted members of the Navy and Navy Reserve. The trophy is the steel helmet worn by Admiral Burke through the entire Atlantic Campaign of World War II. The trophy is awarded to the Navy competitor (Regular or Reserve) making the highest aggregate score in the National Trophy Individual Rifle Match and the National Trophy Rifle Team Match.

*B-39. The General Shepherd Trophy*

The General Shepherd Trophy was presented to the NBPRP in 1956 by General Lemuel C. Shepherd, Jr., Commandant of the Marine Corps from 1952 to 1956. The trophy is a bronze replica of the Marine Corps War Memorial depicting the flag-raising on Mount Suribachi during the battle of Iwo Jima in World War II. This trophy is awarded to the Marine competitor (Regular or Reserve) making the highest aggregate score in the National Trophy Individual Rifle Match and the National Trophy Rifle Team Match.

*B-40. The Pietroforte Trophy*

The Pietroforte Trophy was donated to the NBPRP by private subscription among members of the US Marine Corps Distinguished Shooters' Association. This trophy honors Warrant Officer Michael Pietroforte, who distinguished himself as one of the finest marksmen in Marine Corps history during his 30 years of service. It is awarded to the Civilian competitor making the highest aggregate score in the National Trophy Individual Rifle Match and the National Trophy Rifle Team Match.

*B–41. The Infantry Trophy*

The Infantry Trophy was presented to the NRA in 1922 by the US Army Infantry through private subscription among its members (officer and enlisted and Regular, Reserve, and National Guard). The NRA placed the trophy in the custody of the NBPRP in 1936. This trophy depicts the combat Infantryman in action and is awarded to the winning team in the National Trophy Infantry Team Match.

*B–42. The Celtic Chieftain Trophy*

The Celtic Chieftain Trophy was purchased by the NBPRP in 1958. The statute represents a bronze figure of Caractacus, British chieftain of the tribe of Cateveillauni, who led the native resistance against the Roman, Aulus Plautus (A.D. 43–47). This trophy is awarded to the highest scoring Reserve Component team in the National Trophy Infantry Team Match.

*B–43. The Leatherneck Trophy*

In 1957, the Marine Corps presented this trophy to the NBPRP in the name of the officers and enlisted members of the Marine Corps. The Leatherneck Trophy is a replica of the life-size "Iron Mike" statue that has stood at the Quantico Marine Corps Base, Virginia, since 1921. It is awarded to the highest scoring Civilian team in the National Trophy Infantry Team Match.

*B–44. The Women's Rifle Trophy*

This trophy was authorized by the NBPRP in 1983 and first presented in 1984. It consists of a pair of Winchester Low Wall, single shot, caliber .22 muskets mounted on a polished hardwood base. This trophy is awarded to the highest scoring Woman competitor in the National Trophy Individual Rifle Match.

*B–45. The Women's Pistol Trophy*

This trophy was authorized by the NBPRP in 1983 and first presented in 1984. It consists of two Colt Army Special caliber .38 revolvers mounted on a polished hardwood base. This trophy is awarded to the highest scoring Woman competitor in the National Trophy Individual Pistol Match.

*B–46. The Police Rifle Trophy*

This trophy was authorized by the NBPRP in 1983 and first presented in 1984. It consists of three Springfield M1903 rifles mounted on a polished hardwood base. This trophy is awarded to the highest scoring Police competitor in the National Trophy Individual Rifle Match.

*B–47. The Junior Pistol Team Trophy*

This trophy was authorized by the NBPRP in 1983 and first presented in 1984. It consists of four caliber .45 pistol facsimilies mounted on a polished hardwood base. This trophy is awarded to the highest scoring Junior team in the National Trophy Pistol Team Match.

*B–48. The Junior Pistol Trophy*

This trophy was authorized by the NBPRP in 1983 and first presented in 1984. It consists of two Colt Ace caliber .22 pistols mounted on a polished hardwood base. The trophy is awarded to the highest scoring Junior competitor in the National Trophy Individual Pistol Match.

*B–49. The Junior Infantry Team Trophy*

This trophy was recommended by the NBPRP in 1983 and first presented in 1984. It consists of three Springfield M1903 rifles mounted on a polished hardwood base. The Springfield rifles were used in the design because of their prominence in the Infantry Trophy; the fact that a distinctive award has been established to promote junior participation in a singularly military type of marksmanship competition is considered most appropriate. The trophy is awarded to the highest scoring Junior team in the National Infantry Trophy Team match.

*B–50. The National Guard Association Trophy (Rifle)*

The National Guard Association Trophy (Rifle) was presented to the NBPRP in 1983, replacing the original trophy that was established in 1979. The trophy depicts a helmeted Guardsman in bronze, mounted on a two-tiered walnut base. This trophy is awarded to the highest scoring National Guard competitor in the National Trophy Individual Rifle Match.

**Glossary**

Section I
Abbreviations
AEF—American Expeditionary Forces
AG—adjutant general
AMC—US Army Material Command
CECOM—US Army Communications-Electronics Command
CG—commanding general
CMP—Civilian Marksmanship Program
CONUS—continental United States
DARCOM—US Army Material Development and Readiness Command
DCM—Director of Civilian Marksmanship
DNMIC (Ops/Svcs)—Deputy National Matches Installation Commander (Operations and Services)
EIC—excellence-in-competition
FORSCOM—US Army Forces Command
LNO—Liaison officer
MR—midrange
NBPRP—National Board of the Promotion of Rifle Practice
NGB—National Guard Bureau
NMIC—National Matches Installation Commander
NMPAO—National Matches Public Affairs Officer
NMSC—National Matches Support Coordinator
NMSD—National Matches Support Detachment
NRA—National Rifle Association
OHARNG—Ohio Army National Guard
OSO—Ordnance Safety Officer
ROTC—Reserve Officers' Training Corps
SA—Secretary of the Army
SAFS—Small Arms Firing Schools
SPT—Support
SR—short range
TRADOC—US Army Training and Doctrine Command
USC—US Code
XO, NM—Executive Officer, National Matches
XO, CMP (SPT)—Executive Officer, Civilian Marksmanship Program (Support)

**Section II**

*Terms*

*Complete the Match.* To fire recorded shots in all stages of a match. For team matches, this term means that all firing members fire recorded shots in all stages of the match.

*Completed Match.* A match in which all competitors have had the opportunity to fire in all stages of the match.

*Distinguished Designation.* Award of the Distinguished Pistol Shot or Distinguished Rifleman Badge. These awards are made to individuals who have earned the required number of credit points.

*Excellence-in-Competition (EIC) Matches.* Matches in which credit toward the Distinguished designation may be earned and EIC badges awarded.

*Fire in the Match.* To fire one or more recorded shots in any stage of the match. For team matches, this term means that one or more team members fire one or more recorded shots in any stage of the match.

**John O. Roach, II,**

*Army Liaison Officer with the Federal Register.*

[FR Doc. 85–2644 Filed 2–21–85; 10:13 am]

BILLING CODE 3810-08-M

Friday
February 22, 1985

Federal Register

Part VI

# Department of Agriculture

Farmers Home Administration

7 CFR Part 1945

Emergency Loans for Citrus Grove Rehabilitation and/or Reestablishment; Interim Rule

## DEPARTMENT OF AGRICULTURE

### Farmers Home Administration

### 7 CFR Part 1945

### Emergency Loans for Citrus Grove Rehabilitation and/or Reestablishment

**AGENCY:** Farmers Home Administration, USDA.

**ACTION:** Interim rule.

**SUMMARY:** The Farmers Home Administration (FmHA) amends its Emergency loan making regulation, Part 1945, Subpart D, to incorporate a special provision which will afford citrus growers more realistic loan terms and which will provide a method of loan funds disbursement that will enable them to recover from severe natural disaster losses.

**EFFECTIVE DATE:** February 22, 1985. This interim rule is subject to revision following a comment period ending March 25, 1985.

**ADDRESSES:** Submit written comments in duplicate to the office of the Chief, Directives Management Branch, Farmers Home Administration, United States Department of Agriculture, Room 6348, South Agriculture Building, 14th and Independence Avenue, SW., Washington, D.C. 20250. All written comments made pursuant to this notice will be available for public inspection during regular working hours at the above address.

**FOR FURTHER INFORMATION CONTACT:** Mr. Morris Monesson, Acting Director, Emergency Division, Farmers Home Administration, USDA, Room 5418–South Building, Washington, D.C. 20250, Telephone Number (202) 382–1632 or Mr. Wilbert Cambell, Designation and Loan Processing Branch Chief, Emergency Division, Farmers Home Administration, USDA, Room 5416–South Building, Washington, D.C. 20250, Telephone Number (202) 382–1650.

**SUPPLEMENTARY INFORMATION:** This action has been reviewed under USDA procedures established in Departmental Regulations 1512–1, which implements Executive Order 12291 and has been determined to be "non-major," because it will not have an annual effect on the economy of $100 million or more; and there will be no major increase in cost or prices for consumers, individual industries, Federal, state, or local Government Agencies, or geographic regions; nor will it have 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.

#### Discussion of Interim Rule

FmHA is implementing the special Emergency (EM) physical loss loan provision immediately via publication of this interim rule. It is the policy of this Department that rules relating to public property, loans, grants, benefits or contracts shall be published for comment, not withstanding the exemptions in U.S.C. 553 with respect to such rules. This action, however, is not published for Proposed Rule making because of the extreme financial stress presently being experienced by many citrus growers due to devastation of their citrus groves during the past three years.

Many citrus producers are currently experiencing severe financial difficulties, which threaten their ability to continue in operation. The unavailability of suitable credit, high costs of grove rehabilitation and/or reestablishment, and expected negative cash flow, because of loss in production capacity during the grove reestablishment period, have seriously reduced citrus grove operators' chances for recovery from their disaster losses.

Citrus trees in a 250,000 acre area were damaged by the 1983 freeze, as farmers pruned the trees to encourage new growth. When temperatures dropped into the the teens and held there for an extended period on January 21–22, 1985, much of this new growth was destroyed. Early estimates indicate that the January 1985 freeze damaged as much as 50 percent of the current cirtrus crop available for fruit and juice, and killed back much of the one and two year old wood (producing wood), causing losses to citrus growers in Florida estimated to be as much as 1 billion dollars. Citrus producers need that relief that this regulation revision provide; and they need the relief as soon as possible, if they are to overcome the effects of these disasters. The alternative is to have many producers forced out of business.

It is found, upon good cause, that notice and other public procedures, with respect to this interim action, are impracticable; and good cause is found for making this action effective in less than 30 days after publication of this document in the **Federal Register**. Unless the provisions contained in this Interim Rule are implemented promptly, many citrus growers will be forced out of business unnecessarily, since suitable credit will not be available to them in time.

#### Programs Affected

This modification affects the following FmHA program as listed in the *Catalog of Federal Domestic Assistance:* 10.404—Emergency Loans.

#### Intergovernmental Consultation

Intergovernmental consultation should be carried out in accordance with 7 CFR Part 3015, Subpart V, "Intergovernmental Review of Department of Agriculture Programs and Activities." For affected programs, see FmHA Instruction 1940–J, available in any FmHA office.

#### Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR Part 1940, Subpart G, "Environmental Program." It is the determination of FmHA that the proposed action does not constitute a major Federal action significantly affecting the quality of the human environmental and, in accordance with the National Environmental Policy Act of 1969, Pub. L. 91–190, an Environmental Impact Statement is not required.

#### Background

The current FmHA regulation for emergency loan making must be amended to incorporate these changes. The changes, as set out below in Exhibit D, Part 1945, Subpart D provide for emergency (EM) physical loss loan funds, which are used for citrus grove rehabilitation and/or reestablishment, to be disbursed over a maximum period of 5 years; and to have the loan repayment postponed, except for at least a partial payment of interest, for a period of up to 5 years.

#### Alternative #1

Make no change.

*Effects:* Natural disaster losses force many citrus growers to incur abnormally high capital and operational costs to rehabilitate or reestablish groves. Low income during the recovery period reduces the affected citrus growers' repayment capacities; and without suitable financing, many growers will be forced out of business. The existing regulation provides for a postponement of payment for a maximum of 3 annual installments. That is not sufficient time for citrus crops to be restored to profitable production, when trees are killed and have to be replanted.

#### Alternative #2

The modifications set forth in this Exhibit D will provide eligible citrus growers the opportunity to rehabilitate and/or reestablish their citrus groves by

affording them an extended period of temporary relief from repaying the loan. This will be accomplished by postponing the loan repayment, except for at least a partial payment of interest, for a period of up to 5 years. In addition, EM physical loss loan future advances will be permitted to be disbursed over a period of up to 5 years. This will allow the loan to be disbursed to pay certain annual operating expenses as needed during the recovery period, which is normally characterized by a drastic reduction in cash flow.

*Effects:* This action will enable many smaller sized citrus operators to recover from the devastation of natural disasters and return to a profitable operation.

These changes affect emergency physical loss loans only.

**List of Subjects in 7 CFR part 1945**

Agriculture, Disaster assistance, Loan programs—Agriculture.

Accordingly, Subpart D of Part 1945, Chapter XVIII, Title 7, Code of Federal Regulations, is amended as follows:

## PART 1945—EMERGENCY

### Subpart D—Emergency Loan Policies, Procedures and Authorizations

1. Section 1945.153 is added to read as follows:

**§ 1945.153 Loans for citrus grove rehabilitation or reestablishment.**

Exhibit D of this subpart, which deals with loans made to operators of citrus groves, modifies some of the provisions contained in this subpart.

2. Exhibit D of Part 1945, Subpart D is added to read as follows:

### Exhibit D to Subpart D—Emergency Loans for Citrus Grove Rehabilitation and/or Reestablishment

I. *General:* Emergency (EM) loans may be made for rehabilitation and/or reestablishment of citrus groves, in areas which are determined not to be freeze prone areas, subject to the requirements of this subpart, except as modified and supplemented herein. This exhibit shall be effective on February 22, 1985 for citrus growers who have applications pending or who file applications in the future.

A. Authority. The authorizations contained in this exhibit provide the criteria to be used in (1) determining the feasibility of a request for an EM loan to rehabilitate and/or reestablish a citrus grove(s) and (2) establishing the dollar amount of physical losses to be compensated in a single EM loan and disbursed in future advances over a period of up to 5 years.

B. Policy. It is the policy of FmHA to make EM physical loss loans to citrus growers under this exhibit, provided their citrus groves can be reestablished or rehabilitated with the EM funds advanced over a period not to exceed 5 years. If additional funds are needed and a longer recovery period is required, the applicant must plan at the outset to obtain the additional financing needed from either his/her own cash flow resources or from another lender(s), since FmHA has no authority to provide any subsequent EM physical loss loans based on the same disaster.

II. *Program Objectives:* The objective for making EM loans to rehabilitate or reestablish citrus groves is to enable eligible applicants to restore their damaged citrus groves to normal production, provided (1) the proposed citrus operation can be reestablished on a reasonably sound basis; and (2) the rehabilitated citrus grove(s) will afford long range prospects for a reasonably successful operation.

III. *Definitions:*

A. "Grove rehabilitation" means the renovation of an existing grove, made necessary because of severe damages to trees resulting from a natural or major disaster occurring in a designated/declared county(ies).

B. "Grove reestablishment" means the planting of new trees to replace those that were killed or damaged beyond economic rehabilitation, made necessary because of severe damages resulting from a natural or major disaster occurring in a designated/declared county(ies). (Both paragraphs III A and III B involve real estate development which will require more than one year to complete. Normally 3–5 years will be required for groves to become productive again under these two types of development procedures.)

IV. *Eligibility: Sections 1945.163 and 1945.175* of this subpart are supplemented to the extent that EM loans may be made, under the provisions of this exhibit, *only* to otherwise eligible applicants who are owner-operators or long term lessee-operators (whose lease meets the requirements of Section 1943.62(a)(7) of Subpart B of Part 1943 of this chapter) of citrus groves. To be eligible, applicants must:

A. Project, at the outset, realistic annual plans of operation for the total farming operation, showing positive cash flows. These plans will be prepared by the County Supervisor and the applicant/borrower for each year of the adjustment period, until the citrus grove(s), as projected, is brought into profitable production.

B. Provide verification of income from other farming enterprises and/or dependable off-farm income in sufficient amount to cover all family living expenses and all farm operating expenses not related to the rehabilitation or reestablishment of the citrus grove(s) to be financed by FmHA.

C. Limit their request for an EM physical loss loan to the actual physical losses sustained, which will not exceed the value of the established grove (trees and land), as appraised on the day before the disaster occurred, or one year and one day before the disaster designation was requested by a State Governor or an FmHA State Director, whichever date has the higher value, *minus* the present market value of the land and any remaining trees. The maximum EM loan limit of $5000 per borrower for each designated disaster as prescribed in § 1945.163(d) of this subpart, will prevail.

V. *Loan Purposes:* EM loans for citrus grove rehabilitation and/or reestablishment may be made to eligible applicants for the purposes authorized by Section 1945.166 of this subpart, including the following:

A. Operating purposes. Payment of:

(1) Hired labor, not including operator's own labor.

(2) Actual cost of pruning trees and top grafting.

(3) Purchase of fertilizer, herbicides and fungicides.

(4) Actual cost of land preparation and cultivation.

(5) Machinery and equipment maintenance; repair and replacement, as needed to sustain the citrus enterprise only.

(6) Actual cost of fuel associated with the citrus enterprise. (For operation of machinery, irrigation systems, frost protection, etc.).

(7) Accrued interest on outstanding citrus operation debt.

(8) Real estate taxes and real property insurance premiums.

(9) Miscellaneous operating costs associated with the citrus enterprise.

B. Real Estate purposes. Payment of:

(1) Hired labor, not including operator's own labor.

(2) Removal of destroyed trees and debris.

(3) Land preparation.

(4) Purchase and planting of replacement trees.

(5) Secured and unsecured debts incurred during the disaster year as related to the citrus enterprise.

(6) Miscellaneous expenses directly related to long term improvement of the citrus grove(s) rehabilitation and reestablishment.

VI. *Loan Limitations:* Loan funds will *not* be approved or advanced for:

A. Family living expenses.

B. Operating or real estate expenses not directly related to the rehabilitation and/or reestablishment of the citrus grove(s) damaged or destroyed by the declared/designated disaster.

VII. *Rehabilitation and/or Reestablishment Requirements:* Citrus growers receiving EM loans under this exhibit will rehabilitate and/or reestablish their damaged or destroyed citrus groves for production of similar type(s) citrus crops grown during the disaster year. The applicant/borrower will also agree to replant or top graft the trees, as necessary, with a variety(ies) of trees recommended by the Cooperative Extension Service. This will become a condition of loan approval and will be inserted in Item 41 of Form FmHA 1940–1, "Request For Obligation of Funds." The replacement citrus trees and any scion wood used for top grafting must be certified, in writing, as being disease free and true to variety by the selling nurseryman or other supplier.

VIII. *Rates and Terms:* See FmHA Instruction 440.1, Exhibit B (available in any FmHA office), for current interest rates charged on EM loans. Section 1945.168 of this subpart is hereby modified, authorizing future

advances of EM loan funds to be disbursed over a period of up to 5 years, when such loan funds are used to rehabilitate and/or reestablish a citrus grove(s). EM loans may have reduced annual installments scheduled, of at least partial interest, for up to 5 years. However, such reduced installments will not be scheduled longer than the amount of time projected as being needed to bring the citrus grove(s) back into profitable production. After the adjustment period, the promissory note may describe a graduated schedule of annual installments to coincide with projected increasing cash flow. A State Supplement will be issued setting forth several examples of a 5-year adjustment period showing scheduled annual installments.

*The maximum repayment period will not exceed 30 years.* In cases where successive natural disaster losses severely affect the total farming operation, loans may be rescheduled with a new period of adjustment, provided subparagraphs A and B of paragraph IV of this exhibit can continue to be met.

IX. *Security Requirements:* Section 1945.169 of this subpart is hereby modified to show that the EM loans made for citrus grove rehabilitation and/or reestablishment will be secured by the following collateral and lien positions:

A. A first lien on the citrus crop being brought into production;

B. The best lien obtainable on real estate or leasehold interest on which the citrus is to be grown, having sufficient collateral equity to fully secure the EM loan, based on the per acre appraised value of the citrus grove(s) as established on the day before the disaster occurred, or one year and one day before the disaster designation was requested by a State Governor or an FmHA State Director, whichever date has the higher value.

C. The best lien obtainable on all other assets owned by the applicant/borrower, when an individual proprietorship. When the applicant/borrower is an entity, all assets owned by the entity and the individual(s) as a member, partner or stockholder of the entity will be taken as collateral; and

D. Full personal liability of all principal members, partners or stockholders of the borrower entity.

X. *Loan Approval and Administrative Determinations:* Before an EM loan is approved under this exhibit, the loan approval official must make the determinations required by §§ 1945.182 and 1945.183 of this subpart, and the following additional determinations:

A. That postponement of loan repayment is needed to accomplish projections of positive cash flows for each year of postponement; and as necessary, repayment of the loan, except for at least an annual partial payment(s) of interest, will be postponed for up to 5 annual installments with a graduated schedule of annual installments after the adjustment period; and a maximum repayment term, as justified by realistic income and expense projections, but not in excess of 30 years from the date of promissory note, will be given.

B. That multiple future advances of loan funds are scheduled over the period of years needed to bring the citrus grove(s) into profitable production, but not in excess of 5 years.

C. That annual plans of operation and accompanying cash flow statements are scheduled for review and revision annually to reflect current circumstances, and a determination made and documented by the FmHA servicing official that recovery of the citrus operation is still feasible, before *each* future advance is disbursed.

D. That the projected annual plans show the initial and all future EM advances will be fully secured by equity in the farm real estate to be rehabilitated or reestablished, and which will serve as collateral for the EM loan, using the "as improved" appraised value.

XI. *Understandings and Agreements with Applicant:* In the event a determination is made, at any time during the recovery period, that the operation is no longer economically feasible (cannot meet its cash flow requirements), the undisbursed future advances will be cancelled by the County Supervisor after consultation with the District Director and the State Director; and appropriate servicing actions will be pursued. Also, the grove rehabilitation and/or reestablishment will be considered "complete" when profitable production is achieved. If this occurs ahead of schedule, the remaining future advances will be cancelled and consideration given to rescheduling the unpaid EM loan balance. The County Supervisor may cancel a future advance(s) after consultation with the District Director and the State Director. This will be acknowledged by the borrower(s) by initialling changes in the Promissory Note, Form FmHA 1940–17, as follows: on page 1 delete the second sentence of the third paragraph from the bottom of the page which reads, "Approval by the Government will be given provided the advance is requested for a purpose authorized by the Government."; and add at the bottom of page 1, "The Government will approve advances of loan funds which were not advanced at loan closing, provided the funds will be used for authorized purposes, the borrower has complied with all loan agreements, FmHA determines that the operation is economically feasible, and FmHA determines that FmHA loan funds are needed." Each Promissory Note thus modified will be initialled at both changes by the borrower(s) at the time of loan closing and an explanation of the implications of the changes given to the borrower(s) by the escrow agent or the FmHA official conducting the closing.

XII. *Issuance of State Supplement:* A State Supplement will be issued to provide guidance on appraising citrus groves, and projecting Farm and Home Plans or Coordinated Financial Statements during the period of grove rehabilitation and/or reestablishment. This Supplement will also contain examples of how loan installments may be scheduled during the period of adjustment. (See paragraph VIII of this exhibit.)

(7 U.S.C. 1989; 7 CFR 2.23; 7 CFR 2.70)

Dated: January 25, 1985.

**Charles W. Shuman,**

*Administrator, Farmers Home Administration.*

FR Doc. 85–4592 Filed 2–21–85; 11:27 am]

BILLING CODE 3410-07-M

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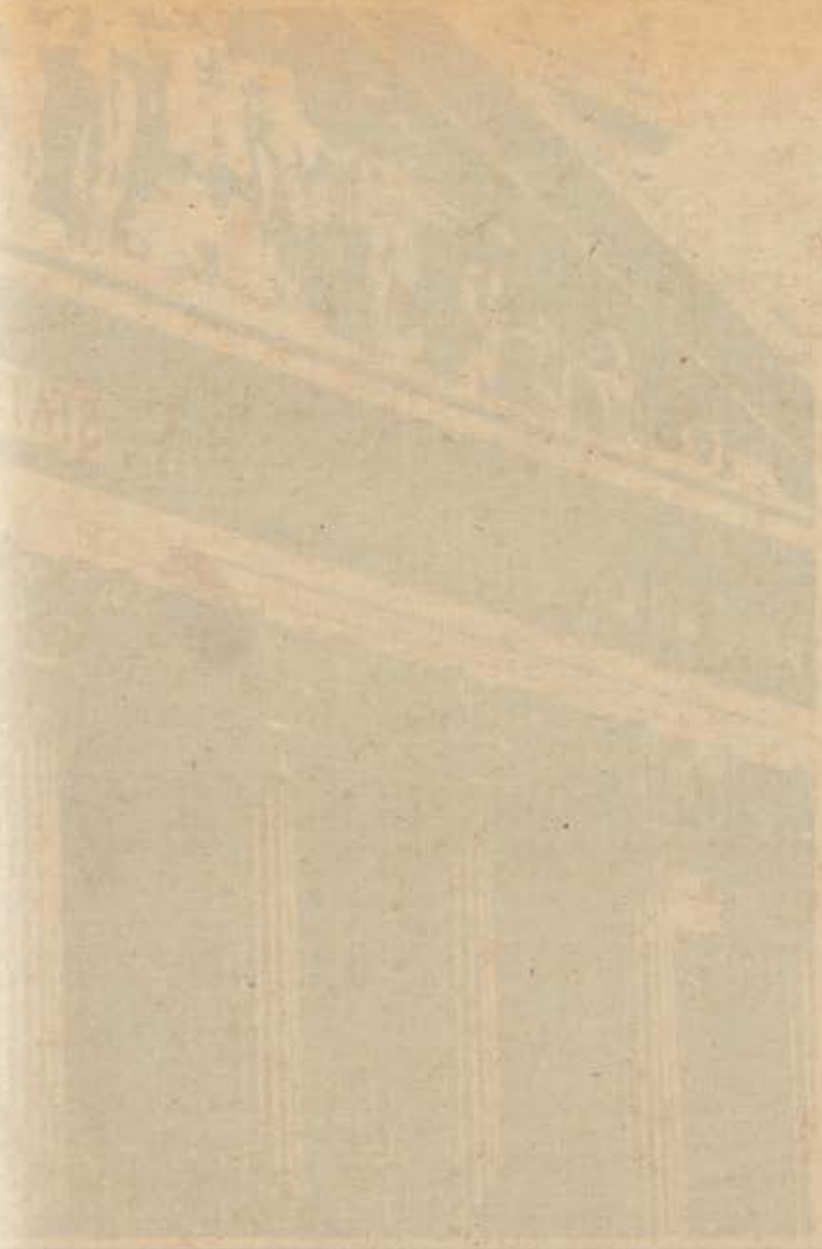
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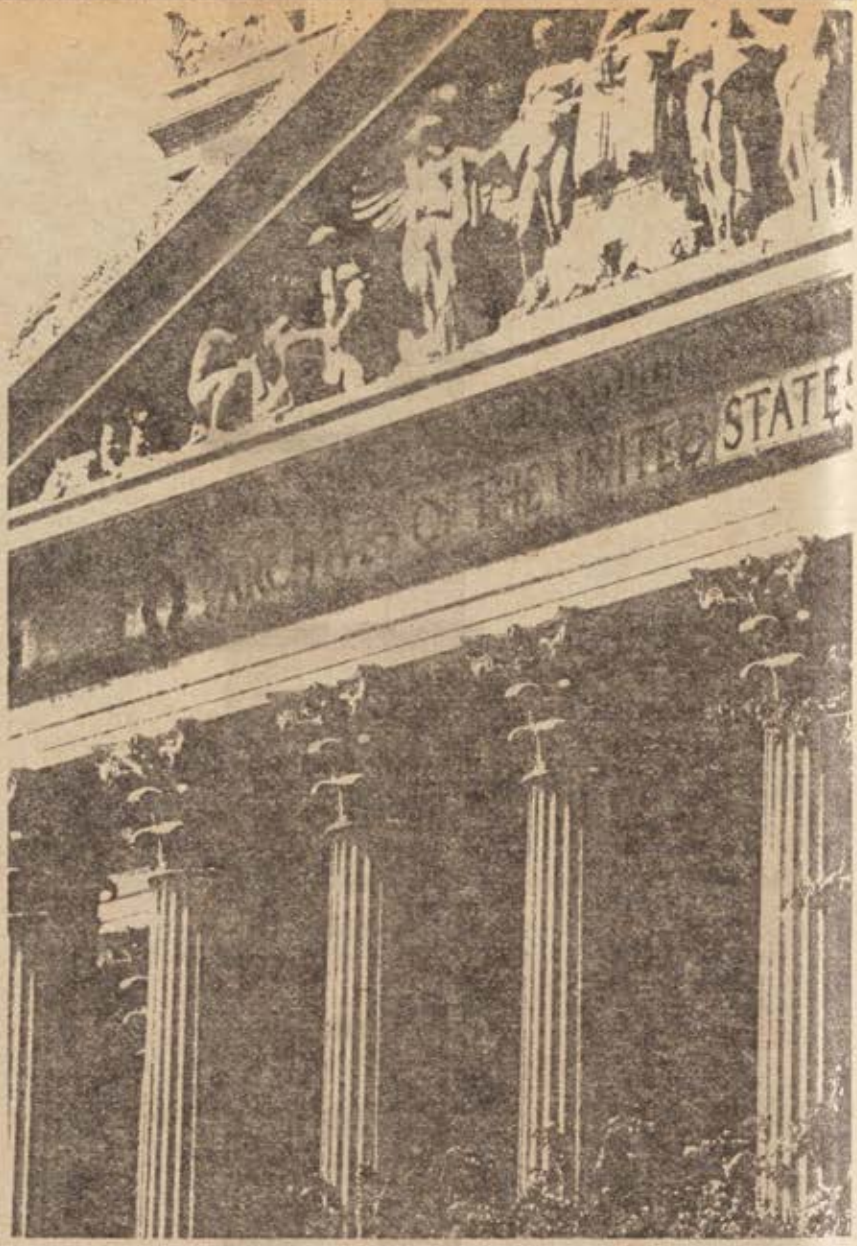
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